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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–1176; Project Identifier AD–2020–01231–T; Amendment 39–21402; AD 2021–02–19]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain The Boeing Company Model 787–8, 787–9, and 787–10 airplanes. This AD requires repetitive general visual inspections of the bilge barriers located in the forward and aft cargo compartments for disengaged or damaged decompression panels, reinstallation of disengaged but undamaged decompression panels, and replacement of damaged decompression panels. This AD was prompted by reports of multiple incidents of torn decompression panels being found in the bilge area. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective March 8, 2021.

The FAA must receive comments on this AD by April 5, 2021.

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 *https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Examining the AD Docket

You may examine the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–1176; 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, any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Brandon Lucero, Aerospace Engineer, Cabin Safety and Environmental Systems Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3569; email: *brandon.lucero@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA has received reports of multiple incidents of torn decompression panels being found in the bilge area. These torn decompression panels were found after accomplishment of the actions required by AD 2018–05–06, Amendment 39–19215 (83 FR 9688, March 7, 2018) (AD 2018–05–06), which requires repetitive inspections of the bilge barriers in the forward and aft cargo compartments for disengaged decompression panels; reinstalling any disengaged panels; and replacing the decompression panels with new panels and straps. The torn decompression panels present a different unsafe condition than that addressed by AD 2018–05–06, so the FAA is issuing this AD to address the new unsafe condition. In the event of a cargo fire, significant leakage in the bilge area could result in insufficient Halon concentrations to adequately control the fire. This condition, if not addressed, could result in the loss of continued safe flight and landing of the airplane.

In addition to this AD addressing a different unsafe condition than the one specified in AD 2018–05–06, this AD also includes models that are not affected by the unsafe condition specified in AD 2018–05–06. Both ADs include reinstallation and replacement actions as part of the required on-condition actions. AD 2018–05–06 requires certain service information for the reinstallation and replacement instructions, which refer to airplane maintenance manual (AMM) procedures. However, this AD requires using the operator's maintenance or inspection program, as applicable, for the reinstallation and replacement instructions.

FAA's Determination

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

AD Requirements

This AD requires repetitive inspections of the bilge barriers located in the forward and aft cargo compartments for disengaged or damaged (torn) decompression panels, reinstalling panels that are disengaged but undamaged, and replacing damaged panels.

Interim Action

The FAA considers this AD interim action. The manufacturer is currently developing a modification that will address the unsafe condition identified in this AD. Once this modification is developed, approved, and available, the FAA might consider additional rulemaking.

FAA's Justification and Determination of the Effective Date

An unsafe condition exists that requires the immediate adoption of this AD without providing an opportunity for public comments prior to adoption. The FAA has found that the risk to the flying public justifies waiving notice and comment prior to adoption of this rule because, in the event of a cargo fire, significant leakage in the bilge area could result in insufficient Halon concentrations to adequately control the fire. This condition, if not addressed, could result in the loss of continued safe flight and landing. In addition, the compliance time for the required action is shorter than the time necessary for the public to comment and for publication of the final rule. Therefore, the FAA finds good cause that notice and opportunity for prior public comment are impracticable. In addition, for the

reasons stated above, the FAA finds that good cause exists for making this amendment effective in less than 30 days.

Comments Invited

The FAA invites you to send any written data, views, or arguments about this final rule. Send your comments to an address listed under **ADDRESSES**. Include the docket number FAA–2020–1176 and Project Identifier AD–2020–01231–T at the beginning of your comments. The most helpful comments reference a specific portion of the final rule, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this final rule because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to *https://www.regulations.gov,* including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this final rule.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this AD contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this AD, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this AD. Submissions containing CBI should be sent to Brandon Lucero, Aerospace Engineer, Cabin Safety and Environmental Systems Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3569; email: *brandon.lucero@faa.gov.* Any commentary that the FAA receives that is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Regulatory Flexibility Act (RFA)

The requirements of the RFA do not apply when an agency finds good cause pursuant to 5 U.S.C. 553 to adopt a rule without prior notice and comment. Because the FAA has determined that it has good cause to adopt this rule without notice and comment, RFA analysis is not required.

Costs of Compliance

The FAA estimates that this AD affects 222 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Repetitive inspections ...	3 work-hours × $85 per hour = $255 per inspection cycle.	$0	$255 per inspection cycle.	$56,610 per inspection cycle.

The FAA estimates the following costs to do any necessary replacements that would be required based on the results of the inspections. The FAA has no way of determining the number of aircraft that might need these replacements:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Replacement	1 work-hour × $85 per hour = $85	* $	* $85

* The FAA has received no definitive data on which to base the parts cost estimates for the replacements specified in this AD.

Authority for This Rulemaking

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

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, and

(2) Will not affect intrastate aviation in Alaska.

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:

2021–02–19 The Boeing Company: Amendment 39–21402 ; Docket No. FAA–2020–1176; Project Identifier AD–2020–01231–T.

(a) Effective Date

This airworthiness directive (AD) is effective March 8, 2021.

(b) Affected ADs

None.

(c) Applicability

This AD applies to The Boeing Company airplanes identified in paragraphs (c)(1) through (3) of this AD, certificated in any category.

(1) Model 787–8 airplanes equipped with bilge assemblies with decompression panels having part number (p/n) C412707–107, C412705–117, C412705–119, or C412705–121.

(2) Model 787–9 airplanes equipped with bilge assemblies with decompression panels having p/n C419701–123, C419701–125, C419701–127, or C419701–129.

(3) Model 787–10 airplanes equipped with bilge assemblies with decompression panels having p/n 852Z0151–100, 852Z0153–101, or 852Z0156–103.

(d) Subject

Air Transport Association (ATA) of America Code 26, Fire protection.

(e) Unsafe Condition

This AD was prompted by reports of multiple incidents of torn decompression panels being found in the bilge area. The FAA is issuing this AD to address the possibility of leakage in the bilge area, which could, in the event of a cargo fire, result in insufficient Halon concentrations to adequately control the fire. This condition, if not addressed, could result in the loss of continued safe flight and landing of the airplane.

(f) Compliance

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

(g) Requirements

Within 30 days after the effective date of this AD, do a general visual inspection of the bilge barriers located in the forward and aft cargo compartments for disengaged or damaged (torn) decompression panels. If any disengaged but undamaged panel is found: Before further flight, reinstall the panel. If any damaged panel is found: Before further flight, replace the panel with a new or serviceable panel. Reinstallations and replacements must be done in accordance with the operator's maintenance or inspection program, as applicable. Repeat the inspections thereafter at intervals not to exceed 120 days.

(h) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards 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 (i) of this AD. Information may be emailed to: *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards 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, Seattle 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.

(i) Related Information

For more information about this AD, contact Brandon Lucero, Aerospace Engineer, Cabin Safety and Environmental Systems Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3569; email: *brandon.lucero@faa.gov.*

(j) Material Incorporated by Reference

None.

Issued on January 19, 2021.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–03462 Filed 2–17–21; 11:15 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2021–0040]

Special Local Regulations; Mark Hahn Memorial 300 PWC Endurance Race, Lake Havasu City, AZ

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the Mark Hahn Memorial 300 PWC Endurance Race special local regulations on the waters of Lake Havasu, Arizona from February 27 through February 28, 2021. These special local regulations are necessary to provide for the safety of the participants, crew, spectators, sponsor vessels, and general users of the waterway. During the enforcement period, persons and vessels are prohibited from anchoring, blocking, loitering, or impeding within this regulated area unless authorized by the Captain of the Port, or his designated representative.

DATES: The regulations in 33 CFR 100.1102 will be enforced from 7 a.m. until 6 p.m., each day from February 27, 2021 through February 28, 2021 for Item 14 in Table 1 of Section 100.1102.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice of enforcement, call or email Lieutenant John Santorum, Waterways Management, U.S. Coast Guard Sector San Diego, CA; telephone 619–278–7656, email *MarineEventsSD@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the special local regulations in 33 CFR 100.1102 for the Mark Hahn Memorial 300 PWC Endurance Race on Lake Havasu, AZ in 33 CFR 100.1102, Table 1, Item 14 of that section from 7 a.m. to 6 p.m. daily, on February 27, 2021 and February 28, 2021. This enforcement action is being taken to provide for the safety of life on navigable waterways during the event. The Coast Guard's regulation for annual marine events on the Colorado River, between Davis Dam (Bullhead City, Arizona) and Headgate Dam (Parker, Arizona) identifies the regulated entities and area for this event. Under the provisions of 33 CFR 100.1102, persons and vessels are prohibited from anchoring, blocking, loitering, or impeding within this regulated area, unless authorized by the Captain of the Port, or his designated representative. The Coast Guard may be assisted by other Federal, State, or local law enforcement agencies in enforcing this regulation.

In addition to this document in the **Federal Register**, the Coast Guard will provide the maritime community with advance notification of this enforcement period via the Local Notice to Mariners and local advertising by the event sponsor.

If the Captain of the Port Sector San Diego or his designated representative determines that the regulated area need not be enforced for the full duration stated on this document, he or she may use a Broadcast Notice to Mariners or other communications coordinated with

the event sponsor to grant general permission to enter the regulated area.

Dated: February 11, 2021.

T.J. Barelli,

Captain, U.S. Coast Guard, Captain of the Port San Diego.

[FR Doc. 2021–03312 Filed 2–18–21; 8:45 am]

BILLING CODE 9110–04–P

LIBRARY OF CONGRESS

Copyright Office

37 CFR Part 202

[Docket No. 2017–8]

Secure Tests

AGENCY: U.S. Copyright Office, Library of Congress.

ACTION: Interim rule.

SUMMARY: The U.S. Copyright Office is issuing an interim rule amending its regulations governing the registration of copyright claims in secure tests and secure test items in order to address a temporary disruption caused by the COVID–19 pandemic. The interim rule allows for examination of these claims via secure videoconference during the national emergency.

DATE: Effective February 19, 2021.

FOR FURTHER INFORMATION CONTACT: Regan A. Smith, General Counsel and Associate Register of Copyrights, *regans@copyright.gov,* or Robert J. Kasunic, Associate Register of Copyrights and Director of Registration Policy and Practice, *rkas@copyright.gov.* They can be reached by telephone at 202–707–3000.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 408 of the Copyright Act, the U.S. Copyright Office is responsible for registering copyright claims.[1] In so doing, the Office is obligated to obtain a registration deposit that is sufficient to verify the claim and to provide an archival record of what was examined and registered.[2] Deposits of unpublished material must be kept for the full term of copyright protection,[3] and all deposits are available for public inspection.[4] The Act, however, authorizes the Office to issue regulations establishing ''the nature of the copies . . . to be deposited'' in specific classes of works and to ''permit, for particular classes, the deposit of identifying material instead of copies or phonorecords.'' [5]

Pursuant to that authority, the Office has long provided special registration procedures for ''secure tests'' that require the maintenance of confidentiality of their contents. These tests include tests ''used in connection with admission to educational institutions, high school equivalency, placement in or credit for undergraduate and graduate course work, awarding of scholarships, and professional certification.'' [6] Current regulations define a secure test as ''a nonmarketed test administered under supervision at specified centers on scheduled dates, all copies of which are accounted for and either destroyed or returned to restricted locked storage or secure electronic storage following each administration.'' [7]

On June 12, 2017, the Office issued an interim rule (the ''June 2017 Interim Rule'') that memorialized certain aspects of its secure test procedure and adopted new processes to increase the efficiency of its examination of such works.[8] Under this rule, applicants must, among other things, submit an online application, a redacted copy of the entire test, and a brief questionnaire about the test through the electronic registration system.[9] This procedure allows the Office to prescreen an application to determine whether the work appears to be eligible for registration as a secure test. If the test appears to qualify, the Office will schedule an in-person appointment for examination of an unredacted copy of the test.[10] All in-person appointments take place at the Copyright Office, located in Washington, DC, at the James Madison Memorial Building of the Library of Congress.

During the in-person meeting, the examiner reviews the redacted and unredacted copies in a secure location in the presence of the applicant or its representative.[11] If the examiner determines that the relevant legal and formal requirements have been met, he or she will register the claim(s) and add an annotation to the certificate reflecting that the work was examined under the secure test procedure. The registration is effective as of the date that the Office received—in proper form—the application, filing fee, and the redacted copy that was uploaded to the electronic registration system.[12] The June 2017 Interim Rule thus gives applicants the benefit of establishing as their effective date of registration the date when those redacted materials are initially submitted to, and received by, the Office electronically, rather than the later date when the in-person examination of the unredacted material takes place.

In response to concerns raised by stakeholders following the June 2017 Interim Rule, the Office issued a second interim rule on November 13, 2017 (the ''November 2017 Interim Rule'') to permit the registration of a group of test items (*i.e.,* sets of questions and answers) stored in a database or test bank and used to create secure tests.[13] For these claims, the November 2017 Interim Rule adopted most of the registration procedures that apply to secure tests under the June 2017 Interim Rule.

On May 8, 2020, the Office issued a third interim rule to address a disruption caused by the COVID–19 pandemic (the ''May 2020 Interim Rule'').[14] Specifically, certain tests that normally would qualify for registration as secure tests could be rendered ineligible for this option, because they were being administered remotely rather than at specified testing centers due to pandemic-related restrictions. The interim rule amended the definition of a ''secure test'' to allow otherwise-eligible tests currently being administered online during the national emergency to qualify as secure tests, provided the test administrator employed sufficient security measures.[15] The rule did not specify particular measures required to meet this standard, in order to afford applicants flexibility to tailor such processes to their specific needs. The Office noted that the rule did not alter the requirement that a secure test be administered ''under supervision,'' meaning that ''test proctors or the equivalent supervise the administration of the test.'' [16]

[1] 17 U.S.C. 408.

[2] *Id.* 408(b), 705(a).

[3] *Id.* 704(d).

[4] *Id.* 705(b).

[5] *Id.* 408(c)(1).

[6] 42 FR 59302, 59304 & n.2 (Nov. 16, 1977); *see also* 43 FR 763, 768 (Jan. 4, 1978) (adopting the definition of a secure test).

[7] 37 CFR 202.13(b)(1).

[8] 82 FR 26850 (June 12, 2017); *see* 37 CFR 202.13, 202.20(b)(3), (c)(2)(vi) (implementing the June 2017 Interim Rule).

[9] 37 CFR 202.13(c)(2).

[10] *Id.*

[11] The applicant must bring to the meeting, among other materials, a signed declaration confirming that the redacted copy brought to the meeting is identical to the redacted copy that was uploaded to the electronic registration system. *Id.* 202.13(c)(3)(iv).

[12] 82 FR at 26853.

[13] 82 FR 52224 (Nov. 13, 2017). *See* 37 CFR 202.4(b), (k), 202.13 (implementing the November 2017 Interim Rule).

[14] 85 FR 27296 (May 8, 2020). *See* 37 CFR 202.13(b)(1) (implementing the May 2020 Interim Rule).

[15] 37 CFR 202.13(b)(1).

[16] 85 FR at 27298; *see* 37 CFR 202.13(b)(3).

The Office made clear that the modifications made under the May 2020 Interim Rule were temporary and would last only until the COVID–19 emergency ended.[17] The Office also noted that the accommodation made under the May 2020 Interim Rule was not determinative of the final rule in this proceeding, but that the Office would monitor the operation of the rule to evaluate whether and under what conditions tests that are remotely administered by the test publishers should qualify as ''secure tests'' under the Office's regulations once the emergency period ends.[18]

The Office also noted that it was exploring possible options to examine secure test claims via secure videoconference. To that end, the Office invited comments on the technological requirements that would be needed for test publishers to participate if the Office decided to implement such a process. The Office specifically sought comment on the feasibility of using the WebEx platform for remote examination, as that program is currently supported by the Library of Congress.[19] The Office received five comments in response.[20] As discussed further below, the comments generally supported the use of WebEx, or other secure videoconferencing platforms.[21]

The comments also reiterated previous concerns regarding the Office's ''secure test'' definition set forth in 37 CFR 202.13(b), primarily the requirement that a test must be administered on ''scheduled dates'' at a ''specified center'' where ''test takers are physically assembled at the same time.'' [22] NCTA and ATP referred to points previously made by several commenters in this proceeding ''that existing testing technology already supports the identical testing outcomes provided'' in the May 2020 Interim Rule.[23] They contend that the Office's ''attempt to limit the [May 2020] Interim Rule to tests that were 'formerly conducted in person' fails to recognize that there is simply no difference in at home/remote proctored testing because of COVID–19—the same type of testing that was occurring on a daily basis before COVID–19, and will continue to occur in exactly the same manner following a time when in-person testing may resume.'' [24] They conclude ''there is no basis for requiring users of the [May] 2020 Interim Rule to 'return' to in-person testing'' whenever the national emergency ends and urge the Office to make the May 2020 Interim Rule permanent.[25]

II. The Interim Rule

While the Office continues to evaluate the secure tests regulations as a whole—taking into consideration the concerns of test publishers expressed throughout this rulemaking—to determine whether changes may be warranted before issuing a final rule, it issues this additional interim rule to allow for the remote examination of secure test claims by Copyright Office staff during the national emergency. Although applicants continue to submit these claims during the Office's closure, the Office cannot conduct in-person examinations. As a result, the Office now has more than 1,500 secure test claims pending and expects that this number will otherwise continue to grow for the duration of the COVID–19 emergency. The accumulation of claims has created a backlog of secure test claims that cannot be examined until the Office resumes normal operations. To address this issue, the Office has devised a process that it is now adopting that will allow its staff to perform secure test examinations remotely during the national emergency.

A. Examination Under the Existing Rules and Considerations for a Remote Examination Process

Currently, applicants seeking registration of a secure test or a group of secure test items must submit the following materials through the Office's electronic registration system: (1) The application, (2) a filing fee, (3) a brief questionnaire, and (4) a redacted copy of the work(s). The examiner assigned to the claim reviews the submitted materials to determine if the work(s) qualify as a secure test or secure test items.[26] If so, the examiner contacts the applicant to schedule an in-person appointment.

At the in-person examination, under the 2017 Interim Rules, applicants are required to bring the following materials to the Office: (1) A copy of the completed online application, (2) a nonrefundable secure test examination fee (calculated on an hourly basis), (3) a copy of the redacted version of the work(s) uploaded to the electronic registration system, (4) a signed declaration that the redacted copy brought to the in-person appointment is identical to the redacted copy uploaded through the electronic registration system, and (5) an unredacted copy of the actual test that is administered to test takers at specified centers on scheduled dates or an unredacted copy of the actual test items included in the group registration. The redacted and unredacted copies may be brought to the appointment in electronic form, provided they are stored on a CD–ROM, DVD, flash drive, or other external storage device. In such cases, the applicant must bring a laptop or other electronic device for the examiner to view the secure test materials. In recognition that the national coronavirus emergency made testing administration at specified centers infeasible, the May 2020 Interim Rule temporarily suspended this requirement, ''provided the test administrator employs measures to maintain the security and integrity of the test that it reasonably determines to be substantially equivalent to the security and integrity provided by in-person proctors.'' [27]

The examiner then reviews the redacted and unredacted copies in the applicant's presence. Upon completion of the in-person examination, the examiner will stamp the date of the appointment on the redacted and unredacted copies. If paper copies are examined, the examiner date-stamps both the redacted and unredacted versions. If electronic copies are examined, the examiner places the external storage device (such as a flash drive, CD, etc.) in its container, seals the container with tamper-proof tape, stamps the date of the appointment on a label, and applies that label to the container. Then the examiner returns the physical or electronic copies to the applicant. The signed declaration and the previously uploaded redacted copy of the work(s) are retained in the

[17] Pursuant to her authority under section 710(a) of the Copyright Act, the Register determined that the disruptions to the copyright system resulting from the national emergency remain in effect as of January 7, 2021. *See* U.S. Copyright Office, *Copyright Office Further Extends Timing Adjustments for Persons Affected by the COVID–19 Emergency* (Jan. 7, 2021), *https://www.copyright.gov/newsnet/2021/871.html.*

[18] 85 FR at 27298.

[19] *Id.*

[20] The public comments received in this proceeding may be accessed from the Office's website at *https://www.copyright.gov/rulemaking/securetests/.*

[21] *See* Comments of the National College Testing Association at 7–8 (June 8, 2020) (''NCTA Comments''); Comments of Association of Test Publishers at 9–11 (June 8, 2020) (''ATP Comments''); Comments of Association of American Medical Colleges at 1–2 (June 5, 2020) (''AAMC Comments''); Comments of Educational Testing Service (May 20, 2020) (''ETS Comments'').

[22] *See* NCTA Comments at 4; ATP Comments at 6–7.

[23] NCTA Comments at 4; ATP Comments at 5.

[24] NCTA Comments at 4; ATP Comments at 5–6.

[25] NCTA Comments at 4; ATP Comments at 6.

[26] For ease of reference, the term ''secure tests'' is used interchangeably in this notice to refer to both secure tests and groups of secure test items.

[27] 37 CFR 202.13(b)(1); 85 FR at 27298.

Office's records and may be made available to the public under appropriate circumstances. If the work(s) contain sufficient creative authorship, a registration certificate will be mailed to the applicant within a few weeks of approval. Because of the national emergency, in-person examinations have been suspended since March 2020.

The comments received in response to the May 2020 Interim Rule suggested various security protocols and other procedures for the Office to consider in implementing remote examination. The National College Testing Association (NCTA) supported examination by videoconference and suggested various software protocols that the Office could consider to maintain security, such as confirming compliance with National Institute of Standards and Technology (''NIST'') Federal Information Processing Standards, employment of appropriate encryption techniques, and enhanced training of Office examiners in the use of secure virtual meeting technologies.[28] The Association of Test Publishers (ATP) echoed these suggestions and also suggested that the Office employ dual screen control and dual scrolling software.[29] The Association of American Medical Colleges (AAMC) endorsed the use of WebEx, and suggested that for security reasons, the applicant should be the host of any teleconference.[30]

After reviewing these comments, the Literary Division of the Registration Program solicited responses from frequent submitters of secure test applications to determine their willingness and ability to participate in a ''test run'' of a remote examination. The National Board of Medical Examiners (''NBME'') expressed interest in participating. NBME proposed that the ''test run'' be conducted using a fabricated deposit copy created specifically for use in the ''test run;'' the remote examination would be performed through the WebEx platform, since it is currently supported by the Library.[31]

The ''test run'' examination took place on June 12, 2020. NBME set up the 30-minute appointment through WebEx and provided the link to the examiner. NBME shared its computer screen with the examiner through WebEx and displayed redacted and unredacted deposit copies side-by-side, as would occur at an in-person examination. NBME used the dual-scrolling software ''Setup Scrolling,'' which allows for the viewing of two PDF documents side-by-side and scrolling through both documents at the same time, while keeping the pages from each document aligned. This feature permits the examiner to easily compare the two PDF documents. NBME gave the examiner control of its computer in order to scroll through and examine the deposit material, much in the same manner and at the same speed as in an in-person examination.

Overall, the remote examination proceeded smoothly. NBME, however, raised several logistical issues, including questions regarding the submission of the signed declaration and the date-stamping of the unredacted deposit. The Office has developed proposed solutions to these issues, addressed below. Given the success of the ''test run,'' the Office now is prepared to move forward with the examination of secure test applications through secure videoconference for the duration of the national emergency.

B. The Remote Examination Procedure Under This Interim Rule

Based on this input, the Office is now adopting a procedure for examining secure tests that is generally the same as outlined in the current regulation, except as described below.[32] Participation in the process set forth in today's Interim Rule is strictly voluntary. Applicants may opt for an in-person examination, recognizing that such examinations cannot occur until the national emergency ends and the Office resumes normal operations.

Applicants are still required to submit the application, filing fee, questionnaire, and redacted copy of the work(s) through the electronic registration system. As before, the examiner will review these materials to determine if the work(s) qualifies as a secure test or a group of secure test items. If any issues arise during this review, the examiner will communicate with the applicant to resolve such issues before scheduling a remote examination.

Once any issues regarding the submitted materials have been resolved, the examiner will work with the applicant to schedule the appointment for the remote examination. The applicant is responsible for setting up the appointment through the WebEx platform or other similar teleconferencing platforms that have been approved for use by the Library of Congress,[33] and sending the videoconference information to the email address provided by the examiner.

The day before the scheduled appointment, the examiner will enable the ''Upload Deposit'' function in the electronic registration system to allow the applicant to upload the declaration form attesting that the redacted copy uploaded through the system and the redacted copy displayed at the remote examination are identical. The declaration must include a legally binding signature. The Office will accept an electronic signature as defined in 15 U.S.C. 7006, such as ''/s/ Jane Doe,'' a digital image of a handwritten signature on the form, or other verified electronic signature. By contrast, the applicant need not supply a completed copy of the online application; the examiner can retrieve a copy from the electronic registration system, if necessary.

On the day of the appointment, the examiner will log into the approved teleconferencing platform at the appropriate time using the information provided by the applicant. All participants must use a personal computer that has a camera and a microphone so that the applicant and examiner will be able to see and communicate with each other during the videoconference. During the examination, the applicant will pull up the redacted and unredacted copies side-by-side when instructed by the examiner. The applicant must have so-called ''dual-scrolling'' software that is compatible with the teleconferencing platform being used in order to participate in a remote examination allowed under today's interim rule. The applicant must remain available to answer any questions the examiner may have during the course of the examination.

[28] NCTA Comments at 7–8. NCTA also stated that the Office should permanently adopt the principal alterations in the 2020 Interim Rule—particularly allowing remote testing, remote proctoring, and electronic storage of tests. *Id.* at 3–6.

[29] ATP Comments at 9–11. ATP also suggested that the Office create a document that contains the material being registered that was returned to the applicant, in essence, generating the unredacted deposit. *Id.* The interim rule retains that responsibility with the applicant. ATP also stated that the Office should adopt many of the interim rule changes permanently, principally remote testing and proctoring, and secure electronic storage. *Id.* at 4–9.

[30] AAMC Comments at 1–2.

[31] *See* 85 FR at 27298. No registrations were issued as a result of this test run; it was conducted solely to determine the feasibility of the process.

[32] Today's interim rule provides an overview of how remote examination will work; more detailed instructions can be found in the Office's circular on secure tests (Circular 64), available at *https://www.copyright.gov/circs/.*

[33] In its circular on secure tests, the Office will provide a representative list of software programs that provide this functionality.

Normally, at the conclusion of the in-person examination, the examiner would date-stamp the redacted and unredacted paper copies of the deposit, or, if the applicant brought electronic copies to the appointment, the examiner would place the physical storage device in its container, seal the container with tamper-proof tape, stamp the date of the appointment on a label, and apply that label to the container.

As this step is not possible in a remote examination, applicant will be responsible for maintaining its copy of the unredacted deposit, in the event it is needed for litigation or other purposes. The interim rule specifies that the metadata of the unredacted deposit file must include the date of the examination, and the service request number generated by the electronic registration system. The redacted deposit that was uploaded to the electronic registration system can be used to identify the material examined by the Office by comparing the redacted and unredacted copies examined during the videoconference session to determine if they match. In connection with the Office's overall continuing analysis of the registration option for secure tests, the Office is considering whether to impose a records retention requirement upon applicants who register under these conditions, similar to other regulatory records retention provisions.[34]

After the appointment, the examiner will prepare a Secure Test Appointment Receipt, containing the following information: (1) Date of appointment; (2) time of appointment; (3) name of work examined; (4) name of examiner conducting examination; (5) applicant's representative(s); and (6) the fee charged per hour. This receipt will be uploaded into the record in the electronic registration system. The examiner will email a copy of this receipt to the applicant, along with instructions for submitting the secure test examination fee.[35] The fee must be paid through *pay.gov* or charged to an active deposit account. The Office will not issue a registration certificate until it receives full payment of this fee. Calculation of the fee will be done on an hourly basis, in the same manner as for an in-person examination.

If the Office issues a registration certificate, the examiner will add an annotation that includes the date of the appointment. The effective date of registration will be the date that the Office received—in proper form—the application, filing fee, and the redacted copy of the test that was uploaded to the electronic registration system, consistent with the current procedure.[36]

As with the other interim rules issued in this proceeding, the Office will monitor the operation of today's interim rule to evaluate whether remote examination of secure tests and groups of secure test items via secure videoconference should continue once the national emergency period ends. The Office understands the concerns of, and importance to, test publishers that the definition for a ''secure test'' reflect the current testing practices and testing technology, as well as other issues raised by commenters throughout this rulemaking proceeding. The Office takes these concerns seriously and continues to carefully consider them. The Office anticipates issuing a future separate notice that will revisit the regulatory definition for a ''secure test.''

In light of the ongoing national emergency, the Copyright Office finds good cause to publish these amendments as an interim rule effective immediately, and without first publishing a notice of proposed rulemaking, ''because of the demonstrable urgency of the conditions they are designed to correct.'' [37]

List of Subjects in 37 CFR Part 202

Copyright, Preregistration and Registration of Claims to Copyright.

For the reasons set forth in the preamble, the Copyright Office amends 37 CFR part 202 as follows:

PART 202—PREREGISTRATON AND REGISTRATION OF CLAIMS TO COPYRIGHT

■ 1. The authority citation for part 202 continues to read as follows:

Authority: 17 U.S.C. 408(f), 702.

■ 2. Amend § 202.13 as follows:
■ a. In paragraph (c)(1), remove ''standard application'' and add ''Standard Application'' in its place;
■ b. Revise paragraph (c)(2);
■ c. In paragraph (c)(3) introductory text, remove ''bring'' and add in its place ''provide''; and
■ d. Revise paragraph (c)(3)(v) and (c)(4).

The revisions read as follows:

§ 202.13 Secure tests.

* * * * *

(c) * * *

(2) In case of a secure test, the applicant must submit a redacted copy of the entire test. In the case of a group of test items prepared for use in a secure test, the applicant must submit a redacted copy of each test item. In all cases the redacted copy must contain a sufficient amount of visible content to reasonably identify the work(s). In addition, the applicant must complete and submit the secure test questionnaire that is posted on the Copyright Office's website. The questionnaire and the redacted copy must be contained in separate electronic files, and each file must be uploaded to the electronic registration system in Portable Document Format (PDF). The Copyright Office will review these materials to determine if the work(s) qualify for an examination under secure conditions. If they appear to be eligible, the Copyright Office will contact the applicant to schedule an appointment to examine an unredacted copy of the work(s). The examination may be conducted in-person or through remote access as directed by the instructions provided on the Office's website.

(3) * * *

(v) In the case of a secure test, the applicant must provide an unredacted copy of the entire test. In the case of a group of test items prepared for use in a secure test, the applicant must provide an unredacted copy of all the test items. The applicant shall include the following information in the metadata of an unredacted electronic file:

(A) The date of the examination; and

(B) The service request number generated by the electronic registration system.

(4) The Copyright Office will examine the copies specified in paragraphs (c)(3)(iii) and (v) of this section under secure conditions. The Office will retain the signed declaration and the redacted copy that was uploaded to the electronic registration system. If the examination is conducted in-person, the Office will stamp the date of the appointment on the copies and will return them to the applicant when the examination is complete.

* * * * *

Dated: February 3, 2021.

Shira Perlmutter,

Register of Copyrights and Director of the U.S. Copyright Office.

Approved by:

Carla D. Hayden,

Librarian of Congress.

[FR Doc. 2021–03097 Filed 2–18–21; 8:45 am]

BILLING CODE 1410–30–P

[34] *See, e.g.,* 37 CFR 210.27(m); 85 FR 58114, 58154 (Sept. 17, 2020).

[35] *See* 37 CFR 201.3(d)(5).

[36] *See* 82 FR at 26853.

[37] H.R. Rep. No. 79–1980, at 260 (1946). *See* 5 U.S.C. 553(b)(3)(B) (notice and comment is not necessary upon agency determination that it would be ''impracticable, unnecessary, or contrary to the public interest''); *id.* at 553(d) (30-day notice not required where agency finds good cause).

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2020–0146; FRL–10018–54]

Complex Polymeric Polyhydroxy Acids (CPPA); Amendment to the Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends the existing tolerance exemption for residues of Complex Polymeric Polyhydroxy Acids (CPPA) in or on all food commodities as a plant growth regulator to add use as a nematicide in pesticide formulations. FBSciences, Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA) requesting this amendment. This regulation adds use as a nematicide to the existing tolerance exemption of CPPA under FFDCA.

DATES: This regulation is effective February 19, 2021. Objections and requests for hearings must be received on or before April 20, 2021, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2020–0146, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805.

Due to the public health concerns related to COVID–19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Charles Smith, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *BPPDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

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

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

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

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Publishing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

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

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2020–0146 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before April 20, 2021. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2020–0146, by one of the following methods:

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

II. Background

In the **Federal Register** of May 05, 2020 (85 FR 26684) (FRL–10008–46), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 0F8822) by FBSciences, Inc., 153 N. Main Street, Ste. 100, Collierville, TN 38017–2691. The petition requested that 40 CFR 180.1321 be amended by the addition of use as a nematicide to the already established exemption from the requirement of a tolerance for residues of Complex Polymeric Polyhydroxy Acids (CPPA). That document referenced a summary of the petition prepared by the petitioner FBSciences, Inc., which is available in the docket for this action at *http://www.regulations.gov.* Although comments were received on the notice of filing, none were relevant to this tolerance rulemaking.

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement of a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is ''safe.'' Section 408(c)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings but does not include occupational exposure. Pursuant to FFDCA section 408(c)(2)(B), in making a determination to establish or maintain in effect an exemption from the

requirement of a tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C), which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .'' Additionally, FFDCA section 408(b)(2)(D) requires that the Agency consider ''available information concerning the cumulative effects of such residues and other substances that have a common mechanism of toxicity. . . .''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

II. Toxicological Profile

Consistent with FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action and considered its risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

A. Overview of Complex Polymeric Polyhydroxy Acids

Complex Polymeric Polyhydroxy Acids (CPPA) is a complex mixture of naturally occurring organic substances found in dead plant materials. The components of CPPA are widespread in nature, being found in soils and fresh and saltwater environments as a result of decaying plant materials and are used to condition agricultural soils. Its major components are humic acid, fulvic acid, and tannins, and their relative concentrations in soil and water systems are influenced by environmental conditions, such as climate, soil types, vegetation, and hydrology. CPPA is made by concentrating the organic substances from water leached through forest soil using a proprietary manufacturing process.

B. Biochemical Pesticide Toxicology Data Requirements

All applicable mammalian toxicology data requirements supporting the existing tolerance exemption for residues of CPPA in or on all food commodities as a plant growth regulator have been fulfilled. The mammalian toxicology data requirements supporting the addition of nematicide use to the existing tolerance exemption have also been fulfilled as EPA has relied upon the same mammalian toxicology data that supported the existing tolerance exemption for CPPA. No acute, subchronic, or chronic toxicity endpoints were identified in guideline studies or in data obtained from open technical literature. Moreover, CPPA is not a mutagen, and is not a developmental toxicant. There are no known effects on endocrine systems via oral, dermal, or inhalation exposure. A more in-depth synopsis of the data upon which EPA relied and its human health risk assessment based on that data can be found in the document ''Biopesticides Registration Action Document, Complex Polymeric Polyhydroxy Acids (CPPA),'' which is available in Docket Number EPA–HQ–OPP–2009–0917–0011, as well as the docket for this action, via *www.regulations.gov* as described under **ADDRESSES**.

IV. Aggregate Exposures

In examining aggregate exposure, FFDCA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

A. Dietary Exposure

The proposed use pattern may result in dietary exposure with possible residues in or on agricultural commodities. No significant exposure via drinking water is expected beyond what is already present, when CPPA is used according to the product label directions, because the active ingredient biodegrades rapidly (half-life = 25.7 days) in the environment, is applied at low application rates, and is not directly applied to water. Should exposure occur, however, minimal to no risk is expected for the general population, including infants and children, due to low toxicity of CPPA and its components as demonstrated in the data submitted and evaluated by the Agency. In addition, the lack of reported incidents in spite of the exposure from use in commercial agriculture for years to condition soils and its abundance in nature support a conclusion that minimal to no risk is expected.

B. Other Non-Occupational Exposure

Non-occupational exposure is not expected because CPPA will be applied as a plant growth regulator and nematicide for agricultural purposes only and there are no residential uses.

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

Section 408(b)(2)(D)(v) of FFDCA requires that, in establishing a tolerance or tolerance exemption for a pesticide chemical residue, the Agency consider ''available information concerning the cumulative effects of such residues and other substances that have a common mechanism of toxicity. . . .'' EPA has determined CPPA to have a non-toxic mode of action; therefore, 408(b)(2)(D)(v) does not apply.

VI. Determination of Safety for U.S. Population, Infants and Children

FFDCA section 408(b)(2)(C) provides that, in establishing a tolerance or tolerance exemption for a pesticide chemical residue, EPA shall assess the available information about consumption patterns among infants and children, special susceptibility of infants and children to pesticide chemical residues, and the cumulative effects on infants and children of the residues and other substances with a common mechanism of toxicity. In addition, FFDCA section 408(b)(2)(C) provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure, unless EPA determines that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor. In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data are available to support the choice of a different safety factor. As part of its qualitative assessment, EPA evaluated the available toxicity and exposure data on CPPA and considered its validity, completeness, and reliability, as well as the relationship of this information to human risk. EPA considers the toxicity database to be complete and has identified no residual uncertainty with regard to prenatal and postnatal toxicity or exposure. No hazard was identified based on the available studies. Based upon its evaluation, EPA concludes that there are no threshold effects of concern to infants, children, or adults when CPPA

is applied as a plant growth regulator or nematicide and used in accordance with label directions and good agricultural practices. As a result, EPA concludes that no additional margin of exposure (safety) is necessary.

VII. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for Complex Polymeric Polyhydroxy Acids (CPPA) because EPA is amending an exemption from the requirement of a tolerance without any numerical limitation.

B. International Residue Limits

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

VIII. Conclusion

EPA concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of CPPA. Therefore, EPA is establishing an exemption from the requirement of a tolerance for residues of CPPA in or on all food commodities when applied as a nematicide and used in accordance with good agricultural practices.

IX. Statutory and Executive Order Reviews

This action establishes a tolerance exemption under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), nor is it considered a regulatory action under Executive Order 13771, entitled ''Reducing Regulations and Controlling Regulatory Costs'' (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.,* nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

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

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

X. Congressional Review Act

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

List of Subjects in 40 CFR Part 180

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

Dated: February 16, 2021.

Charles Smith,

Acting Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

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

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

■ 2. Revise § 180.1321 to read as follows:

§ 180.1321 Complex Polymeric Polyhydroxy Acids; exemption from the requirement of a tolerance.

(a) An exemption from the requirement of a tolerance is established for the residues of complex polymeric polyhydroxy acids in or on all food commodities when applied as a plant growth regulator and used in accordance with good agricultural practices.

(b) An exemption from the requirement of a tolerance is established for the residues of complex polymeric polyhydroxy acids in or on all food commodities when applied as a nematicide and used in accordance with good agricultural practices.

[FR Doc. 2021–03362 Filed 2–18–21; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Part 1001

RIN 0936–AA08

Fraud And Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees; Delayed Effective Date

AGENCY: Office of Inspector General (OIG), Health and Human Services (HHS).

ACTION: Final rule; notification of court-ordered delay of effective date.

SUMMARY: As required by an order issued by the U.S. District Court for the District of Columbia, this action provides notice of the delay of the effective date of certain amendments to the safe harbors to the Federal anti-kickback statute that were promulgated in a final rule (''Fraud And Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals And Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees'') published on November 30, 2020. The new effective date for these certain amendments is January 1, 2023.

DATES: As of February 19, 2021, this action delays the published effective date of the amendments to 42 CFR 1001.952(h)(5) published November 30, 2020, at 85 FR 76666, and corrected at 86 FR 7815, February 2, 2021, until January 1, 2023.

FOR FURTHER INFORMATION CONTACT: Aaron Zajic, (202) 619–0335.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 30, 2020, the Department issued a final rule establishing four changes to the regulatory safe harbors to the Federal anti-kickback statute (Social Security Act Section 1128B(b)). Specifically, the final rule (1) amended 42 CFR 1001.952(h)(5) to remove safe harbor protection for reductions in price for prescription pharmaceutical products provided to plan sponsors under Part D; (2) created a new safe harbor at § 1001.952(cc) for certain point-of-sale reductions in price offered by manufacturers on prescription pharmaceutical products that are payable under Medicare Part D or by Medicaid managed care organizations that meet certain criteria; (3) created a new safe harbor at § 1001.952(dd) for fixed fees that manufacturers pay to pharmacy benefit managers (PBMs) for services rendered to the manufacturers that meet specified criteria; and (4) added new paragraphs (6)–(9) to 42 CFR 1001.952(h), defining certain terms. The final rule was published with an effective date of January 29, 2021, except for the amendments to 42 CFR 1001.952(h)(5), which were to be effective on January 1, 2022.[1]

On January 12, 2021, a lawsuit challenging the final rule was filed in the U.S. District Court for the District of Columbia.[2] On January 30, 2021, the Court issued an order postponing until January 1, 2023 the effective date of all provisions of the final rule that were scheduled to take effect on January 1, 2022.[3] Consistent with that order, the Department is taking this action to notify the public that the effective date of the amendments to paragraph 42 CFR 1001.952 (h)(5) in the final rule is now January 1, 2023. Pursuant to the court order, any obligation to comply with a deadline tied to the effective date of these amendments is similarly postponed, and those obligations and deadlines are now tied to the postponed effective date.

To the extent that 5 U.S.C. 553 applies to this action, implementation of this action without opportunity for public comment is based on the good cause exception in 5 U.S.C. 553(b)(B). Seeking public comment is impracticable, unnecessary, and contrary to the public interest. The one-year postponement of the effective date, until January 1, 2023, is required by court order in accordance with the court's authority to postpone a rule's effective date pending judicial review (5 U.S.C. 705). Seeking prior public comment on this postponement would have been impracticable, as well as contrary to the public interest in the orderly issue and implementation of regulations.

Norris Cochran,

Acting Secretary.

[FR Doc. 2021–03167 Filed 2–18–21; 8:45 am]

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[1] The effective date of the amendments to 42 CFR 1001.952 (h)(6) through (9), (cc), and (dd) published at 85 FR 76666, November 30, 2020, was subsequently delayed until March 22, 2021. 86 FR 7815 (Feb. 2, 2021).

[2] *Pharmaceutical Care Management Association* v. *United States Department of Health & Human Services et al.,* No. 1:21–cv–00095 (D. DC. filed Jan. 12, 2021).

[3] *Pharmaceutical Care Management Association* v. *United States Department of Health & Human Services et al.,* No. 1:21–cv–00095 (D. DC Jan. 30, 2021)) (order granting joint stipulation and postponing effective date), Doc. No. 19.

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 0, 1, 27, 90

[ET Docket No. 18–295; FCC 20–51; WT Docket No. 17–200; FCC 20–67, FRS 17383]

Unlicensed Use of the 6 GHz Band; Review of the Commission's Rules Governing the 896–901/935–940 MHz Band

AGENCY: Federal Communications Commission.

ACTION: Final rule; announcement of compliance date.

SUMMARY: In this document, the Commission announces that the Office of Management and Budget has approved the information collection requirements associated with the rules and policies adopted in the Federal Communications Commission's 6 GHz Report and Order, FCC 20–51, making 1,200 megahertz of spectrum in the 6 GHz band (5.925–7.125 GHz) available for unlicensed use, and 900 MHz Report and Order, FCC 20–67, establishing rules for broadband license operations in the 897.5–900.5/936.5–939.5 MHz segment of the 900 MHz band (896–901/935–940 MHz), and that compliance with the new requirements is now required.

DATES: *Compliance date:* Compliance with 47 CFR 27.1503 and 27.1505, published at 85 FR 43124 on July 16, 2020, is required on February 19, 2021.

FOR FURTHER INFORMATION CONTACT: Jaclyn Rosen, Mobility Division, Wireless Telecommunications Bureau, at (202) 418–0154 or *Jaclyn.Rosen@fcc.gov.*

SUPPLEMENTARY INFORMATION: This document announces that the Office of Management and Budget (OMB) approved the information collection requirements in 47 CFR 27.1503(b)(1), (b)(2), (b)(3), (c)(1) and 47 CFR 27.1505(a), (b), on December 10, 2020. These rules were adopted in the 6 GHz Order, FCC 20–51, published at 85 FR 31390 on May 26, 2020, and, 900 MHz Report and Order, FCC 20–67, published at 85 FR 43124 on July 16, 2020. Compliance with all new or amended rules adopted in the 6 GHz Order that do not require OMB approval

is required as of July 27, 2020, see 85 FR 31390 (May 26, 2020). Compliance with all new or amended rules adopted in the 900 MHz Report and Order that do not require OMB approval is required as of August 17, 2020, see 85 FR 43124 (July 16, 2020).

If you have any comments on the burden estimates listed below, or how the Commission can improve the collections and reduce any burdens caused thereby, please contact Cathy Williams, *Cathy.Williams@fcc.gov,* regarding OMB Control Number 3060–0798. Please include the OMB Control Number in your correspondence.

To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY).

Synopsis

As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), the Commission is notifying the public that it received final OMB approval on December 10, 2020, for the information collection requirements contained in 47 CFR 27.1503(b)(1), (b)(2), (b)(3), (c)(1) and 27.1505(a), (b). Under 5 CFR part 1320, an agency may not conduct or sponsor a collection of information unless it displays a current, valid OMB Control Number.

No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act that does not display a current, valid OMB Control Number. The OMB Control Number for the information collection requirements in 47 CFR 27.1503(b)(1), (b)(2), (b)(3), (c)(1), 27.1505(a), (b) is 3060–0798.

The foregoing notice is required by the Paperwork Reduction Act of 1995, Public Law 104–13, October 1, 1995, and 44 U.S.C. 3507.

The total annual reporting burdens and costs for the respondents are as follows:

OMB Control Number: 3060–0798.

OMB Approval Date: December 10, 2020.

OMB Expiration Date: December 31, 2023.

Title: FCC Application for Radio Service Authorization Wireless Telecommunications Bureau; Public Safety and Homeland Security Bureau.

Form Number: FCC Form 601.

Respondents: Individuals and households; Business or other for-profit entities; State, Local or Tribal Government; Not for profit institutions.

Number of Respondents and Responses: 255,552 respondents; 255,552 responses.

Estimated Time per Response: 0.5 hours to 1.25 hours.

Frequency of Response: Recordkeeping requirement; third party disclosure requirement; on occasion reporting requirement and periodic reporting requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. 151, 152, 154, 155(c), 157, 201, 202, 208, 214, 301, 302a, 303, 307, 308, 309, 310, 311, 314, 316, 319, 324, 331, 332, 333, 336, 534, 535 and 554.

Total Annual Burden: 225,808 hours.

Total Annual Cost: $72,474,000.

Privacy Act Impact Assessment: Yes.

Nature and Extent of Confidentiality: The information collected under this collection will be made publicly available. However, to the extent information submitted pursuant to this information collection is determined to be confidential, it will be protected by the Commission. If a respondent seeks to have information collected pursuant to this information collection withheld from public inspection, the respondent may request confidential treatment pursuant to section 0.459 of the Commission's rules for such information.

Needs and Uses: FCC Form 601 is a consolidated, multi-part application form that is used for market-based and site-based licensing for wireless telecommunications services, including public safety, which are filed through the Commission's Universal Licensing System (ULS) or any other electronic filing interface the Commission develops. FCC Form 601 is composed of a main form that contains administrative information and a series of schedules used for filing technical and other information. This form is used to apply for a new license, to amend or withdraw a pending application, to modify or renew an existing license, cancel a license, request a duplicate license, submit required notifications, request an extension of time to satisfy construction requirements, request an administrative update to an existing license (such as mailing address change), or request a Special Temporary Authority License. Respondents are encouraged to submit FCC Form 601 electronically and are required to do so when applying for an authorization for which the applicant was the winning bidder in a spectrum auction.

On April 23, 2020, the Commission adopted a Report and Order and Further Notice of Proposed Rulemaking in ET Docket 18–295, FCC 20–51, (6 GHz Report and Order) that requires temporary fixed microwave licensees to register temporary fixed links in the ULS database in order to receive protection from unlicensed devices operating in the 6 GHz band. Automated frequency coordination (AFC) administrators will use this information to determine where unlicensed devices can operate. Temporary fixed licensees were not previously required to file applications with the Commission when they commenced operation, so this is a new filing requirement. In addition to creating this new filing requirement, two new data fields will be required to describe when the temporary fixed links will be operational, so that the AFCs will know when to protect the temporary fixed links. For this purpose, a ''start date'' and ''end date'' will be added to the Form 601, Schedule I.

Further, on May 13, 2020, the Commission adopted a Report and Order, 20–67 (900 MHz Report and Order), which realigned the 900 MHz band to make available six of the band's ten megahertz for the deployment of broadband services and technologies. The 900 MHz band currently is designated for narrowband land mobile radio communications by Business/Industrial/Land Transportation (B/ILT) Pool licensees and Specialized Mobile Radio (SMR) providers. The 900 MHz Report and Order realigned the 900 MHz band to enable a broadband transition from interleaved SMR and B/ILT blocks to one broadband segment and two narrowband segments. To facilitate the transition, the Commission adopted a negotiation-based mechanism which, if private agreements are reached, will make available on a county-by-county basis six megahertz of low-band spectrum for the development of broadband technologies and services, while reserving the remaining four megahertz of the band for continued narrowband operations. If negotiations for the acquisition, relocation, and protection of 900 MHz incumbents in a market are successful and granting an application is otherwise in the public interest, the Commission will issue new initial licenses to applicants meeting eligibility requirements.

The 900 MHz Report and Order established license application requirements, including requirements that an applicant for a new 900 MHz broadband license demonstrate, as part of its application, that it satisfies the eligibility conditions (Eligibility Certification) and submit a plan for transitioning the 900 MHz band in a particular county (Transition Plan), to assess whether a grant of a 900 MHz

broadband license is in the public interest.

In addition, the Commission adopted a two-fold performance requirement whereby a 900 MHz broadband licensee must: (1) Provide reliable signal coverage and offer broadband service; and (2) meet either (a) a population coverage requirement, or (b) a geographic coverage requirement.

The information required in this collection will be used to ensure that a grant of a 900 MHz broadband license is in the public interest and to ensure that licensees use 900 MHz spectrum productively, provide service in a timely manner, and promote the provision of innovative services and technologies in unserved areas, particularly rural markets. The collection is also necessary for the Commission to satisfy its oversight responsibilities and/or agency specific/government-wide reporting obligations.

Federal Communications Commission.

Marlene Dortch,

Secretary.

[FR Doc. 2021–00782 Filed 2–18–21; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 160426363–7275–02]

RTID 0648–XA879

Coastal Migratory Pelagic Resources of the Gulf of Mexico and Atlantic Region; 2020–2021 Commercial Hook-and-Line Closure for King Mackerel in the Gulf of Mexico Southern Zone

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS implements an accountability measure (AM) to close the hook-and-line component of the commercial sector for king mackerel in the Gulf of Mexico (Gulf) southern zone. This closure is necessary to protect the Gulf king mackerel resource.

DATES: This temporary rule is effective from 12:01 a.m., local time, on February 22, 2021, through June 30, 2021.

FOR FURTHER INFORMATION CONTACT: Kelli O'Donnell, NMFS Southeast Regional Office, telephone: 727–824–5305, email: *kelli.odonnell@noaa.gov.*

SUPPLEMENTARY INFORMATION: The fishery for coastal migratory pelagic fish in the Gulf includes king mackerel, Spanish mackerel, and cobia, and is managed under the Fishery Management Plan for the Coastal Migratory Pelagic Resources of the Gulf of Mexico and Atlantic Region (FMP). The FMP was prepared by the Gulf of Mexico and South Atlantic Fishery Management Councils and is implemented by NMFS under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) through regulations at 50 CFR part 622. All weights for Gulf migratory group king mackerel (Gulf king mackerel) apply as either round or gutted weight.

The commercial sector for Gulf king mackerel is divided into western, northern, and southern zones. The southern zone encompasses an area of the exclusive economic zone (EEZ) off Collier and Monroe Counties in south Florida. The southern zone includes the EEZ south of a line extending due west from the boundary of Lee and Collier Counties on the Florida west coast, and south of a line extending due east from the boundary of Monroe and Miami-Dade Counties on the Florida east coast (50 CFR 622.369(a)(1)(iii)).

The commercial annual catch limit (ACL) for Gulf king mackerel is divided into separate ACLs for the hook-and-line and run-around gillnet components of the commercial sector. The commercial hook-and-line quota (equivalent to the commercial hook-and-line ACL) for Gulf king mackerel in the southern zone is 575,400 lb (260,997 kg) for the current fishing year of July 1, 2020, through June 30, 2021 (50 CFR 622.384(b)(1)(iii)(A)).

Regulations at 50 CFR 622.388(a)(1) require NMFS to close any component of the king mackerel commercial sector when its applicable quota has been reached or is projected to be reached by filing a notification with the Office of the Federal Register. NMFS has determined the 2020–2021 hook-and-line commercial quota for Gulf king mackerel in the southern zone will be reached by February 22, 2021. Accordingly, the hook-and-line component of the commercial sector for Gulf king mackerel in the southern zone is closed from February 22, 2021, through the end of the fishing year on June 30, 2021. The commercial hook-and-line component for Gulf king mackerel in the southern zone will reopen on July 1, 2021.

NMFS has also determined that the Gulf king mackerel commercial quota for vessels using run-around gillnet gear in the southern zone was reached on January 28, 2021, and therefore on that date, NMFS closed the southern zone to commercial king mackerel fishing using run-around gillnet gear (86 FR 7815, February 2, 2021). Accordingly, all commercial fishing for Gulf king mackerel in the southern zone is closed effective at 12:01 a.m. local time on February 22, 2021. The commercial run-around gillnet component for Gulf king mackerel in the southern zone will reopen at 6 a.m. local time on January 18, 2022.

A person aboard a vessel that has a valid Federal commercial permit for king mackerel may continue to retain king mackerel under the recreational bag and possession limits specified in 50 CFR 622.382(a)(1)(ii) and (a)(2), as long as the recreational sector for Gulf king mackerel is open (50 CFR 622.384(e)(1)).

During the commercial closure, king mackerel caught with hook-and-line gear from the closed zone may not be purchased or sold, including those harvested under the recreational bag and possession limits. This prohibition does not apply to king mackerel caught with hook-and-line gear from the closed zone that were harvested, landed ashore, and sold prior to the closure and were held in cold storage by a dealer or processor (50 CFR 622.384(e)(2)).

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act. This action is required by 50 CFR 622.388(a)(1), which was issued pursuant to section 304(b) of the Magnuson-Stevens Act, and is exempt from review under Executive Order 12866.

Pursuant to 5 U.S.C. 553(b)(B), there is good cause to waive prior notice and an opportunity for public comment on this action, as notice and comment is unnecessary and contrary to the public interest. Such procedures are unnecessary because the regulations associated with the commercial quota and associated AM for Gulf king mackerel have already been subject to notice and public comment, and all that remains is to notify the public of the closure. Prior notice and opportunity for public comment on this action is contrary to the public interest because of time required to provide notice and an opportunity for public comment. There is a need to immediately implement the closure to protect the Gulf king mackerel resource, because the capacity of the fishing fleet allows for rapid harvest of the commercial quota, and any delay in the closure could result in the commercial quota being exceeded.

For the aforementioned reasons, there is good cause under 5 U.S.C. 553(d)(3)

to waive the 30-day delay in effectiveness of this action.

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

Dated: February 12, 2021.

Jennifer M. Wallace,

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

[FR Doc. 2021–03351 Filed 2–16–21; 4:15 pm]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 210210–0018]

RTID 0648–XY115

Fisheries of the Exclusive Economic Zone Off Alaska; Gulf of Alaska; Final 2021 and 2022 Harvest Specifications for Groundfish

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

ACTION: Final rule; harvest specifications and closures.

SUMMARY: NMFS announces final 2021 and 2022 harvest specifications, apportionments, and Pacific halibut prohibited species catch limits for the groundfish fishery of the Gulf of Alaska (GOA). This action is necessary to establish harvest limits for groundfish during the remainder of the 2021 and the start of the 2022 fishing years and to accomplish the goals and objectives of the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP). The 2021 harvest specifications supersede those previously set in the final 2020 and 2021 harvest specifications, and the 2022 harvest specifications will be superseded in early 2022 when the final 2022 and 2023 harvest specifications are published. The intended effect of this action is to conserve and manage the groundfish resources in the GOA in accordance with the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act).

DATES: Harvest specifications and closures are effective at 1200 hours, Alaska local time (A.l.t.), February 19, 2021, through 2400 hours, A.l.t., December 31, 2022.

ADDRESSES: Electronic copies of the Final Alaska Groundfish Harvest Specifications Environmental Impact Statement (EIS), Record of Decision (ROD), and the annual Supplementary Information Reports (SIRs) to the EIS prepared for this action are available from *https://www.regulations.gov.* The 2020 Stock Assessment and Fishery Evaluation (SAFE) report for the groundfish resources of the GOA, dated November 2020, and SAFE reports for previous years are available from the North Pacific Fishery Management Council (Council) at 1007 West 3rd Avenue, Suite 400, Anchorage, AK 99501, phone 907–271–2809, or from the Council's website at *https://www.npfmc.org.*

FOR FURTHER INFORMATION CONTACT: Obren Davis, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the GOA groundfish fisheries in the exclusive economic zone of the GOA under the FMP. The Council prepared the FMP under the authority of the Magnuson-Stevens Act, 16 U.S.C. 1801 *et seq.* Regulations governing U.S. fisheries and implementing the FMP appear at 50 CFR parts 600, 679, and 680.

The FMP and its implementing regulations require that NMFS, after consultation with the Council, specify the total allowable catch (TAC) for each target species, the sum of which must be within the optimum yield (OY) range of 116,000 to 800,000 metric tons (mt) (50 CFR 679.20(a)(1)(i)(B)). Section 679.20(c)(1) further requires that NMFS publish and solicit public comment on proposed annual TACs and apportionments thereof, Pacific halibut prohibited species catch (PSC) limits, and seasonal allowances of pollock and Pacific cod. Upon consideration of public comment received under § 679.20(c)(1), NMFS must publish notice of final harvest specifications for up to two fishing years as annual TACs and apportionments, Pacific halibut PSC limits, and seasonal allowances of pollock and Pacific cod, per § 679.20(c)(3)(ii). The final harvest specifications set forth in Tables 1 through 29 of this rule reflect the outcome of this process, as required at § 679.20(c).

The proposed 2021 and 2022 harvest specifications for groundfish of the GOA and Pacific halibut PSC limits were published in the **Federal Register** on December 3, 2020 (85 FR 78076). Comments were invited and accepted through January 4, 2021. NMFS did not receive any comments on the proposed harvest specifications. In December 2020, NMFS consulted with the Council regarding the 2021 and 2022 harvest specifications. After an opportunity for public comment, and after considering more recent biological and socioeconomic data that were available at the Council's December 2020 meeting, NMFS is implementing the final 2021 and 2022 harvest specifications, as recommended by the Council. Differences between the proposed specifications and the final specifications are discussed below. For 2021, the sum of the TAC amounts is 407,975 mt. For 2022, the sum of the TAC amounts is 409,039 mt.

Other Actions Affecting the 2021 and 2022 Harvest Specifications

Amendment 109 to the FMP: Revisions to the GOA Pollock Seasons and Pacific Cod Seasonal Allocations

On June 25, 2020, NMFS published a final rule to implement Amendment 109 to the FMP (85 FR 38093), effective January 1, 2021 (see also correction 85 FR 79139, December 9, 2020). The final rule revised the pollock seasons and allocations, along with Pacific cod season allocations, in the Western and Central Regulatory Areas of the GOA. Amendment 109 modified the existing annual pollock TAC allocation to two equal seasonal allocations (50 percent of TAC), rather than four equal seasonal allocations (25 percent of TAC). The pollock A and B seasons were combined into a January 20 through May 31 A season, and the pollock C and D seasons were combined into a September 1 through November 1 B season. Additionally, Amendment 109 revised the Pacific cod TAC seasonal apportionments to the trawl catcher vessel (CV) sector by increasing the A season allocation and decreasing the B season allocation. The December 9, 2020, correction clarified existing seasonal apportionments of Pacific cod for the jig sector. The revisions implemented by Amendment 109 are incorporated into these final 2021 and 2022 harvest specifications.

Amendment 110 to the FMP: Reclassify Sculpins as an Ecosystem Component Species

On July 10, 2020, NMFS published the final rule to implement Amendment 110 to the FMP (85 FR 41427). The final rule reclassified sculpins in the FMP as an ''Ecosystem Component'' species, which is a category of non-target species that are not in need of conservation and management. Accordingly, NMFS will no longer set an Overfishing Level (OFL), acceptable biological catch (ABC), and TAC for sculpins in the GOA groundfish harvest specifications.

ABC and TAC Specifications

In December 2020, the Council's Scientific and Statistical Committee (SSC), its Advisory Panel (AP), and the

Council reviewed the most recent biological and harvest information about the condition of the GOA groundfish stocks. The Council's GOA Groundfish Plan Team (Plan Team) compiled and presented this information in the 2020 SAFE report for the GOA groundfish fisheries, dated November 2020 (see **ADDRESSES**). The SAFE report contains a review of the latest scientific analyses and estimates of each species' biomass and other biological parameters, as well as summaries of the available information on the GOA ecosystem and the economic condition of the groundfish fisheries off Alaska. From these data and analyses, the Plan Team recommends, and the SSC sets, an OFL and ABC for each species or species group. The 2020 SAFE report was made available for public review during the public comment period for the proposed harvest specifications.

In previous years, the greatest changes from the proposed to the final harvest specifications have been based on recent NMFS stock surveys, which provide updated estimates of stock biomass and spatial distribution, and changes to the models used for producing stock assessments. At the November 2020 Plan Team meeting, NMFS scientists presented updated and new survey results, changes to stock assessment models, and accompanying stock assessment estimates for groundfish species and species groups that are included in the 2020 SAFE report per the stock assessment schedule found in the 2020 SAFE report introduction. The SSC reviewed this information at the December 2020 Council meeting. Changes from the proposed to the final 2021 and 2022 harvest specifications are discussed below.

The final 2021 and 2022 OFLs and ABCs are based on the best available biological information, including projected biomass trends, information on assumed distribution of stock biomass, and revised methods used to calculate stock biomass, and the final 2021 and 2022 TACs are based on the best available biological and socioeconomic information. The FMP specifies the formulas, or tiers, to be used to compute OFLs and ABCs. The formulas applicable to a particular stock or stock complex are determined by the level of reliable information available to fisheries scientists. This information is categorized into a successive series of six tiers to define OFL and ABC amounts, with Tier 1 representing the highest level of information quality available and Tier 6 representing the lowest level of information quality available. The Plan Team used the FMP tier structure to calculate OFL and ABC amounts for each groundfish species. The SSC adopted the final 2021 and 2022 OFLs and ABCs recommended by the Plan Team for most groundfish species, with the exception of sablefish.

The Alaska-wide sablefish ABC is apportioned between six areas within the Bering Sea and Aleutian Islands (BSAI) and Gulf of Alaska (Bering Sea, Aleutian Islands, Western Gulf, Central Gulf, West Yakutat, and East Yakutat/Southeast areas). Since 2013, a fixed apportionment methodology has been used to apportion the ABC between those six areas. However, a new apportionment methodology will be used for 2021 and 2022 that affects the apportionment of sablefish ABC and the area TACs that are allocated between the trawl and fixed gear sectors. The Joint BSAI and GOA Groundfish Plan Team, SSC, and Council reviewed a range of apportionment approaches for the sablefish ABC for the harvest specifications, including a range from the status quo (fixed apportionment) and the sablefish assessment authors' recommended non-exponential 5-year survey moving average. The Joint Plan Team recommended that, from a biological perspective, moving away from the fixed apportionment toward the true distribution would be preferred, to the extent practical. The SSC recommended a 25 percent stair step from the current (fixed) apportionment percentages toward the non-exponential 5-year survey moving average proposed by the assessment authors. The Council and NMFS have adopted the SSC's recommendation for the 2021 and 2022 ABC apportionments. For 2021 this increases the ABC apportionments in all areas (for example, up to 60 percent in the Aleutian Islands subarea), with smaller increases in areas that have recently been apportioned a greater percentage under the fixed apportionment methodology than suggested by recent survey observations (for example, only a 17 percent increase in the East Yakutat/Southeast area).

The Council adopted the SSC's OFLs and ABCs and the AP's TAC recommendations, with the exception of the sablefish TACs (further described below). The final TAC recommendations are based on the ABCs and are adjusted for other biological and socioeconomic considerations, including maintaining the sum of all TACs within the required OY range of 116,000 to 800,000 mt.

The Council recommended 2021 and 2022 TACs that are equal to ABCs for pollock in the Southeast Outside (SEO) District, shallow-water flatfish in the Central GOA and the West Yakutat and SEO Districts, deep-water flatfish, rex sole, arrowtooth flounder in the Central GOA, flathead sole in the West Yakutat and SEO Districts, Pacific ocean perch, northern rockfish, shortraker rockfish, dusky rockfish, rougheye and blackspotted rockfish, demersal shelf rockfish, thornyhead rockfish, ''other rockfish'' in the Western/Central GOA and West Yakutat District, big skate, longnose skate, other skates, sharks, and octopuses in the GOA. The Council recommended TACs for 2021 and 2022 that are less than the ABCs for pollock for the combined Western and Central GOA and West Yakutat District area, Pacific cod, shallow-water flatfish in the Western GOA, arrowtooth flounder in the Western GOA and the West Yakutat and SEO Districts, flathead sole in the Western and Central GOA, Atka mackerel, and ''other rockfish'' in the SEO District. The Council recommended 2021 sablefish TACs that are less than the 2021 ABCs, and 2022 sablefish TACs that are equal to 2022 ABCs. Setting the 2021 sablefish TACs less than 2021 ABCs is intended to provide an incremental increase to the 2021 sablefish TACs, rather than the very large increase in the 2021 sablefish TACs if they were set equal to ABCs. The Council recommended setting the TAC for each GOA management area to be 25 percent higher than the 2020 sablefish TACs.

The combined Western, Central, and West Yakutat pollock TAC and the GOA Pacific cod TACs are set to accommodate the State of Alaska's (State's) guideline harvest levels (GHLs) so that the ABCs for pollock and Pacific cod are not exceeded. The Western GOA shallow-water flatfish, Western GOA arrowtooth flounder, and Western GOA flathead sole TACs are set to allow for increased harvest opportunities for these target species while conserving the halibut PSC limit for use in other, more fully utilized fisheries. Similarly, the Western Yakutat and SEO Districts arrowtooth flounder TACs and the Central GOA flathead sole TAC are set lower than ABC to conserve halibut PSC limit for use in other fisheries or because there is limited commercial interest and participation in these fisheries. The Atka mackerel TAC is set to accommodate incidental catch amounts in other fisheries. The ''other rockfish'' TAC in the SEO District is set to reduce the amount of discards of the species in that complex.

The final 2021 and 2022 harvest specifications approved by the Secretary of Commerce are unchanged from those recommended by the Council, and are consistent with the preferred harvest strategy alternative outlined in the FMP and EIS (see **ADDRESSES**).

NMFS finds that the Council's recommended OFLs, ABCs, and TACs are consistent with the biological condition of the groundfish stocks as described in the final 2020 SAFE report. NMFS also finds that the Council's recommendations for TACs are consistent with the biological condition of groundfish stocks as adjusted for other biological and socioeconomic considerations, including maintaining the sum of all TACs within the OY range. NMFS reviewed the Council's recommended TACs and apportionments, and NMFS approves these harvest specifications under 50 CFR 679.20(c)(3)(ii). The apportionment of TAC amounts among gear types and sectors, processing sectors, and seasons is discussed below.

Tables 1 and 2 list the final 2021 and 2022 OFLs, ABCs, TACs, and area apportionments of groundfish in the GOA. The 2021 harvest specifications set in this final action will supersede the 2021 harvest specifications previously set in the final 2020 and 2021 harvest specifications (85 FR 13802, March 10, 2020). The 2022 harvest specifications will be superseded in early 2022 when the final 2022 and 2023 harvest specifications are published. Pursuant to this final action, the 2021 harvest specifications therefore will apply for the remainder of the current year (2021), while the 2022 harvest specifications are projected only for the following year (2022) and will be superseded in early 2022 by the final 2022 and 2023 harvest specifications. Because this final action (published in early 2021) will be superseded in early 2022 by the publication of the final 2022 and 2023 harvest specifications, it is projected that this final action will implement the harvest specifications for the Gulf of Alaska for approximately one year.

Specification and Apportionment of TAC Amounts

NMFS's apportionment of groundfish species is based on the distribution of biomass among the regulatory areas over which NMFS manages the species. Additional regulations govern the apportionment of pollock, Pacific cod, and sablefish and are described below.

The ABC for the pollock stock in the combined Western and Central Regulatory Areas and the West Yakutat (WYK) District of the Eastern Regulatory Area (the W/C/WYK) includes the amount for the GHL established by the State for the Prince William Sound (PWS) pollock fishery. The Plan Team, SSC, AP, and Council have recommended that the sum of all State water and Federal water pollock removals from the GOA not exceed ABC recommendations. For 2021 and 2022, the SSC recommended and the Council approved the W/C/WYK pollock ABC, including the amount to account for the State's PWS GHL. At the November 2020 Plan Team meeting, State fisheries managers recommended setting the PWS pollock GHL at 2.5 percent of the annual W/C/WYK pollock ABC. For 2021, this yields a PWS pollock GHL of 2,643 mt, a decrease of 69 mt from the 2020 PWS pollock GHL of 2,712 mt. For 2022, the PWS pollock GHL is 2,298 mt, a decrease of 414 mt from the 2020 PWS pollock GHL of 2,712 mt. After the GHL reductions, the 2021 and 2022 pollock ABCs for the combined W/C/WYK areas are then apportioned between four statistical areas (Areas 610, 620, 630, and 640) as both ABCs and TACs, as described below and detailed in Tables 1 and 2. The total ABCs and TACs for the four statistical areas, plus the State PWS GHL, do not exceed the combined W/C/WYK ABC.

Apportionments of pollock to the W/C/WYK areas are considered to be ''apportionments of annual catch limits (ACLs)'' rather than ''ABCs.'' This more accurately reflects that such apportionments address management, rather than biological or conservation, concerns. In addition, apportionments of the ACL in this manner allow NMFS to balance any transfer of TAC among Areas 610, 620, and 630 pursuant to § 679.20(a)(5)(iv)(B) to ensure that the combined W/C/WYK ACL, ABC, and TAC are not exceeded.

NMFS establishes pollock TACs in the Western (Area 610) and Central (Areas 620 and 630) Regulatory Areas and the West Yakutat (Area 640) and the SEO (Area 650) Districts of the GOA (see Tables 1 and 2). NMFS also establishes seasonal apportionments of the annual pollock TACs in the Western and Central Regulatory Areas of the GOA among Statistical Areas 610, 620, and 630. Additional detail on area apportionments and seasonal allowances is provided in a subsequent section in this rule; Tables 3 and 4 list these amounts.

The 2021 and 2022 Pacific cod TACs are set to accommodate the State's GHLs for Pacific cod in State waters in the Western and Central Regulatory Areas, as well as in PWS. The Plan Team, SSC, AP, and Council recommended that the sum of all State water and Federal water Pacific cod removals from the GOA not exceed ABC recommendations. The Council set the 2021 and 2022 Pacific cod TACs in the Western, Central, and Eastern Regulatory Areas to account for State GHLs. Therefore, the 2021 Pacific cod TACs are less than the ABCs by the following amounts: (1) Western GOA, 2,396 mt; (2) Central GOA, 3,414 mt; and (3) Eastern GOA, 496 mt. The 2022 Pacific cod TACs are less than the ABCs by the following amounts: (1) Western GOA, 3,868 mt; (2) Central GOA, 5,511 mt; and (3) Eastern GOA, 801 mt. These amounts reflect the State's 2021 and 2022 GHLs in these areas, which are 30 percent of the Western GOA ABC and 25 percent of the Eastern and Central GOA ABCs.

The Western and Central GOA Pacific cod TACs are allocated among various gear and operational sectors. NMFS also establishes seasonal apportionments of the annual Pacific cod TAC in the Western and Central Regulatory Areas. The Pacific cod sector and seasonal apportionments are discussed in detail in a subsequent section and in Tables 5 and 6 of this rule.

The Council's recommendation for sablefish area apportionments takes into account the prohibition on the use of trawl gear in the SEO District of the Eastern Regulatory Area (§ 679.7(b)(1)) and makes available 5 percent of the combined Eastern Regulatory Area TACs to vessels using trawl gear for use as incidental catch in other trawl groundfish fisheries in the WYK District (§ 679.20(a)(4)(i)). Tables 7 and 8 list the final 2021 and 2022 allocations of sablefish TAC to fixed gear and trawl gear in the GOA.

Changes From the Proposed 2021 and 2022 Harvest Specifications in the GOA

In October 2020, the Council's recommendations for the proposed 2021 and 2022 harvest specifications (85 FR 78076, December 3, 2020) were based largely on information contained in the final 2019 SAFE report for the GOA groundfish fisheries, dated November 2019. The final 2019 SAFE report for the GOA is available from the Council (see **ADDRESSES**). The Council proposed that the final OFLs, ABCs, and TACs established for the 2021 groundfish fisheries (85 FR 13802, March 10, 2020) be used for the proposed 2021 and 2022 harvest specifications (85 FR 78076, December 3, 2020), pending completion and review of the 2020 SAFE report at the Council's December 2020 meeting.

As described previously, the SSC recommended the final 2021 and 2022 OFLs and ABCs as recommended by the Plan Team, with the exception of sablefish ABCs. The Council adopted as its recommendations the SSC's OFL and ABC recommendations and the AP's TAC recommendations (except for sablefish) for 2021 and 2022.

The final 2021 ABCs are higher than the proposed 2021 ABCs published in the proposed 2021 and 2022 harvest

specifications (85 FR 78076, December 3, 2020) for Pacific cod, arrowtooth flounder, flathead sole, Pacific ocean perch, northern rockfish, dusky rockfish, rougheye/blackspotted rockfish, and demersal shelf rockfish. The final 2021 ABCs are lower than the proposed 2021 ABCs for pollock, sablefish, shallow-water flatfish, thornyhead rockfish, and sharks.

The final 2022 ABCs are higher than the proposed 2022 ABCs for Pacific cod, sablefish, shallow-water flatfish, flathead sole, Pacific ocean perch, northern rockfish, dusky rockfish, rougheye/blackspotted rockfish, and demersal shelf rockfish. The final 2022 ABCs are lower than the proposed 2022 ABCs for pollock, arrowtooth flounder, thornyhead rockfish, and sharks. For the remaining target species, the Council recommended the final 2021 and 2022 ABCs that are the same as the proposed 2021 and 2022 ABCs.

Additional information explaining the changes between the proposed and final ABCs is included in the final 2020 SAFE report, which was not completed and available when the Council made its proposed ABC and TAC recommendations in October 2020. At that time, the most recent stock assessment information was contained in the final 2019 SAFE report. The final 2020 SAFE report contains the best and most recent scientific information on the condition of the groundfish stocks, as previously discussed in this preamble, and is available for review (see **ADDRESSES**). The Council considered the 2020 SAFE report in December 2020 when it made recommendations for the final 2021 and 2022 harvest specifications. In the GOA, the total final 2021 TAC amount is 407,975 mt, an increase of 1.3 percent from the total proposed 2021 TAC amount of 402,783 mt. The total final 2022 TAC amount is 409,039 mt, an increase of 1.6 percent from the total proposed 2022 TAC amount of 402,783 mt. Table 1a summarizes the difference between the proposed and final TACs.

Annual stock assessments incorporate a variety of new or revised inputs, such as survey data or catch information, as well as changes to the statistical models used to estimate a species' biomass and population trend. Changes to biomass and ABC estimates are primarily based on fishery catch updates to species' assessment models. Some species, such as pollock and sablefish, have additional surveys conducted on an annual basis, which resulted in additional data being available for the 2020 assessments for these stocks.

The changes from the proposed 2021 TACs to the final 2021 TACs are within a range of plus 169 percent or minus 60 percent, and the changes from the proposed 2022 TACs to the final 2022 TACs are within a range of plus 335 percent or minus 60 percent. Based on changes in the estimates of overall biomass in the stock assessment for 2021 and 2022, as compared to the estimates previously made for 2020 and 2021, the species or species group with the greatest TAC percentage increases are Pacific cod, Pacific ocean perch, northern rockfish, and dusky rockfish. Based on changes in the estimates of biomass, the species or species group with the greatest decreases in TACs are sablefish, other rockfish, and sharks, as well as pollock (2022 TAC). The 2021 sablefish TAC decreases by 19 percent, but increases in 2022 by 13 percent, compared to estimates previously made for 2020 and 2021. For all other species and species groups, changes from the proposed 2021 TACs to the final 2021 TACs and changes from the proposed 2022 TACs to the final 2022 TACs are less than a 10 percent change (either increase or decrease). These TAC changes correspond to associated changes in the ABCs and TACs, as recommended by the SSC, AP, and Council.

Detailed information providing the basis for the changes described above is contained in the final 2020 SAFE report. The final TACs are based on the best scientific information available, including biological and socioeconomic information. These TACs are specified in compliance with the harvest strategy described in the proposed and final rules for the 2021 and 2022 harvest specifications.

TABLE 1A—COMPARISON OF PROPOSED AND FINAL 2021 AND 2022 GOA TOTAL ALLOWABLE CATCH LIMITS

[Values are rounded to the nearest metric ton and percentage]

Species	2021 and 2022 Proposed TAC	2021 Final TAC	2021 Final minus 2021 Proposed TAC	Percentage difference	2022 Final TAC	2022 Final minus 2022 Proposed TAC	Percentage difference
Pollock	119,239	113,227	–6,012	–5	99,784	–19,455	–16
Pacific cod	6,431	17,321	10,890	169	27,961	21,530	335
Sablefish	22,252	17,992	–4,260	–19	25,231	2,979	13
Shallow-water flatfish	45,403	45,263	–140	0	45,673	270	1
Deep-water flatfish	5,926	5,926	0	0	5,926	0	0
Rex sole	15,416	15,416	0	0	15,416	0	0
Arrowtooth flounder	94,983	97,372	2,389	3	95,454	471	0
Flathead sole	28,386	28,392	6	0	28,445	59	0
Pacific ocean perch	29,983	36,177	6,194	21	34,602	4,619	15
Northern rockfish	4,106	5,357	1,251	30	5,099	993	24
Shortraker rockfish	708	708	0	0	708	0	0
Dusky rockfish	3,598	5,389	1,791	50	5,295	1,697	47
Rougheye/blackspotted rockfish	1,211	1,212	1	0	1,221	10	1
Demersal shelf rockfish	238	257	19	8	257	19	8
Thornyhead rockfish	2,016	1,953	–63	–3	1,953	–63	–3
Other rockfish	4,053	1,609	–2,444	–60	1,609	–2,444	–60
Atka mackerel	3,000	3,000	0	0	3,000	0	0
Big skate	3,208	3,208	0	0	3,208	0	0
Longnose skate	2,587	2,587	0	0	2,587	0	0
Other skates	875	875	0	0	875	0	0
Sharks	8,184	3,755	–4,429	–54	3,755	–4,429	–54
Octopuses	980	980	0	0	980	0	0
Total	402,783	407,975	5,193	1.3	409,039	6,256	1.6

The final 2021 and 2022 TAC amounts for the GOA are within the OY range established for the GOA and do not exceed the ABC for any species or species group. Tables 1 and 2 list the final OFL, ABC, and TAC amounts for

GOA groundfish for 2021 and 2022, respectively.

TABLE 1—FINAL 2021 OFLS, ABCS, AND TACS OF GROUNDFISH FOR THE WESTERN/CENTRAL/WEST YAKUTAT, WESTERN, CENTRAL, EASTERN REGULATORY AREAS, THE WEST YAKUTAT AND SOUTHEAST OUTSIDE DISTRICTS OF THE EASTERN REGULATORY AREA, AND GULFWIDE DISTRICTS OF THE GULF OF ALASKA

[Values are rounded to the nearest metric ton]

Species	Area [1]	OFL	ABC	TAC
Pollock [2]	Shumagin (610)	n/a	18,477	18,477
	Chirikof (620)	n/a	54,870	54,870
	Kodiak (630)	n/a	24,320	24,320
	WYK (640)	n/a	5,412	5,412
	W/C/WYK (subtotal) [2]	123,455	105,722	103,079
	SEO (650)	13,531	10,148	10,148
	Total	136,986	115,870	113,227
Pacific cod [3]	W	n/a	7,986	5,590
	C	n/a	13,656	10,242
	E	n/a	1,985	1,489
	Total	28,977	23,627	17,321
Sablefish [4]	W	n/a	3,224	2,428
	C	n/a	9,527	8,056
	WYK	n/a	3,451	2,929
	SEO	n/a	5,273	4,579
	E (WYK and SEO) (subtotal)	n/a	8,724	7,508
	Total	60,426	21,475	17,991
Shallow-water flatfish [5]	W	n/a	24,151	13,250
	C	n/a	28,082	28,082
	WYK	n/a	2,808	2,808
	SEO	n/a	1,123	1,123
	Total	68,841	56,164	45,263
Deep-water flatfish [6]	W	n/a	225	225
	C	n/a	1,914	1,914
	WYK	n/a	2,068	2,068
	SEO	n/a	1,719	1,719
	Total	7,040	5,926	5,926
Rex sole	W	n/a	3,013	3,013
	C	n/a	8,912	8,912
	WYK	n/a	1,206	1,206
	SEO	n/a	2,285	2,285
	Total	18,779	15,416	15,416
Arrowtooth flounder	W	n/a	32,377	14,500
	C	n/a	69,072	69,072
	WYK	n/a	8,380	6,900
	SEO	n/a	17,141	6,900
	Total	151,723	126,970	97,372
Flathead sole	W	n/a	14,209	8,650
	C	n/a	20,826	15,400
	WYK	n/a	2,427	2,427
	SEO	n/a	1,915	1,915
	Total	47,982	39,377	28,392
Pacific ocean perch [7]	W	n/a	1,643	1,643
	C	n/a	27,429	27,429
	WYK	n/a	1,705	1,705
	W/C/WYK subtotal	36,563	30,777	30,777
	SEO	6,414	5,400	5,400
	Total	42,977	36,177	36,177
Northern rockfish [8]	W	n/a	2,023	2,023
	C	n/a	3,334	3,334
	E	n/a	1	
	Total	6,396	5,358	5,357
Shortraker rockfish [9]	W	n/a	52	52
	C	n/a	284	284
	E	n/a	372	372

TABLE 1—FINAL 2021 OFLS, ABCS, AND TACS OF GROUNDFISH FOR THE WESTERN/CENTRAL/WEST YAKUTAT, WESTERN, CENTRAL, EASTERN REGULATORY AREAS, THE WEST YAKUTAT AND SOUTHEAST OUTSIDE DISTRICTS OF THE EASTERN REGULATORY AREA, AND GULFWIDE DISTRICTS OF THE GULF OF ALASKA—Continued

[Values are rounded to the nearest metric ton]

Species	Area [1]	OFL	ABC	TAC
	Total	944	708	708
Dusky rockfish [10]	W	n/a	270	270
	C	n/a	4,548	4,548
	WYK	n/a	468	468
	SEO	n/a	103	103
	Total	8,655	5,389	5,389
Rougheye and Blackspotted rockfish [11]	W	n/a	168	168
	C	n/a	456	456
	E	n/a	588	588
	Total	1,456	1,212	1,212
Demersal shelf rockfish [12]	SEO	405	257	257
Thornyhead rockfish	W	n/a	352	352
	C	n/a	910	910
	E	n/a	691	691
	Total	2,604	1,953	1,953
Other rockfish [13 14]	W and C	n/a	940	940
	WYK	n/a	369	369
	SEO	n/a	2,744	300
	Total	5,320	4,053	1,609
Atka mackerel	GW	6,200	4,700	3,000
Big skate [15]	W	n/a	758	758
	C	n/a	1,560	1,560
	E	n/a	890	890
	Total	4,278	3,208	3,208
Longnose skate [16]	W	n/a	158	158
	C	n/a	1,875	1,875
	E	n/a	554	554
	Total	3,449	2,587	2,587
Other skates [17]	GW	1,166	875	875
Sharks	GW	5,006	3,755	3,755
Octopus	GW	1,307	980	980
Total		610,917	476,037	407,975

[1] Regulatory areas and districts are defined at § 679.2. (W=Western Gulf of Alaska; C=Central Gulf of Alaska; E=Eastern Gulf of Alaska; WYK=West Yakutat District; SEO=Southeast Outside District; GW=Gulf-wide).

[2] The total for the W/C/WYK Regulatory Areas pollock ABC is 105,722 mt. After deducting 2.5 percent (2,643 mt) of that ABC for the State's pollock GHL fishery, the remaining pollock ABC of 103,079 mt (for the W/C/WYK Regulatory Areas) is apportioned among four statistical areas (Areas 610, 620, 630, and 640). These apportionments are considered subarea ACLs, rather than ABCs, for specification and reapportionment purposes. The ACLs in Areas 610, 620, and 630 are further divided by season, as detailed in Table 3 (final 2021 seasonal biomass distribution of pollock in the Western and Central Regulatory Areas, area apportionments, and seasonal allowances). In the West Yakutat (Area 640) and Southeast Outside (Area 650) Districts of the Eastern Regulatory Area, pollock is not divided into seasonal allowances.

[3] The annual Pacific cod TAC is apportioned, after seasonal apportionment to the jig sector, as follows: (1) 63.84 percent to the A season and 36.16 percent to the B season and (2) 64.16 percent to the A season and 35.84 percent to the B season in the Western and Central Regulatory Areas of the GOA, respectively. Pacific cod TAC in the Eastern Regulatory Area of the GOA is allocated 90 percent to vessels harvesting Pacific cod for processing by the inshore component and 10 percent to vessels harvesting Pacific cod for processing by the offshore component. Table 5 lists the final 2021 Pacific cod seasonal apportionments and sector allocations.

[4] The sablefish OFL and ABC is set Alaska-wide (60,426 mt and 29,588 mt, respectively). Additionally, sablefish is allocated to trawl and fixed gear in 2021 and trawl gear in 2022. Table 7 lists the final 2021 allocations of sablefish TACs.

[5] "Shallow-water flatfish" means flatfish not including "deep-water flatfish," flathead sole, rex sole, or arrowtooth flounder.

[6] "Deep-water flatfish" means Dover sole, Greenland turbot, Kamchatka flounder, and deepsea sole.

[7] "Pacific ocean perch" means *Sebastes alutus.*

[8] "Northern rockfish" means *Sebastes polyspinis.* For management purposes, the 1 mt apportionment of ABC to the WYK District of the Eastern Gulf of Alaska has been included in the "other rockfish" species group.

[9] "Shortraker rockfish" means *Sebastes borealis.*

[10] "Dusky rockfish" means *Sebastes variabilis.*

[11] "Rougheye and blackspotted rockfish" mean *Sebastes aleutianus* (rougheye) and *S. melanostictus* (blackspotted).

[12] "Demersal shelf rockfish" means *Sebastes pinniger* (canary), *S. nebulosus* (china), *S. caurinus* (copper), *S. maliger* (quillback), *S. helvomaculatus* (rosethorn), *S. nigrocinctus* (tiger), and *S. ruberrimus* (yelloweye).

[13] "Other rockfish" means *Sebastes aurora* (aurora), *S. melanostomus* (blackgill), *S. paucispinis* (bocaccio), *S. goodei* (chilipepper), *S. crameri* (darkblotch), *S. elongatus* (greenstriped), *S. variegatus* (harlequin), *S. wilsoni* (pygmy), *S. babcocki* (redbanded), *S. proriger* (redstripe), *S. zacentrus* (sharpchin), *S. jordani* (shortbelly), *S. brevispinis* (silvergrey), *S. diploproa* (splitnose), *S. saxicola* (stripetail), *S. miniatus* (vermilion), *S. reedi* (yellowmouth), *S. entomelas* (widow), and *S. flavidus* (yellowtail). In the Eastern GOA only, other rockfish also includes northern rockfish, *S. polyspinis.*

[14] "Other rockfish" in the Western and Central Regulatory Areas and in the West Yakutat District means other rockfish and demersal shelf rockfish. The "other rockfish" species group in the SEO District only includes other rockfish.

[15] "Big skate" means *Raja binoculata.*
[16] "Longnose skate" means *Raja rhina.*
[17] "Other skates" mean *Bathyraja and Raja* spp.

TABLE 2—FINAL 2022 OFLS, ABCS, AND TACS OF GROUNDFISH FOR THE WESTERN/CENTRAL/WEST YAKUTAT, WESTERN, CENTRAL, EASTERN REGULATORY AREAS, THE WEST YAKUTAT AND SOUTHEAST OUTSIDE DISTRICTS OF THE EASTERN REGULATORY AREA, AND GULFWIDE DISTRICTS OF THE GULF OF ALASKA

[Values are rounded to the nearest metric ton]

Species	Area [1]	OFL	ABC	TAC
Pollock [2]	Shumagin (610)	n/a	16,067	16,067
	Chirikof (620)	n/a	47,714	47,714
	Kodiak (630)	n/a	21,149	21,149
	WYK (640)	n/a	4,706	4,706
	W/C/WYK (subtotal) [2]	106,767	91,934	89,636
	SEO (650)	13,531	10,148	10,148
	Total	120,298	102,082	99,784
Pacific cod [3]	W	n/a	12,892	9,024
	C	n/a	22,045	16,534
	E	n/a	3,204	2,403
	Total	46, 587	38,141	27,961
Sablefish [4]	W	n/a	4,165	4,165
	C	n/a	11,111	11,111
	WYK	n/a	4,009	4,009
	SEO	n/a	5,946	5,946
	E (WYK and SEO) (subtotal)	n/a	9,955	9,955
	Total	70,710	25,231	25,231
Shallow-water flatfish [5]	W	n/a	24,460	13,250
	C	n/a	28,442	28,442
	WYK	n/a	2,844	2,844
	SEO	n/a	1,137	1,137
	Total	69,061	56,883	45,673
Deep-water flatfish [6]	W	n/a	225	225
	C	n/a	1,914	1,914
	WYK	n/a	2,068	2,068
	SEO	n/a	1,719	1,719
	Total	7,040	5,926	5,926
Rex sole	W	n/a	3,013	3,013
	C	n/a	8,912	8,912
	WYK	n/a	1,206	1,206
	SEO	n/a	2,285	2,285
	Total	18,779	15,416	15,416
Arrowtooth flounder	W	n/a	31,479	14,500
	C	n/a	67,154	67,154
	WYK	n/a	8,147	6,900
	SEO	n/a	16,665	6,900
	Total	147,515	123,445	95,454
Flathead sole	W	n/a	14,380	8,650
	C	n/a	21,076	15,400
	WYK	n/a	2,456	2,456
	SEO	n/a	1,939	1,939
	Total	48,534	39,851	28,445
Pacific ocean perch [7]	W	n/a	1,572	1,572
	C	n/a	26,234	26,234
	WYK	n/a	1,631	1,631
	W/C/WYK	34,974	29,437	29,437
	SEO	6,136	5,165	5,165
	Total	41,110	34,602	34,602
Northern rockfish [8]	W	n/a	1,926	1,926
	C	n/a	3,173	3,173
	E	n/a	1	.....
	Total	6,088	5,100	5,099
Shortraker rockfish [9]	W	n/a	52	52
	C	n/a	284	284

TABLE 2—FINAL 2022 OFLS, ABCS, AND TACS OF GROUNDFISH FOR THE WESTERN/CENTRAL/WEST YAKUTAT, WESTERN, CENTRAL, EASTERN REGULATORY AREAS, THE WEST YAKUTAT AND SOUTHEAST OUTSIDE DISTRICTS OF THE EASTERN REGULATORY AREA, AND GULFWIDE DISTRICTS OF THE GULF OF ALASKA—Continued

[Values are rounded to the nearest metric ton]

Species	Area [1]	OFL	ABC	TAC
	E	n/a	372	372
	Total	944	708	708
Dusky rockfish [10]	W	n/a	265	265
	C	n/a	4,469	4,469
	WYK	n/a	460	460
	SEO	n/a	101	101
	Total	8,423	5,295	5,295
Rougheye and Blackspotted rockfish [11]	W	n/a	170	170
	C	n/a	459	459
	n/a	592	592	
	Total	1,467	1,221	1,221
Demersal shelf rockfish [12]	SEO	405	257	257
Thornyhead rockfish	W	n/a	352	352
	C	n/a	910	910
	E	n/a	691	691
	Total	2, 604	1,953	1,953
Other rockfish [13 14]	W and C	n/a	940	940
	WYK	n/a	369	369
	SEO	n/a	2,744	300
	Total	5,320	4,053	1,609
Atka mackerel	GW	6,200	4,700	3,000
Big skate [15]	W	n/a	758	758
	C	n/a	1,560	1,560
	E	n/a	890	890
	Total	4, 278	3,208	3,208
Longnose skate [16]	W	n/a	158	158
	C	n/a	1,875	1,875
	E	n/a	554	554
	Total	3,449	2,587	2,587
Other skates [17]	GW	1,166	875	875
Sharks	GW	5,006	3,755	3,755
Octopus	GW	1,307	980	980
Total		616,921	476,269	409,039

[1] Regulatory areas and districts are defined at § 679.2. (W=Western Gulf of Alaska; C=Central Gulf of Alaska; E=Eastern Gulf of Alaska; WYK=West Yakutat District; SEO=Southeast Outside District; GW=Gulf-wide).

[2] The total for the W/C/WYK Regulatory Areas pollock ABC is 91,934 mt. After deducting 2.5 percent (2,298 mt) of that ABC for the State's pollock GHL fishery, the remaining pollock ABC of 89,636 mt (for the W/C/WYK Regulatory Areas) is apportioned among four statistical areas (Areas 610, 620, 630, and 640). These apportionments are considered subarea ACLs, rather than ABCs, for specification and reapportionment purposes. The ACLs in Areas 610, 620, and 630 are further divided by season, as detailed in Table 4 (final 2022 seasonal biomass distribution of pollock in the Western and Central Regulatory Areas, area apportionments, and seasonal allowances). In the West Yakutat (Area 640) and Southeast Outside (Area 650) Districts of the Eastern Regulatory Area, pollock is not divided into seasonal allowances.

[3] The annual Pacific cod TAC is apportioned, after seasonal apportionment to the jig sector, as follows: (1) 63.84 percent to the A season and 36.16 percent to the B season and (2) 64.16 percent to the A season and 35.84 percent to the B season in the Western and Central Regulatory Areas of the GOA, respectively. Pacific cod TAC in the Eastern Regulatory Area of the GOA is allocated 90 percent to vessels harvesting Pacific cod for processing by the inshore component and 10 percent to vessels harvesting Pacific cod for processing by the offshore component. Table 6 lists the final 2022 Pacific cod seasonal apportionments and sector allocations.

[4] The sablefish OFL and ABC is set Alaska-wide (70,710 mt and 36,955 mt, respectively). Additionally, sablefish is allocated only to trawl gear for 2022. Table 8 lists the final 2022 allocation of sablefish TACs to trawl gear.

[5] "Shallow-water flatfish" means flatfish not including "deep-water flatfish," flathead sole, rex sole, or arrowtooth flounder.

[6] "Deep-water flatfish" means Dover sole, Greenland turbot, Kamchatka flounder, and deepsea sole.

[7] "Pacific ocean perch" means *Sebastes alutus.*

[8] "Northern rockfish" means *Sebastes polyspinis.* For management purposes, the 1 mt apportionment of ABC to the WYK District of the Eastern Gulf of Alaska has been included in the "other rockfish" species group.

[9] "Shortraker rockfish" means *Sebastes borealis.*

[10] "Dusky rockfish" means *Sebastes variabilis.*

[11] "Rougheye and blackspotted rockfish" mean *Sebastes aleutianus* (rougheye) and *S. melanostictus* (blackspotted).

[12] "Demersal shelf rockfish" means *Sebastes pinniger* (canary), *S. nebulosus* (china), *S. caurinus* (copper), *S. maliger* (quillback), *S. helvomaculatus* (rosethorn), *S. nigrocinctus* (tiger), and *S. ruberrimus* (yelloweye).

[13] "Other rockfish" means *Sebastes aurora* (aurora), *S. melanostomus* (blackgill), *S. paucispinis* (bocaccio), *S. goodei* (chilipepper), *S. crameri* (darkblotch), *S. elongatus* (greenstriped), *S. variegatus* (harlequin), *S. wilsoni* (pygmy), *S. babcocki* (redbanded), *S. proriger* (redstripe), *S. zacentrus* (sharpchin), *S. jordani* (shortbelly), *S. brevispinis* (silvergrey), *S. diploproa* (splitnose), *S. saxicola* (stripetail), *S. miniatus* (vermilion), *S. reedi* (yellowmouth), *S. entomelas* (widow), and *S. flavidus* (yellowtail). In the Eastern GOA only, other rockfish also includes northern rockfish, *S. polyspinis.*

[14] "Other rockfish" in the Western and Central Regulatory Areas and in the West Yakutat District means other rockfish and demersal shelf rockfish. The "other rockfish" species group in the SEO District only includes other rockfish.
[15] "Big skate" means *Raja binoculata.*
[16] "Longnose skate" means *Raja rhina.*
[17] "Other skates" mean *Bathyraja and Raja* spp.

Apportionment of Reserves

Section 679.20(b)(2) requires NMFS to set aside 20 percent of each TAC for pollock, Pacific cod, flatfish, sharks, and octopuses in reserve for possible apportionment at a later date during the fishing year. For 2021 and 2022, NMFS proposed reapportionment of all the reserves in the proposed 2021 and 2022 harvest specifications published in the **Federal Register** on December 3, 2020 (85 FR 78076). NMFS did not receive any public comments on the proposed reapportionments. For the final 2021 and 2022 harvest specifications, NMFS reapportioned, as proposed, all the reserves for pollock, Pacific cod, flatfish, sharks, and octopuses back to the original TAC limit from which the reserve was derived (§ 679.20(b)(3)). This was done because NMFS expects, based on recent harvest patterns, that such reserves are not necessary and that the entire TAC for each of these species will be caught. The TACs listed in Tables 1 and 2 reflect reapportionments of reserve amounts to the original TAC limit for these species and species groups, *i.e.,* each final TAC for the above mentioned species or species groups contains the full TAC recommended by the Council.

Apportionments of Pollock TAC Among Seasons and Regulatory Areas, and Allocations for Processing by Inshore and Offshore Components

In the GOA, pollock is apportioned by season and area, and is further allocated for processing by inshore and offshore components. The pollock TACs in the Western and Central Regulatory Areas of the GOA are apportioned among Statistical Areas 610, 620, and 630. These apportionments are divided into two equal seasonal allowances of 50 percent to the A season (January 20 through May 31) and 50 percent to the B season (September 1 through November 1) (§§ 679.20(a)(5)(iv)(B) and 679.23(d)(2)). As described earlier in the preamble, the regulatory revisions implemented by Amendment 109 to the FMP (85 FR 38093, published June 25, 2020, effective January 1, 2021) decreased the number of seasons to two and established two equal seasonal allowances of 50 percent. NMFS incorporated these regulatory revisions into the harvest specifications for the GOA, and Tables 3 and 4, below, reflect the revised seasons and seasonal allowances implemented by Amendment 109 to the FMP.

The GOA pollock stock assessment continues to use a four-season methodology to determine pollock distribution in the Western and Central Regulatory Areas of the GOA to maintain continuity in the historical pollock apportionment time-series. Pollock TACs in the Western and Central Regulatory Areas of the GOA are apportioned among Statistical Areas 610, 620, and 630 in proportion to the distribution of pollock biomass determined by the most recent NMFS surveys, pursuant to § 679.20(a)(5)(iv)(A). The pollock chapter of the 2020 SAFE report (see **ADDRESSES**) contains a comprehensive description of the apportionment and reasons for the minor changes from past apportionments. For purposes of specifying pollock TAC between two seasons for the Western and Central Regulatory Areas of the GOA, NMFS has summed the A and B season apportionments and the C and D season apportionments as calculated in the 2020 GOA pollock assessment. This yields the seasonal amounts specified for the A season and the B season, respectively.

Within any fishing year, the amount by which a pollock seasonal allowance is underharvested or overharvested may be added to, or subtracted from, subsequent seasonal allowances for the Western and Central Regulatory Areas in a manner to be determined by the Regional Administrator (§ 679.20(a)(5)(iv)(B)). The rollover amount is limited to 20 percent of the subsequent seasonal TAC apportionment for the statistical area. Any unharvested pollock above the 20-percent limit could be further distributed to the other statistical areas, in proportion to the estimated biomass in the subsequent season in those statistical areas and in an amount no more than 20 percent of the seasonal TAC apportionment in those statistical areas (§ 679.20(a)(5)(iv)(B)). The pollock TACs in the WYK and the SEO Districts of 5,412 mt and 10,148 mt, respectively, in 2021, and 4,706 mt and 10,148 mt, respectively, in 2022, are not allocated by season.

Tables 3 and 4 list the final 2021 and 2022 seasonal biomass distribution of pollock in the Western and Central Regulatory Areas, area apportionments, and seasonal allowances. The amounts of pollock for processing by the inshore and offshore components are not shown. Section 679.20(a)(6)(i) requires the allocation of 100 percent of the pollock TAC in all GOA regulatory areas and all seasonal allowances to vessels catching pollock for processing by the inshore component after subtraction of pollock amounts projected by the Regional Administrator to be caught by, or delivered to, the offshore component incidental to directed fishing for other groundfish species. Thus, the amount of pollock available for harvest by vessels harvesting pollock for processing by the offshore component is that amount that will be taken as incidental catch during directed fishing for groundfish species other than pollock, up to the maximum retainable amounts allowed by § 679.20(e) and (f). At this time, these incidental catch amounts of pollock are unknown and will be determined during the fishing year during the course of fishing activities by the offshore component.

TABLE 3—FINAL 2021 DISTRIBUTION OF POLLOCK IN THE WESTERN AND CENTRAL REGULATORY AREAS OF THE GULF OF ALASKA; AREA APPORTIONMENTS; AND SEASONAL ALLOWANCES OF ANNUAL TAC

[Values are rounded to the nearest metric ton [1]]

Season [2]	Shumigan (Area 610)	Chirikof (Area 620)	Kodiak (Area 630)	Total [3]
A (January 20–May 31)	799	41,737	6,297	48,833
B (September 1–November 1)	17,677	13,133	18,023	48,833

TABLE 3—FINAL 2021 DISTRIBUTION OF POLLOCK IN THE WESTERN AND CENTRAL REGULATORY AREAS OF THE GULF OF ALASKA; AREA APPORTIONMENTS; AND SEASONAL ALLOWANCES OF ANNUAL TAC—Continued

[Values are rounded to the nearest metric ton [1]]

Season [2]	Shumigan (Area 610)	Chirikof (Area 620)	Kodiak (Area 630)	Total [3]
Annual Total	18,477	54,870	24,320	97,667

[1] Area apportionments and seasonal allowances may not total precisely due to rounding.
[2] As established by § 679.23(d)(2), the A and B season allowances are available from January 20 through May 31 and September 1 through November 1, respectively. The amounts of pollock for processing by the inshore and offshore components are not shown in this table.
[3] The West Yakutat and Southeast Outside District pollock TACs are not allocated by season and are not included in the total pollock TACs shown in this table.

TABLE 4—FINAL 2022 DISTRIBUTION OF POLLOCK IN THE WESTERN AND CENTRAL REGULATORY AREAS OF THE GULF OF ALASKA; AREA APPORTIONMENTS; AND SEASONAL ALLOWANCES OF ANNUAL TAC

[Values are rounded to the nearest metric ton [1]]

Season [2]	Shumigan (Area 610)	Chirikof (Area 620)	Kodiak (Area 630)	Total [3]
A (January 20–May 31)	695	36,294	5,476	42,465
B (September 1–November 1)	15,372	11,420	15,672	42,465
Annual Total	16,067	47,714	21,149	84,929

[1] Area apportionments and seasonal allowances may not total precisely due to rounding.
[2] As established by § 679.23(d)(2), the A and B season allowances are available from January 20 through May 31 and September 1 through November 1, respectively. The amounts of pollock for processing by the inshore and offshore components are not shown in this table.
[3] The West Yakutat and Southeast Outside District pollock TACs are not allocated by season and are not included in the total pollock TACs shown in this table.

Annual and Seasonal Apportionments of Pacific Cod TAC

Pursuant to § 679.20(a)(12)(i), NMFS seasonally allocates the 2021 and 2022 Pacific cod TACs in the Western and Central Regulatory Areas of the GOA among gear and operational sectors. In the Western and Central Regulatory Areas, a portion of the annual TAC is apportioned to the A season for hook-and-line, pot, and jig gear from January 1 through June 10, and for trawl gear from January 20 through June 10, and a portion of the annual TAC is apportioned to the B season for jig gear from June 10 through December 31, for hook-and-line and pot gear from September 1 through December 31, and for trawl gear from September 1 through November 1 (§§ 679.20(a)(12) and 679.23(d)(3)). NMFS also allocates the Pacific cod TACs annually between the inshore (90 percent) and offshore (10 percent) components in the Eastern Regulatory Area of the GOA (§ 679.20(a)(6)(ii)).

In the Central GOA, the Pacific cod TAC is apportioned seasonally first to vessels using jig gear, and then among CVs less than 50 feet in length overall using hook-and-line gear, CVs equal to or greater than 50 feet in length overall using hook-and-line gear, catcher/processors (CPs) using hook-and-line gear, CVs using trawl gear, CPs using trawl gear, and vessels using pot gear (§ 679.20(a)(12)(i)(B)). In the Western GOA, the Pacific cod TAC is apportioned seasonally first to vessels using jig gear, and then among CVs using hook-and-line gear, CPs using hook-and-line gear, CVs using trawl gear, CPs using trawl gear, and vessels using pot gear (§ 679.20(a)(12)(i)(A)). Excluding seasonal apportionments to the jig sector, the seasonal apportionments of the annual TAC among the non-jig sectors in the Western GOA are 63.84 percent to the A season and 36.16 percent to the B season, and in the Central GOA are 64.16 percent to the A season and 35.84 percent to the B season.

Under § 679.20(a)(12)(ii), any overage or underage of the Pacific cod season allowance from the A season may be subtracted from, or added to, the subsequent B season allowance. In addition, any portion of the hook-and-line, trawl, pot, or jig sector allocations that is determined by NMFS as likely to go unharvested by a sector may be reallocated to other sectors for harvest during the remainder of the fishery year.

Pursuant to §§ 679.20(a)(12)(i)(A) and (B), a portion of the annual Pacific cod TACs in the Western and Central GOA will be allocated to vessels with a Federal fisheries permit that use jig gear before the TACs are apportioned among other non-jig sectors. In accordance with the FMP, the annual jig sector allocations may increase to up to 6 percent of the annual Western and Central GOA Pacific cod TACs, depending on the annual performance of the jig sector (see Table 1 of Amendment 83 to the FMP for a detailed discussion of the jig sector allocation process (76 FR 74670, December 1, 2011)). Jig sector allocation increases are established for a minimum of two years.

NMFS has evaluated the historical harvest performance of the jig sector in the Western and Central GOA, and is establishing the 2021 and 2022 Pacific cod apportionments to this sector based on its historical harvest performance through 2019. NMFS did not evaluate the 2020 performance of the jig sectors in the Western and Central GOA: Since NMFS prohibited directed fishing for all Pacific cod sectors in 2020, the catch for the jig sectors could not reach 90 percent of the initial allocation required for a performance increase (84 FR 70438, December 23, 2019). For 2021 and 2022, NMFS allocates the jig sector 3.5 percent of the annual Pacific cod TAC in the Western GOA. The 2021 and 2022 allocations consist of a base allocation of 1.5 percent of the Western GOA Pacific cod TAC, and prior additional performance increases of 2.0 percent. For 2021 and 2022, NMFS allocates the jig sector 1.0 percent of the annual Pacific cod TAC in the Central GOA. The 2021 and 2022 allocations consist of a base allocation of 1.0 percent of the Central GOA Pacific cod TAC, and no additional performance increase in the Central GOA.

For 2021 and 2022, NMFS is apportioning the jig sector allocations for the Western and Central GOA between the A season (60 percent) and the B season (40 percent), pursuant to § 679.20(a)(12)(i) and the correction to the final rule to implement Amendment 109 (85 FR 79139, December 9, 2020). This is the same jig sector seasonal apportionments implemented in prior groundfish harvest specifications for the GOA and is consistent with Amendment 83 to the FMP (76 FR 44700, July 26, 2011).

As discussed earlier in this preamble, NMFS published a final rule to implement Amendment 109 to the FMP (85 FR 38093, June 25, 2020). With respect to Pacific cod, Amendment 109 revised the Pacific cod TAC seasonal apportionments to the trawl CV sector by increasing the A season allocation and decreasing the B season allocation, with the intent of decreasing the annual underharvest of Pacific cod by this sector. NMFS incorporated the revised seasonal apportionments to trawl CVs between the A and B seasons in accordance with regulatory changes made under Amendment 109. The A season apportionment for trawl CVs has increased to 31.54 percent and 25.29 percent in the Western and Central Regulatory Areas of the GOA, respectively. The B season apportionment for trawl CVs has decreased to 6.86 percent and 16.29 percent in the Western and Central Regulatory Areas of the GOA, respectively.

Tables 5 and 6 list the seasonal apportionments and allocations of the 2021 and 2022 Pacific cod TACs.

TABLE 5—FINAL 2021 SEASONAL APPORTIONMENTS AND ALLOCATION OF PACIFIC COD TOTAL ALLOWABLE CATCH (TAC) AMOUNTS IN THE GOA; ALLOCATIONS IN THE WESTERN GOA AND CENTRAL GOA SECTORS, AND THE EASTERN GOA INSHORE AND OFFSHORE PROCESSING COMPONENTS

[Values are rounded to the nearest metric ton]

Regulatory area and sector	Annual allocation (mt)	A Season		B Season	
		Sector percentage of annual non-jig TAC	Seasonal allowances (mt)	Sector percentage of annual non-jig TAC	Seasonal allowances (mt)
Western GOA					
Jig (3.5% of TAC)	196	N/A	117	N/A	78
Hook-and-line CV	76	0.70	38	0.70	38
Hook-and-line CP	1,068	10.90	588	8.90	480
Trawl CV	2,071	31.54	1,701	6.86	370
Trawl CP	129	0.90	49	1.50	81
All Pot CV and Pot CP	2,050	19.80	1,068	18.20	982
Total	5,590	63.84	3,561	36.16	2,029
Central GOA					
Jig (1.0% of TAC)	102	N/A	61	N/A	41
Hook-and-line < 50 CV	1,481	9.32	945	5.29	536
Hook-and-line ≥ 50 CV	680	5.61	569	1.10	111
Hook-and-line CP	518	4.11	416	1.00	101
Trawl CV [1]	4,216	25.29	2,565	16.29	1,652
Trawl CP	426	2.00	203	2.19	223
All Pot CV and Pot CP	2,819	17.83	1,808	9.97	1,011
Total	10,242	64.16	6,567	35.84	3,675
Eastern GOA		Inshore (90% of Annual TAC)		Offshore (10% of Annual TAC)	
	1,489		1,340		149

[1] Trawl catcher vessels participating in Rockfish Program cooperatives receive 3.81 percent, or 390 mt, of the annual Central GOA TAC, which is deducted from the Trawl CV B season allowance (see Table 12. Final 2021 Apportionments of Rockfish Secondary Species in the Central GOA and Table 28c to 50 CFR part 679).

TABLE 6—FINAL 2022 SEASONAL APPORTIONMENTS AND ALLOCATION OF PACIFIC COD TOTAL ALLOWABLE CATCH (TAC) AMOUNTS IN THE GOA; ALLOCATIONS IN THE WESTERN GOA AND CENTRAL GOA SECTORS, AND THE EASTERN GOA INSHORE AND OFFSHORE PROCESSING COMPONENTS

[Values are rounded to the nearest metric ton]

Regulatory area and sector	Annual allocation (mt)	A Season		B Season	
		Sector percentage of annual non-jig TAC	Seasonal allowances (mt)	Sector percentage of annual non-jig TAC	Seasonal allowances (mt)
Western GOA					
Jig (3.5% of TAC)	316	N/A	190	N/A	126
Hook-and-line CV	122	0.70	61	0.70	61
Hook-and-line CP	1,724	10.90	949	8.90	775
Trawl CV	3,344	31.54	2,747	6.86	597

TABLE 6—FINAL 2022 SEASONAL APPORTIONMENTS AND ALLOCATION OF PACIFIC COD TOTAL ALLOWABLE CATCH (TAC) AMOUNTS IN THE GOA; ALLOCATIONS IN THE WESTERN GOA AND CENTRAL GOA SECTORS, AND THE EASTERN GOA INSHORE AND OFFSHORE PROCESSING COMPONENTS—Continued

[Values are rounded to the nearest metric ton]

Regulatory area and sector	Annual allocation (mt)	A Season		B Season	
		Sector percentage of annual non-jig TAC	Seasonal allowances (mt)	Sector percentage of annual non-jig TAC	Seasonal allowances (mt)
Trawl CP	209	0.90	78	1.50	131
All Pot CV and Pot CP	3,309	19.80	1,724	18.20	1,585
Total	9,024	63.84	5,749	36.16	3,275
Central GOA					
Jig (1.0% of TAC)	165	N/A	99	N/A	66
Hook-and-line < 50 CV	2,390	9.32	1,525	5.29	865
Hook-and-line ≥ 50 CV	1,098	5.61	918	1.10	180
Hook-and-line CP	836	4.11	672	1.00	163
Trawl CV [1]	6,807	25.29	4,140	16.29	2,667
Trawl CP	687	2.00	328	2.19	359
All Pot CV and Pot CP	4,551	17.83	2,918	9.97	1,633
Total	16,534	64.16	10,601	35.84	5,933
Eastern GOA		Inshore (90% of Annual TAC)		Offshore (10% of Annual TAC)	
	2,403	.....	.....	2,163	240

[1] Trawl catcher vessels participating in Rockfish Program cooperatives receive 3.81 percent, or 630 mt, of the annual Central GOA TAC, which is deducted from the Trawl CV B season allowance (see Table 13. Final 2022 Apportionments of Rockfish Secondary Species in the Central GOA and Table 28c to 50 CFR part 679).

Allocations of the Sablefish TAC Amounts to Vessels Using Fixed and Trawl Gear

Sections 679.20(a)(4)(i) and (ii) require allocations of sablefish TACs for each of the regulatory areas and districts to fixed and trawl gear. In the Western and Central Regulatory Areas, 80 percent of each TAC is allocated to fixed gear, and 20 percent of each TAC is allocated to trawl gear. In the Eastern Regulatory Area, 95 percent of the TAC is allocated to fixed gear, and 5 percent is allocated to trawl gear. The trawl gear allocation in the Eastern Regulatory Area may only be used to support incidental catch of sablefish using trawl gear while directed fishing for other target species (§ 679.20(a)(4)(i)).

In recognition of the prohibition against trawl gear in the SEO District of the Eastern Regulatory Area, the Council recommended and NMFS approves specifying for incidental catch the allocation of 5 percent of the combined Eastern Regulatory Area sablefish TAC to trawl gear in the WYK District of the Eastern Regulatory Area. The remainder of the WYK District sablefish TAC is allocated to vessels using fixed gear. NMFS allocates 100 percent of the sablefish TAC in the SEO District to vessels using fixed gear. This action results in a 2021 allocation of 375 mt to trawl gear and 2,554 mt to fixed gear in the WYK District, a 2021 allocation of 4,579 mt to fixed gear in the SEO District, and a 2022 allocation of 498 mt to trawl gear in the WYK District. Table 7 lists the allocations of the 2021 sablefish TACs to fixed and trawl gear. Table 8 lists the allocations of the 2022 sablefish TACs to trawl gear.

The Council recommended that a trawl sablefish TAC be established for two years so that retention of incidental catch of sablefish by trawl gear could commence in January in the second year of the groundfish harvest specifications. Both the 2021 and 2022 trawl allocations are specified in these final harvest specifications, in Tables 7 and 8, respectively.

The Council also recommended that the fixed gear sablefish TAC be established annually to ensure that this Individual Fishing Quota (IFQ) fishery is conducted concurrently with the halibut IFQ fishery and is based on the most recent survey information. Since there is an annual assessment for sablefish and since the final harvest specifications are expected to be published before the IFQ season begins in March 2020, the Council recommended that the fixed gear sablefish TAC be set annually, rather than for two years, so that the best scientific information available could be considered in establishing the sablefish TACs. Accordingly, Table 7 lists the 2021 fixed gear allocations, and the 2022 fixed gear allocations will be specified in the 2022 and 2023 harvest specifications.

With the exception of the trawl allocations that are provided to the Rockfish Program (see Table 28c to 50 CFR part 679), directed fishing for sablefish with trawl gear in the GOA is closed during the fishing year. Also, fishing for groundfish with trawl gear is prohibited prior to January 20 (§ 679.23(c)). Therefore, it is not likely that the sablefish allocation to trawl gear would be reached before the effective date of these final 2021 and 2022 harvest specifications.

TABLE 7—FINAL 2021 SABLEFISH TAC AMOUNTS IN THE GULF OF ALASKA AND ALLOCATIONS TO FIXED AND TRAWL GEAR

[Values are rounded to the nearest metric ton]

Area/District	TAC	Fixed gear allocation	Trawl gear allocation
Western	2,428	1,942	486
Central [1]	8,056	6,444	1,612
West Yakutat [2]	2,929	2,554	375
Southeast Outside	4,579	4,579	0
Total	17,992	15,519	2,473

[1] The trawl allocation of sablefish in the Central Regulatory Area is further apportioned to the Rockfish Program cooperatives (829 mt). See Table 12: Final 2021 Apportionments of Rockfish Secondary Species in the Central GOA. This results in 783 mt being available for the non-Rockfish Program trawl fisheries.

[2] The trawl allocation is based on allocating 5 percent of the combined Eastern Regulatory Area (West Yakutat and Southeast Outside Districts) sablefish TAC as incidental catch to trawl gear in the West Yakutat District.

TABLE 8—FINAL 2022 SABLEFISH TAC AMOUNTS IN THE GULF OF ALASKA AND ALLOCATIONS TO TRAWL GEAR [1]

[Values are rounded to the nearest metric ton]

Area/District	TAC	Fixed gear allocation	Trawl gear allocation
Western	4,165	n/a	833
Central [2]	11,111	n/a	2,222
West Yakutat [3]	4,009	n/a	498
Southeast Outside	5,946	n/a	0
Total	25,231	n/a	3,553

[1] The Council recommended that the final 2022 harvest specifications for the fixed gear sablefish Individual Fishing Quota fisheries not be specified in the final 2021 and 2022 harvest specifications.

[2] The trawl allocation of sablefish in the Central Regulatory Area is further apportioned to the Rockfish Program cooperatives (1,143 mt). See Table 13: Final 2022 Apportionments of Rockfish Secondary Species in the Central GOA. This results in 1,079 mt being available for the non-Rockfish Program trawl fisheries.

[3] The trawl allocation is based on allocating 5 percent of the combined Eastern Regulatory Area (West Yakutat and Southeast Outside Districts) sablefish TAC as incidental catch to trawl gear in the West Yakutat District.

Allocations, Apportionments, and Sideboard Limits for the Rockfish Program

These final 2021 and 2022 harvest specifications for the GOA include the fishery cooperative allocations and sideboard limitations established by the Rockfish Program. Program participants are primarily trawl CVs and trawl CPs, with limited participation by vessels using longline gear. The Rockfish Program assigns quota share and cooperative quota to participants for primary species (Pacific ocean perch, northern rockfish, and dusky rockfish) and secondary species (Pacific cod, rougheye and blackspotted rockfish, sablefish, shortraker rockfish, and thornyhead rockfish), allows a participant holding a license limitation program (LLP) license with rockfish quota share to form a rockfish cooperative with other persons, and allows holders of CP LLP licenses to opt out of the fishery. The Rockfish Program also has an entry level fishery for rockfish primary species for vessels using longline gear. Longline gear includes hook-and-line, jig, troll, and handline gear.

Under the Rockfish Program, rockfish primary species in the Central GOA are allocated to participants after deducting for incidental catch needs in other directed groundfish fisheries (§ 679.81(a)(2)). Participants in the Rockfish Program also receive a portion of the Central GOA TAC of specific secondary species. In addition to groundfish species, the Rockfish Program allocates a portion of the halibut PSC limit (191 mt) from the third season deep-water species fishery allowance for the GOA trawl fisheries to Rockfish Program participants (§ 679.81(d) and Table 28d to 50 CFR part 679). The Rockfish Program also establishes sideboard limits to restrict the ability of harvesters operating under the Rockfish Program to increase their participation in other, non-Rockfish Program fisheries. These restrictions and halibut PSC limits are discussed in a subsequent section in this rule titled ''Rockfish Program Groundfish Sideboard and Halibut PSC Limitations.''

Section 679.81(a)(2)(ii) and Table 28e to 50 CFR part 679 require allocations of 5 mt of Pacific ocean perch, 5 mt of northern rockfish, and 50 mt of dusky rockfish to the entry level longline fishery in 2021 and 2022. The allocation for the entry level longline fishery may increase incrementally each year if the catch exceeds 90 percent of the allocation of a species. The incremental increase in the allocation would continue each year until it reaches the maximum percent of the TAC for that species. In 2020, the catch of Pacific ocean perch, northern rockfish, and dusky rockfish did not attain the 90 percent threshold, and those final allocations for 2021 remain the same as the 2020 allocations. The remainder of the TACs for the rockfish primary species are allocated to the CV and CP cooperatives (§ 679.81(a)(2)(iii)). Table 9 lists the allocations of the 2021 and 2022 TACs for each rockfish primary species to the entry level longline fishery, the potential incremental increases for future years, and the maximum percentages of the TACs assigned to the Rockfish Program that may be allocated to the rockfish entry level longline fishery.

TABLE 9—FINAL 2021 AND INITIAL 2022 ALLOCATIONS OF ROCKFISH PRIMARY SPECIES TO THE ENTRY LEVEL LONGLINE FISHERY IN THE CENTRAL GULF OF ALASKA

Rockfish primary species	2021 and 2022 allocations	Incremental increase in 2022 if >90% of 2021 allocation is harvested	Up to maximum % of TAC
Pacific ocean perch	5 metric tons	5 metric tons	1
Northern rockfish	5 metric tons	5 metric tons	2
Dusky rockfish	50 metric tons	20 metric tons	5

Section 679.81 requires allocations of rockfish primary species among various sectors of the Rockfish Program. Tables 10 and 11 list the final 2021 and 2022 allocations of rockfish primary species in the Central GOA to the entry level longline fishery, and rockfish CV and CP cooperatives in the Rockfish Program. NMFS also is setting aside incidental catch amounts (ICAs) for other directed fisheries in the Central GOA of 2,500 mt of Pacific ocean perch, 300 mt of northern rockfish, and 250 mt of dusky rockfish. These amounts are based on recent average incidental catches in the Central GOA by other groundfish fisheries.

Allocations among vessels belonging to CV or CP cooperatives are not included in these final harvest specifications. Rockfish Program applications for CV cooperatives and CP cooperatives are not due to NMFS until March 1 of each calendar year; therefore, NMFS cannot calculate 2021 and 2022 allocations in conjunction with these final harvest specifications. NMFS will post the 2021 allocations on the Alaska Region website at *https://www.fisheries.noaa.gov/alaska/sustainable-fisheries/alaska-fisheries-management-reports#central-goa-rockfish* when they become available after March 1.

TABLE 10—FINAL 2021 ALLOCATIONS OF ROCKFISH PRIMARY SPECIES IN THE CENTRAL GULF OF ALASKA TO THE ENTRY LEVEL LONGLINE FISHERY AND ROCKFISH COOPERATIVES IN THE ROCKFISH PROGRAM

[Values are rounded to the nearest metric ton]

Rockfish Primary Species	Central GOA annual TAC	Incidental catch allowance	TAC minus ICA	Allocation to the entry level longline [1] fishery	Allocation to the Rockfish cooperatives [2]
Pacific ocean perch	27,429	2,500	24,929	5	24,924
Northern rockfish	3,334	300	3,034	5	3,029
Dusky rockfish	4,548	250	4,298	50	4,248
Total	35,311	3,050	32,261	60	32,201

[1] Longline gear includes hook-and-line, jig, troll, and handline gear (50 CFR 679.2).
[2] Rockfish cooperatives include vessels in CV and CP cooperatives (50 CFR 679.81).

TABLE 11—FINAL 2022 ALLOCATIONS OF ROCKFISH PRIMARY SPECIES IN THE CENTRAL GULF OF ALASKA TO THE ENTRY LEVEL LONGLINE FISHERY AND ROCKFISH COOPERATIVES IN THE ROCKFISH PROGRAM

[Values are rounded to the nearest metric ton]

Rockfish Primary Species	Central GOA annual TAC	Incidental catch allowance	TAC minus ICA	Allocation to the entry level longline [1] fishery	Allocation to the Rockfish cooperatives [2]
Pacific ocean perch	26,234	2,500	23,734	5	23,729
Northern rockfish	3,173	300	2,873	5	2,868
Dusky rockfish	4,469	250	4,219	50	4,169
Total	33,876	3,050	30,826	60	30,766

[1] Longline gear includes hook-and-line, jig, troll, and handline gear (50 CFR 679.2).
[2] Rockfish cooperatives include vessels in CV and CP cooperatives (50 CFR 679.81).

Section 679.81(c) and Table 28c to 50 CFR part 679 require allocations of rockfish secondary species to CV and CP cooperatives in the Central GOA. CV cooperatives receive allocations of Pacific cod, sablefish from the trawl gear allocation, and thornyhead rockfish. CP cooperatives receive allocations of sablefish from the trawl gear allocation, rougheye and blackspotted rockfish, shortraker rockfish, and thornyhead rockfish. Tables 12 and 13 list the apportionments of the 2021 and 2022 TACs of rockfish secondary species in the Central GOA to CV and CP cooperatives.

TABLE 12—FINAL 2021 APPORTIONMENTS OF ROCKFISH SECONDARY SPECIES IN THE CENTRAL GOA TO CATCHER VESSEL AND CATCHER/PROCESSOR COOPERATIVES

[Values are rounded to the nearest metric ton]

Rockfish secondary species	Central GOA annual TAC	Catcher vessel cooperatives		Catcher/processor cooperatives	
		Percentage of TAC	Apportionment (mt)	Percentage of TAC	Apportionment (mt)
Pacific cod	10,242	3.8	390	0.00	0
Sablefish	8,056	6.78	546	3.51	283
Shortraker rockfish	284	0.00	0	40.00	114
Rougheye/blackspotted rockfish	456	0.00	0	58.87	268
Thornyhead rockfish	910	7.84	71	26.50	241

TABLE 13—FINAL 2022 APPORTIONMENTS OF ROCKFISH SECONDARY SPECIES IN THE CENTRAL GOA TO CATCHER VESSEL AND CATCHER/PROCESSOR COOPERATIVES

[Values are rounded to the nearest metric ton]

Rockfish secondary species	Central GOA annual TAC	Catcher vessel cooperatives		Catcher/processor cooperatives	
		Percentage of TAC	Apportionment (mt)	Percentage of TAC	Apportionment (mt)
Pacific cod	16,534	3.81	630	0.00	0
Sablefish	11,111	6.78	753	3.51	390
Shortraker rockfish	284	0.00	0	40.00	114
Rougheye/blackspotted rockfish	459	0.00	0	58.87	270
Thornyhead rockfish	910	7.84	71	26.50	241

Halibut PSC Limits

Section 679.21(d) establishes annual halibut PSC limit apportionments to trawl gear and hook-and-line gear, and authorizes the establishment of apportionments for pot gear. In December 2020, the Council recommended halibut PSC limits of 1,706 mt for trawl gear, 257 mt for hook-and-line gear, and 9 mt for the demersal shelf (DSR) rockfish fishery in the SEO District for both 2021 and 2022.

The DSR fishery in the SEO District is defined at § 679.21(d)(2)(ii)(A). This fishery is apportioned 9 mt of the halibut PSC limit in recognition of its small-scale harvests of groundfish (§ 679.21(d)(2)(i)(A)). The separate halibut PSC limit for the DSR fishery is intended to prevent that fishery from being impacted from the halibut PSC incurred by other GOA fisheries. NMFS estimates low halibut bycatch in the DSR fishery because (1) the duration of the DSR fisheries and the gear soak times are short, (2) the DSR fishery occurs in the winter when there is less overlap in the distribution of DSR and halibut, and (3) the directed commercial DSR fishery has a low DSR TAC. The Alaska Department of Fish and Game sets the commercial GHL for the DSR fishery after deducting estimates of DSR incidental catch in all fisheries (including halibut and subsistence) and allocation to the DSR sport fishery. In 2020, the commercial fishery for DSR was closed due to concerns about declining DSR biomass.

The FMP authorizes the Council to exempt specific gear from the halibut PSC limits. NMFS, after consultation with the Council, exempts pot gear, the sablefish IFQ hook-and-line gear fishery categories, and jig gear from the non-trawl halibut PSC limit for 2021 and 2022. The Council recommended, and NMFS approves, these exemptions because: (1) The pot gear fisheries have low annual halibut bycatch mortality, (2) IFQ program regulations prohibit discard of halibut if any halibut IFQ permit holder on board a catcher vessel holds unused halibut IFQ for that vessel category and the IFQ regulatory area in which the vessel is operating (§ 679.7(f)(11)), (3) some sablefish IFQ fishermen hold halibut IFQ permits and are therefore required to retain the halibut they catch while fishing sablefish IFQ, and (4) NMFS estimates negligible halibut mortality for the jig gear fisheries given the small amount of groundfish harvested by jig gear, the selective nature of jig gear, and the high survival rates of halibut caught and released with jig gear.

The best available information on estimated halibut bycatch consists of data collected by fisheries observers during 2020. The calculated halibut bycatch mortality through December 31, 2020, is 789 mt for trawl gear and 3 mt for hook-and-line gear for a total halibut mortality of 792 mt. This halibut mortality was calculated using groundfish and halibut catch data from the NMFS Alaska Region's catch accounting system. This accounting system contains historical and recent catch information compiled from each Alaska groundfish fishery.

Sections 679.21(d)(4)(i) and (ii) authorize NMFS to seasonally apportion the halibut PSC limits after consultation with the Council. The FMP and regulations require that the Council and NMFS consider the following information in seasonally apportioning halibut PSC limits: (1) Seasonal distribution of halibut; (2) seasonal distribution of target groundfish species relative to halibut distribution; (3) expected halibut bycatch needs on a seasonal basis relative to changes in halibut biomass and expected catch of target groundfish species; (4) expected bycatch rates on a seasonal basis; (5) expected changes in directed groundfish fishing seasons; (6) expected actual start of fishing effort; and (7) economic effects of establishing seasonal halibut allocations on segments of the target groundfish industry. The Council considered information from the 2020 SAFE report, NMFS catch data, State of Alaska catch data, International Pacific Halibut Commission (IPHC) stock assessment and mortality data, and public testimony when apportioning the

halibut PSC limits. NMFS concurs with the Council's recommendations listed in Table 14, which shows the final 2021 and 2022 Pacific halibut PSC limits, allowances, and apportionments.

Sections 679.21(d)(4)(iii) and (iv) specifies that any unused amounts, or overages, of a seasonal apportionment of a halibut PSC limit will be added to or deducted from the next respective seasonal apportionment within the fishing year.

TABLE 14—FINAL 2021 AND 2022 PACIFIC HALIBUT PROHIBITED SPECIES CATCH (PSC) LIMITS, ALLOWANCES, AND APPORTIONMENTS

[Values are in metric tons]

Trawl gear			Hook-and-line gear [1]				
			Other than DSR			DSR	
Season	Percent	Amount	Season	Percent	Amount	Season	Amount
January 20–April 1	30.5	519	January 1–June 10	86	221	January 1–December 31	9
April 1–July 1	20.0	341	June 10–September 1	2	5		
July 1–August 1	27.0	462	September 1–December 31.	12	31		
August 1–October 1	7.5	128					
October 1–December 31	15.0	256					
Total		1,706			257		9

[1] The Pacific halibut prohibited species catch (PSC) limit for hook-and-line gear is allocated to the DSR fishery in the SEO District and to the hook-and-line fisheries other than the DSR fishery. The hook-and-line sablefish IFQ fishery is exempt from halibut PSC limits, as are pot and jig gear for all groundfish fisheries.

Note: Seasonal or sector apportionments may not total precisely due to rounding.

Section 679.21(d)(3)(ii) authorizes further apportionment of the trawl halibut PSC limit to trawl fishery categories listed in § 679.21(d)(3)(iii). The annual apportionments are based on each category's proportional share of the anticipated halibut bycatch mortality during the fishing year and optimization of the total amount of groundfish harvest under the halibut PSC limit. The fishery categories for the trawl halibut PSC limits are: (1) A deep-water species fishery, composed of sablefish, rockfish, deep-water flatfish, rex sole, and arrowtooth flounder; and (2) a shallow-water species fishery, composed of pollock, Pacific cod, shallow-water flatfish, flathead sole, Atka mackerel, and ''other species'' (sharks and octopuses) (§ 679.21(d)(3)(iii)). Halibut mortality incurred while directed fishing for skates with trawl gear accrues towards the shallow-water species fishery halibut PSC limit (69 FR 26320, May 12, 2004).

NMFS will combine available trawl halibut PSC limit apportionments during the second season deep-water and shallow-water species fisheries for use in either fishery from May 15 through June 30 (§ 679.21(d)(4)(iii)(D)). This is intended to maintain groundfish harvest while minimizing halibut bycatch by these sectors to the extent practicable. This provides the deep-water and shallow-water species trawl fisheries additional flexibility and the incentive to participate in fisheries at times of the year that may have lower halibut PSC rates relative to other times of the year.

Table 15 lists the final 2021 and 2022 apportionments of trawl halibut PSC limits between the trawl gear deep-water and shallow-water species fishery categories.

Table 28d to 50 CFR part 679 specifies the amount of the trawl halibut PSC limit that is assigned to the CV and CP sectors that are participating in the Rockfish Program. This includes 117 mt of halibut PSC limit to the CV sector and 74 mt of halibut PSC limit to the CP sector. These amounts are allocated from the trawl deep-water species fishery's halibut PSC third seasonal apportionment. After the combined CV and CP halibut PSC limit allocation of 191 mt to the Rockfish Program, 150 mt remains for the trawl deep-water species fishery's halibut PSC third seasonal apportionment.

Section 679.21(d)(4)(iii)(B) limits the amount of the halibut PSC limit allocated to Rockfish Program participants that could be re-apportioned to the general GOA trawl fisheries during the current fishing year to no more than 55 percent of the unused annual halibut PSC limit apportioned to Rockfish Program participants. The remainder of the unused Rockfish Program halibut PSC limit is unavailable for use by any person for the remainder of the fishing year (§ 679.21(d)(4)(iii)(C)).

TABLE 15—FINAL 2021 AND 2022 APPORTIONMENT OF PACIFIC HALIBUT PROHIBITED SPECIES CATCH LIMITS BETWEEN THE TRAWL GEAR DEEP-WATER SPECIES FISHERY AND THE SHALLOW-WATER SPECIES FISHERY CATEGORIES

[Values are in metric tons]

Season	Shallow-water	Deep-water [1]	Total
January 20–April 1	384	135	519
April 1–July 1	85	256	341
July 1–August 1	121	341	462
August 1–October 1	53	75	128
Subtotal January 20–October 1	643	807	1,450
October 1–December 31 [2]			256

TABLE 15—FINAL 2021 AND 2022 APPORTIONMENT OF PACIFIC HALIBUT PROHIBITED SPECIES CATCH LIMITS BETWEEN THE TRAWL GEAR DEEP-WATER SPECIES FISHERY AND THE SHALLOW-WATER SPECIES FISHERY CATEGORIES—Continued

[Values are in metric tons]

Season	Shallow-water	Deep-water [1]	Total
Total			1,706

[1] Vessels participating in cooperatives in the Central GOA Rockfish Program will receive 191 mt of the third season (July 1 through August 1) deep-water species fishery halibut PSC apportionment.

[2] There is no apportionment between trawl shallow-water and deep-water species fishery categories during the fifth season (October 1 through December 31).

Section 679.21(d)(2)(i)(B) requires that the ''other hook-and-line fishery'' halibut PSC limit apportionment to vessels using hook-and-line gear must be apportioned between CVs and CPs in accordance with § 679.21(d)(2)(iii) in conjunction with these harvest specifications. A comprehensive description and example of the calculations necessary to apportion the ''other hook-and-line fishery'' halibut PSC limit between the hook-and-line CV and CP sectors were included in the proposed rule to implement Amendment 83 to the FMP (76 FR 44700, July 26, 2011) and are not repeated here.

Pursuant to § 679.21(d)(2)(iii), the hook-and-line halibut PSC limit for the ''other hook-and-line fishery'' is apportioned between the CV and CP sectors in proportion to the total Western and Central GOA Pacific cod allocations, which vary annually based on the proportion of the Pacific cod biomass between the Western, Central, and Eastern GOA. Pacific cod is apportioned among these three management areas based on the percentage of overall biomass per area, as calculated in the 2020 Pacific cod stock assessment. Updated information in the final 2020 SAFE report describes this distributional calculation, which allocates ABC among GOA regulatory areas on the basis of the three most recent stock surveys. For 2021 and 2022, the distribution of the total GOA Pacific cod ABC is 32 percent to the Western GOA, 59 percent to the Central GOA, and 9 percent to the Eastern GOA. Therefore, the calculations made in accordance with § 679.21(d)(2)(iii) incorporate the most recent information on GOA Pacific cod distribution with respect to establishing the annual halibut PSC limits for the CV and CP hook-and-line sectors. Additionally, the annual halibut PSC limits for both the CV and CP sectors of the ''other hook-and-line fishery'' are divided into three seasonal apportionments, using seasonal percentages of 86 percent, 2 percent, and 12 percent.

For 2021 and 2022, NMFS apportions halibut PSC limits of 144 mt and 113 mt to the hook-and-line CV and hook-and-line CP sectors, respectively. Table 16 lists the final 2021 and 2022 apportionments of halibut PSC limits between the hook-and-line CV and the hook-and-line CP sectors of the ''other hook-and-line fishery.''

No later than November 1 of each year, NMFS will calculate the projected unused amount of halibut PSC limit by either of the CV or CP hook-and-line sectors of the ''other hook-and-line fishery'' for the remainder of the year. The projected unused amount of halibut PSC limit is made available to the other hook-and-line sector for the remainder of that fishing year (§ 679.21(d)(2)(iii)(C)), if NMFS determines that an additional amount of halibut PSC is necessary for that sector to continue its directed fishing operations.

TABLE 16—FINAL 2021 AND 2022 APPORTIONMENTS OF THE ''OTHER HOOK-AND-LINE FISHERY'' ANNUAL HALIBUT PROHIBITED SPECIES CATCH ALLOWANCE BETWEEN THE HOOK-AND-LINE GEAR CATCHER VESSEL AND CATCHER/PROCESSOR SECTORS

[Values are in metric tons]

''Other than DSR'' allowance	Hook-and-line sector	Sector annual amount	Season	Seasonal percentage	Sector seasonal amount
257	Catcher Vessel	144	January 1–June 10	86	124
			June 10–September 1	2	3
			September 1–December 31	12	17
	Catcher/Processor	113	January 1–June 10	86	97
			June 10–September 1	2	2
			September 1–December 31	12	14

Estimates of Halibut Biomass and Stock Condition

The IPHC annually assesses the abundance and potential yield of the Pacific halibut stock using all available data from the commercial and sport fisheries, other removals, and scientific surveys. Additional information on the Pacific halibut stock assessment may be found in the IPHC's 2020 Pacific halibut stock assessment (December 2020), available on the IPHC website at *www.iphc.int.* The IPHC considered the 2020 Pacific halibut stock assessment at its January 2021 annual meeting when it set the 2021 commercial halibut fishery catch limits.

Halibut Discard Mortality Rates

To monitor halibut bycatch mortality allowances and apportionments, the Regional Administrator uses observed halibut incidental catch rates, halibut discard mortality rates (DMRs), and estimates of groundfish catch to project when a fishery's halibut bycatch mortality allowance or seasonal apportionment is reached. Halibut incidental catch rates are based on observers' estimates of halibut incidental catch in the groundfish fishery. DMRs are estimates of the proportion of incidentally caught halibut that do not survive after being returned to the sea. The cumulative

halibut mortality that accrues to a particular halibut PSC limit is the product of a DMR multiplied by the estimated halibut PSC. DMRs are estimated using the best scientific information available in conjunction with the annual GOA stock assessment process. The DMR methodology and findings are included as an appendix to the annual GOA groundfish SAFE report.

In 2016, the DMR estimation methodology underwent revisions per the Council's directive. An interagency halibut working group (IPHC, Council, and NMFS staff) developed improved estimation methods that have undergone review by the GOA Plan Team, SSC, and the Council. A summary of the revised methodology is contained in the GOA proposed 2017 and 2018 harvest specifications (81 FR 87881, December 6, 2016), and the comprehensive discussion of the working group's statistical methodology is available from the Council (see **ADDRESSES**). The DMR working group's revised methodology is intended to improve estimation accuracy, transparency, and transferability in the methodology used for calculating DMRs. The working group will continue to consider improvements to the methodology used to calculate halibut mortality, including potential changes to the reference period (the period of data used for calculating the DMRs). Future DMRs may change based on additional years of observer sampling, which could provide more recent and accurate data and which could improve the accuracy of estimation and progress on methodology. The new methodology will continue to ensure that NMFS is using DMRs that more accurately reflect halibut mortality, which will inform the different sectors of their estimated halibut mortality and allow specific sectors to respond with methods that could reduce mortality and, eventually, the DMR for that sector.

At the December 2020 meeting, the SSC, AP, and the Council concurred with the revised DMR estimation methodology, and NMFS adopts for 2021 and 2022 the DMRs calculated under the revised methodology, which uses an updated 2-year reference period. The final 2021 and 2022 DMRs in this rule are unchanged from the DMRs in the proposed 2021 and 2022 harvest specifications (85 FR 78076, December 3, 2020). Table 17 lists these final 2021 and 2022 DMRs.

TABLE 17—FINAL 2021 AND 2022 HALIBUT DISCARD MORTALITY RATES FOR VESSELS FISHING IN THE GULF OF ALASKA

[Values are percent of halibut assumed to be dead]

Gear	Sector	Groundfish fishery	Halibut discard mortality rate (percent)
Pelagic trawl	Catcher vessel	All	100
	Catcher/processor	All	100
Non-pelagic trawl	Catcher vessel	Rockfish Program	60
	Catcher vessel	All others	69
	Mothership and catcher/processor	All	84
Hook-and-line	Catcher/processor	All	15
	Catcher vessel	All	13
Pot	Catcher vessel and catcher/processor	All	10

Chinook Salmon Prohibited Species Catch Limits

Amendment 93 to the FMP (77 FR 42629, July 20, 2012) established separate Chinook salmon PSC limits in the Western and Central GOA in the directed pollock trawl fishery. These limits require that NMFS close the pollock directed fishery in the Western and Central Regulatory Areas of the GOA if the applicable Chinook salmon PSC limit in that regulatory area is reached (§ 679.21(h)(8)). The annual Chinook salmon PSC limits in the pollock directed fishery of 6,684 salmon in the Western GOA and 18,316 salmon in the Central GOA are set at § 679.21(h)(2)(i) and (ii).

Amendment 97 to the FMP (79 FR 71350, December 2, 2014) established an initial annual PSC limit of 7,500 Chinook salmon for the trawl non-pollock groundfish fisheries in the Western and Central GOA. This limit is apportioned among the three sectors that conduct directed fishing for groundfish species other than pollock: 3,600 Chinook salmon to trawl CPs; 1,200 Chinook salmon to trawl CVs participating in the Rockfish Program; and 2,700 Chinook salmon to trawl CVs not participating in the Rockfish Program (§ 679.21(h)(4)). NMFS will monitor the Chinook salmon PSC in the trawl non-pollock groundfish fisheries and close an applicable sector if it reaches its Chinook salmon PSC limit.

The Chinook salmon PSC limit for two sectors, trawl CPs and trawl CVs not participating in the Rockfish Program, may be increased in subsequent years based on the performance of these two sectors and their ability to minimize their use of their respective Chinook salmon PSC limits. If either or both of these two sectors limits its use of Chinook salmon PSC to a specified threshold amount in 2020 (3,120 for trawl CPs and 2,340 for Non-Rockfish Program trawl CVs), that sector will receive an incremental increase to its 2021 Chinook salmon PSC limit (§ 679.21(h)(4)). In 2020, the trawl CP sector did not exceed 3,120 Chinook salmon PSC; therefore, the 2021 trawl CP sector Chinook salmon PSC limit will be 4,080 Chinook salmon. In 2020, the Non-Rockfish Program trawl CV sector did not exceed 2,340 Chinook salmon PSC; therefore, the 2021 Non-Rockfish Program trawl CV sector Chinook salmon PSC limit will be 3,060 Chinook salmon.

American Fisheries Act (AFA) Catcher/Processor and Catcher Vessel Groundfish Harvest Limits

Section 679.64 establishes groundfish harvesting and processing sideboard limitations on AFA CPs and CVs in the GOA. These sideboard limits are necessary to protect the interests of fishermen and processors who do not directly benefit from the AFA from those fishermen and processors who receive exclusive harvesting and processing privileges under the AFA. Section 679.7(k)(1)(ii) prohibits listed AFA CPs and CPs designated on a listed AFA CP permit from harvesting any species of groundfish in the GOA. Additionally, § 679.7(k)(1)(iv) prohibits listed AFA CPs and CPs designated on a listed AFA CP permit from processing any pollock harvested in a directed pollock fishery in the GOA and any groundfish harvested in Statistical Area 630 of the GOA.

AFA CVs that are less than 125 feet (38.1 meters) length overall, have annual landings of pollock in the Bering Sea and Aleutian Islands less than 5,100 mt, and have made at least 40 GOA groundfish landings from 1995 through 1997 are exempt from GOA CV groundfish sideboard limits under § 679.64(b)(2)(ii). Sideboard limits for non-exempt AFA CVs in the GOA are based on their traditional harvest levels of TAC in groundfish fisheries covered by the FMP. Section 679.64(b)(3)(iv) establishes the CV groundfish sideboard limitations in the GOA based on the aggregate retained catch of non-exempt AFA CVs of each sideboard species or species group from 1995 through 1997 divided by the sum of the TACs for that species or species group available to CVs over the same period. NMFS published a final rule (84 FR 2723, February 8, 2019) that implemented regulations to prohibit non-exempt AFA CVs from directed fishing for specific groundfish species or species groups subject to sideboard limits (§ 679.20(d)(1)(iv)(D) and Table 56 to 50 CFR part 679). Sideboard limits not subject to the final rule continue to be calculated and included in the GOA annual harvest specifications.

Tables 18 and 19 list the final 2021 and 2022 groundfish sideboard limits for non-exempt AFA CVs. NMFS will deduct all targeted or incidental catch of sideboard species made by non-exempt AFA CVs from the sideboard limits listed in Tables 18 and 19.

TABLE 18—FINAL 2021 GOA NON-EXEMPT AMERICAN FISHERIES ACT CATCHER VESSEL (CV) GROUNDFISH SIDEBOARD LIMITS

[Values are rounded to the nearest metric ton]

Species	Apportionments by season	Area	Ratio of 1995–1997 non-exempt AFA CV catch to 1995–1997 TAC	Final 2021 TACs[3]	Final 2021 non-exempt AFA CV sideboard limit
Pollock	A Season January 20–May 31	Shumagin (610)	0.6047	799	483
		Chirikof (620)	0.1167	41,737	4,871
		Kodiak (630)	0.2028	6,297	1,277
	B Season September 1–November 1	Shumagin (610)	0.6047	17,677	10,689
		Chirikof (620)	0.1167	13,133	1,533
		Kodiak (630)	0.2028	18,023	3,655
	Annual	WYK (640)	0.3495	5,412	1,891
		SEO (650)	0.3495	10,148	3,547
Pacific cod	A Season[1] January 1–June 10	W	0.1331	3,561	474
		C	0.0692	6,567	454
	B Season[2] September 1–December 31	W	0.1331	2,029	270
		C	0.0692	3,675	254
Flatfish, shallow-water	Annual	W	0.0156	13,250	207
		C	0.0587	28,082	1,648
Flatfish, deep-water	Annual	C	0.0647	1,914	124
		E	0.0128	3,787	48
Rex sole	Annual	C	0.0384	8,912	342
Arrowtooth flounder	Annual	C	0.0280	69,072	1,934
Flathead sole	Annual	C	0.0213	15,400	328
Pacific ocean perch	Annual	C	0.0748	27,429	2,052
		E	0.0466	7,105	331
Northern rockfish	Annual	C	0.0277	3,334	92

[1] The Pacific cod A season for trawl gear does not open until January 20.
[2] The Pacific cod B season for trawl gear closes November 1.
[3] The Western and Central GOA and WYK District area apportionments of pollock are considered ACLs.

TABLE 19—FINAL 2022 GOA NON-EXEMPT AMERICAN FISHERIES ACT CATCHER VESSEL (CV) GROUNDFISH SIDEBOARD LIMITS

[Values are rounded to the nearest metric ton]

Species	Apportionments by season	Area	Ratio of 1995–1997 non-exempt AFA CV catch to 1995–1997 TAC	Final 2022 TACs[3]	Final 2022 non-exempt AFA CV sideboard limit
Pollock	A Season January 20–May 31	Shumagin (610)	0.6047	695	420
		Chirikof (620)	0.1167	36,294	4,235
		Kodiak (630)	0.2028	5,476	1,111
	B Season September 1–November 1	Shumagin (610)	0.6047	15,372	9,295
		Chirikof (620)	0.1167	11,420	1,333
		Kodiak (630)	0.2028	15,672	3,178
	Annual	WYK (640)	0.3495	4,706	1,645
		SEO (650)	0.3495	10,148	3,547
Pacific cod	A Season[1] January 1–June 10	W	0.1331	5,749	765
		C	0.0692	10,601	734
	B Season[2] September 1–December 31	W	0.1331	3,275	436
		C	0.0692	5,933	411
Flatfish, shallow-water	Annual	W	0.0156	13,250	207
		C	0.0587	28,442	1,670
Flatfish, deep-water	Annual	C	0.0647	1,914	124
		E	0.0128	3,787	48
Rex sole	Annual	C	0.0384	8,912	342
Arrowtooth flounder	Annual	C	0.0280	67,154	1,880
Flathead sole	Annual	C	0.0213	15,400	328
Pacific ocean perch	Annual	C	0.0748	26,234	1,962
		E	0.0466	6,796	317

TABLE 19—FINAL 2022 GOA NON-EXEMPT AMERICAN FISHERIES ACT CATCHER VESSEL (CV)—Continued GROUNDFISH SIDEBOARD LIMITS

[Values are rounded to the nearest metric ton]

Species	Apportionments by season	Area	Ratio of 1995–1997 non-exempt AFA CV catch to 1995–1997 TAC	Final 2022 TACs [3]	Final 2022 non-exempt AFA CV sideboard limit
Northern rockfish	Annual	C	0.0277	3,173	88

[1] The Pacific cod A season for trawl gear does not open until January 20.
[2] The Pacific cod B season for trawl gear closes November 1.
[3] The Western and Central GOA and WYK District area apportionments of pollock are considered ACLs.

Non-Exempt AFA Catcher Vessel Halibut PSC Limits

The halibut PSC sideboard limits for non-exempt AFA CVs in the GOA are based on the aggregate retained groundfish catch by non-exempt AFA CVs in each PSC target category from 1995 through 1997 divided by the retained catch of all vessels in that fishery from 1995 through 1997 (§ 679.64(b)(4)(ii)). Table 20 lists the final 2021 and 2022 non-exempt AFA CV halibut PSC sideboard limits for vessels using trawl gear in the GOA.

TABLE 20—FINAL 2021 AND 2022 NON-EXEMPT AFA CV HALIBUT PROHIBITED SPECIES CATCH (PSC) SIDEBOARD LIMITS FOR VESSELS USING TRAWL GEAR IN THE GOA

[Values are rounded to nearest metric ton]

Season	Season dates	Target fishery	Ratio of 1995–1997 non-exempt AFA CV retained catch to total retained catch	2021 and 2022 PSC limit	2021 and 2022 non-exempt AFA CV PSC limit
1	January 20–April 1	shallow-water	0.340	384	131
		deep-water	0.070	135	9
2	April 1–July 1	shallow-water	0.340	85	29
		deep-water	0.070	256	18
3	July 1–August 1	shallow-water	0.340	121	41
		deep-water	0.070	341	24
4	August 1–October 1	shallow-water	0.340	53	18
		deep-water	0.070	75	5
5	October 1–December 31	all targets	0.205	256	52
Annual		Total shallow-water			*219
		Total deep-water			56
		Total, all season and categories		1,706	328

Non-AFA Crab Vessel Groundfish Harvest Limitations

Section 680.22 establishes groundfish catch limits for vessels with a history of participation in the Bering Sea snow crab fishery to prevent these vessels from using the increased flexibility provided by the Crab Rationalization (CR) Program to expand their level of participation in the GOA groundfish fisheries. Sideboard limits restrict these vessels' catch to their collective historical landings in each GOA groundfish fishery (except the fixed-gear sablefish fishery). Sideboard limits also apply to catch made using an LLP license derived from the history of a restricted vessel, even if that LLP license is used on another vessel.

The basis for these sideboard limits is described in detail in the final rules implementing the major provisions of the CR Program, including Amendments 18 and 19 to the Fishery Management Plan for Bering Sea/Aleutian Islands King and Tanner Crabs (Crab FMP) (70 FR 10174, March 2, 2005), Amendment 34 to the Crab FMP (76 FR 35772, June 20, 2011), Amendment 83 to the GOA FMP (76 FR 74670, December 1, 2011), and Amendment 45 to the Crab FMP (80 FR 28539, May 19, 2015). Also, NMFS published a final rule (84 FR 2723, February 8, 2019) that implemented regulations to prohibit non-AFA crab vessels from directed fishing for all groundfish species or species groups subject to sideboard limits, except for Pacific cod apportioned to CVs using pot gear in the Western and Central Regulatory Areas (§ 680.22(e)(1)(iii)). Accordingly, the GOA annual harvest specifications will include the non-AFA crab vessel groundfish sideboard limits for only Pacific cod apportioned to CVs using pot gear in the Western and Central Regulatory Areas.

Tables 21 and 22 list the final 2021 and 2022 groundfish sideboard limitations for non-AFA crab vessels. All targeted or incidental catch of sideboard species made by non-AFA crab vessels or associated LLP licenses will be deducted from these sideboard limits.

TABLE 21—FINAL 2021 GOA NON-AMERICAN FISHERIES ACT CRAB VESSEL GROUNDFISH SIDEBOARD LIMITS

[Values are rounded to the nearest metric ton]

Species	Season	Area/gear	Ratio of 1996–2000 non-AFA crab vessel catch to 1996–2000 total harvest	Final 2021 TACs	Final 2021 non-AFA crab vessel sideboard limit
Pacific cod	A Season January 1–June 10.	Western Pot CV	0.0997	3,561	355
		Central Pot CV	0.0474	6,567	311
	B Season September 1–December 31.	Western Pot CV	0.0997	2,029	202
		Central Pot CV	0.0474	3,675	174

TABLE 22—FINAL 2022 GOA NON-AMERICAN FISHERIES ACT CRAB VESSEL GROUNDFISH SIDEBOARD LIMITS

[Values are rounded to the nearest metric ton]

Species	Season	Area/gear	Ratio of 1996–2000 non-AFA crab vessel catch to 1996–2000 total harvest	Final 2022 TACs	Final 2022 non-AFA crab vessel sideboard limit
Pacific cod	A Season January 1–June 10.	Western Pot CV	0.0997	5,749	573
		Central Pot CV	0.0474	10,601	502
	B Season September 1–December 31.	Western Pot CV	0.0997	3,275	327
		Central Pot CV	0.0474	5,933	281

Rockfish Program Groundfish Sideboard and Halibut PSC Limitations

The Rockfish Program establishes three classes of sideboard provisions: CV groundfish sideboard restrictions, CP rockfish sideboard restrictions, and CP opt-out vessel sideboard restrictions (§ 679.82(c)(1)). These sideboards are intended to limit the ability of rockfish harvesters to expand into other GOA groundfish fisheries.

CVs participating in the Rockfish Program may not participate in directed fishing for dusky rockfish, Pacific ocean perch, and northern rockfish in the West Yakutat District and Western GOA from July 1 through July 31. Also, CVs may not participate in directed fishing for arrowtooth flounder, deep-water flatfish, and rex sole in the GOA from July 1 through July 31 (§ 679.82(d)).

CPs participating in Rockfish Program cooperatives are restricted by rockfish and halibut PSC sideboard limits. These CPs are prohibited from directed fishing for dusky rockfish, Pacific ocean perch, and northern rockfish in the West Yakutat District and Western GOA from July 1 through July 31 (§ 679.82(e)(2)). Holders of CP-designated LLP licenses that opt out of participating in a Rockfish Program cooperative will be able to access that portion of each rockfish sideboard limit that is not assigned to rockfish cooperatives (§ 679.82(e)(7)). The sideboard ratio for each fishery in the West Yakutat District and the Western GOA is set forth in § 679.82(e)(4). Tables 23 and 24 list the final 2021 and 2022 Rockfish Program CP sideboard limits in the West Yakutat District and the Western GOA. Due to confidentiality requirements associated with fisheries data, the sideboard limits for the West Yakutat District are not displayed.

TABLE 23—FINAL 2021 ROCKFISH PROGRAM SIDEBOARD LIMITS FOR THE WESTERN GOA AND WEST YAKUTAT DISTRICT BY FISHERY FOR THE CATCHER/PROCESSOR SECTOR

[Values are rounded to the nearest metric ton]

Area	Fishery	CP sector (% of TAC)	Final 2021 TACs	Final 2021 CP limit
Western GOA	Dusky rockfish	72.3	270	195.
	Pacific ocean perch	50.6	1,643	831.
	Northern rockfish	74.3	2,023	1,503.
West Yakutat District	Dusky rockfish	Confidential [1]	468	Confidential.[1]
	Pacific ocean perch	Confidential [1]	1,705	Confidential.[1]

[1] Not released due to confidentiality requirements associated with fish ticket data, as established by NMFS and the State of Alaska.

TABLE 24—FINAL 2022 ROCKFISH PROGRAM SIDEBOARD LIMITS FOR THE WESTERN GOA AND WEST YAKUTAT DISTRICT BY FISHERY FOR THE CATCHER/PROCESSOR SECTOR

[Values are rounded to the nearest metric ton]

Area	Fishery	CP sector (% of TAC)	Final 2022 TACs	Final 2022 CP limit
Western GOA	Dusky rockfish	72.3	265	192.
	Pacific ocean perch	50.6	1,572	795.
	Northern rockfish	74.3	1,926	1,431.
West Yakutat District	Dusky rockfish	Confidential [1]	460	Confidential.[1]
	Pacific ocean perch	Confidential [1]	1,631	Confidential.[1]

[1] Not released due to confidentiality requirements associated with fish ticket data, as established by NMFS and the State of Alaska.

Under the Rockfish Program, the CP sector is subject to halibut PSC sideboard limits for the trawl deep-water and shallow-water species fisheries from July 1 through July 31 (§ 679.82(e)(3) and (5)). Halibut PSC sideboard ratios by fishery are set forth in § 679.82(e)(5). No halibut PSC sideboard limits apply to the CV sector, as CVs participating in cooperatives receive a portion of the annual halibut PSC limit. CPs that opt out of the Rockfish Program are able to access that portion of the deep-water and shallow-water halibut PSC sideboard limit not assigned to CP rockfish cooperatives. The sideboard provisions for CPs that elect to opt out of participating in a rockfish cooperative are described in § 679.82(c), (e), and (f). Sideboard limits are linked to the catch history of specific vessels that may choose to opt out. After March 1, NMFS will determine which CPs have opted-out of the Rockfish Program in 2021, and NMFS will know the ratios and amounts used to calculate opt-out sideboard ratios. NMFS will then calculate any applicable opt-out sideboards for 2021 and post these limits on the Alaska Region website at *https://www.fisheries.noaa.gov/alaska/sustainable-fisheries/alaska-fisheries-management-reports#central-goa-rockfish.* Table 25 lists the final 2021 and 2022 Rockfish Program halibut PSC sideboard limits for the CP sector.

TABLE 25—FINAL 2021 AND 2022 ROCKFISH PROGRAM HALIBUT PSC SIDEBOARD LIMITS FOR THE CATCHER/PROCESSOR SECTOR

[Values are rounded to the nearest metric ton]

Sector	Shallow-water species fishery halibut PSC sideboard ratio (percent)	Deep-water species fishery halibut PSC sideboard ratio (percent)	2021 and 2022 halibut mortality limit (mt)	Annual shallow-water species fishery halibut PSC sideboard limit (mt)	Annual deep-water species fishery halibut PSC sideboard limit (mt)
Catcher/processor	0.10	2.50	1,706	2	43

Amendment 80 Program Groundfish and PSC Sideboard Limits

Amendment 80 to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (Amendment 80 Program) established a limited access privilege program for the non-AFA trawl CP sector. The Amendment 80 Program established groundfish and halibut PSC catch limits for Amendment 80 Program participants to limit the ability of participants eligible for the Amendment 80 Program to expand their harvest efforts in the GOA.

Section 679.92 establishes groundfish harvesting sideboard limits on all Amendment 80 program vessels, other than the fishing vessel (F/V) *Golden Fleece,* to amounts no greater than the limits listed in Table 37 to 50 CFR part 679. Under § 679.92(d), the F/V *Golden Fleece* is prohibited from directed fishing for pollock, Pacific cod, Pacific ocean perch, dusky rockfish, and northern rockfish in the GOA.

Groundfish sideboard limits for Amendment 80 Program vessels operating in the GOA are based on their average aggregate harvests from 1998 through 2004 (72 FR 52668, September 14, 2007). Tables 26 and 27 list the final 2021 and 2022 groundfish sideboard limits for Amendment 80 Program vessels. NMFS will deduct all targeted or incidental catch of sideboard species made by Amendment 80 Program vessels from the sideboard limits in Tables 26 and 27.

TABLE 26—FINAL 2021 GOA GROUNDFISH SIDEBOARD LIMITS FOR AMENDMENT 80 PROGRAM VESSELS

[Values are rounded to nearest metric ton]

Species	Apportionments and allocations by season	Area	Ratio of Amendment 80 sector vessels 1998–2004 catch to TAC	2021 TAC (mt)	2021 Amendment 80 vessel sideboards (mt)
Pollock	A Season January 20–May 31.	Shumagin (610)	0.003	799	2
		Chirikof (620)	0.002	41,737	83
		Kodiak (630)	0.002	6,297	13

TABLE 26—FINAL 2021 GOA GROUNDFISH SIDEBOARD LIMITS FOR AMENDMENT 80 PROGRAM VESSELS—Continued

[Values are rounded to nearest metric ton]

Species	Apportionments and allocations by season	Area	Ratio of Amendment 80 sector vessels 1998–2004 catch to TAC	2021 TAC (mt)	2021 Amendment 80 vessel sideboards (mt)
	B Season September 1–November 1	Shumagin (610)	0.003	17,677	53
		Chirikof (620)	0.002	13,133	26
		Kodiak (630)	0.002	18,023	36
	Annual	WYK (640)	0.002	5,412	11
Pacific cod	A Season [1] January 1–June 10.	W	0.020	3,561	71
		C	0.044	6,567	289
	B Season [2] September 1–December 31.	W	0.020	2,029	41
		C	0.044	3,675	162
	Annual	WYK	0.034	1,489	51
Pacific ocean perch	Annual	W	0.994	1,643	1,633
		WYK	0.961	1,705	1,639
Northern rockfish	Annual	W	1.000	2,023	2,023
Dusky rockfish	Annual	W	0.764	270	206
		WYK	0.896	468	419

[1] The Pacific cod A season for trawl gear does not open until January 20.
[2] The Pacific cod B season for trawl gear closes November 1.

TABLE 27—FINAL 2022 GOA GROUNDFISH SIDEBOARD LIMITS FOR AMENDMENT 80 PROGRAM VESSELS

[Values are rounded to nearest metric ton]

Species	Apportionments and allocations by season	Area	Ratio of Amendment 80 sector vessels 1998–2004 catch to TAC	2022 TAC (mt)	2022 Amendment 80 vessel sideboards (mt)
Pollock	A Season January 20–May 31.	Shumagin (610)	0.003	695	2
		Chirikof (620)	0.002	36,294	73
		Kodiak (630)	0.002	5,476	11
	B Season September 1–November 1	Shumagin (610)	0.003	15,372	46
		Chirikof (620)	0.002	11,420	23
		Kodiak (630)	0.002	15,672	31
	Annual	WYK (640)	0.002	4,706	9
Pacific cod	A Season [1] January 1–June 10.	W	0.020	5,749	115
		C	0.044	10,601	466
	B Season [2] September 1–December 31.	W	0.020	3,275	66
		C	0.044	5,933	261
	Annual	WYK	0.034	2,403	82
Pacific ocean perch	Annual	W	0.994	1,572	1,563
		WYK	0.961	1,631	1,567
Northern rockfish	Annual	W	1.000	1,926	1,926
Dusky rockfish	Annual	W	0.764	265	202
		WYK	0.896	460	412

[1] The Pacific cod A season for trawl gear does not open until January 20.
[2] The Pacific cod B season for trawl gear closes November 1.

The halibut PSC sideboard limits for Amendment 80 Program vessels in the GOA are based on the historic use of halibut PSC by Amendment 80 Program vessels in each PSC target category from 1998 through 2004. These values are slightly lower than the average historic use to accommodate two factors: Allocation of halibut PSC cooperative quota under the Rockfish Program and the exemption of the F/V *Golden Fleece* from this restriction (§ 679.92(b)(2)). Table 28 lists the final 2021 and 2022 halibut PSC sideboard limits for Amendment 80 Program vessels. These tables incorporate the maximum percentages of the halibut PSC sideboard limits that may be used by Amendment 80 Program vessels as contained in Table 38 to 50 CFR part 679. Any residual amount of a seasonal Amendment 80 halibut PSC sideboard limit may carry forward to the next season limit (§ 679.92(b)(2)).

TABLE 28—FINAL 2021 AND 2022 HALIBUT PSC SIDEBOARD LIMITS FOR AMENDMENT 80 PROGRAM VESSELS IN THE GOA

[Values are rounded to nearest metric ton]

Season	Season dates	Target fishery	Historic Amendment 80 use of the annual halibut PSC limit catch (ratio)	2021 and 2022 annual PSC limit (mt)	2021 and 2022 Amendment 80 vessel PSC limit
1	January 20–April 1	shallow-water	0.0048	1,706	8
		deep-water	0.0115	1,706	20
2	April 1–July 1	shallow-water	0.0189	1,706	32
		deep-water	0.1072	1,706	183
3	July 1–August 1	shallow-water	0.0146	1,706	25
		deep-water	0.0521	1,706	89
4	August 1–October 1	shallow-water	0.0074	1,706	13
		deep-water	0.0014	1,706	2
5	October 1–December 31	shallow-water	0.0227	1,706	39
		deep-water	0.0371	1,706	63
Total:					474

Directed Fishing Closures

Pursuant to § 679.20(d)(1)(i), if the Regional Administrator determines (1) that any allocation or apportionment of a target species or species group allocated or apportioned to a fishery will be reached; or (2) with respect to pollock and Pacific cod, that an allocation or apportionment to an inshore or offshore component or sector allocation will be reached, then the Regional Administrator may establish a directed fishing allowance (DFA) for that species or species group. If the Regional Administrator establishes a DFA and that allowance is or will be reached before the end of the fishing season or year, NMFS will prohibit directed fishing for that species or species group in the specified GOA subarea, regulatory area, or district (§ 679.20(d)(1)(iii)).

The Regional Administrator has determined that the TACs for the species listed in Table 29 are necessary to account for the incidental catch of these species in other anticipated groundfish fisheries for the 2021 and 2022 fishing years.

TABLE 29—2021 AND 2022 DIRECTED FISHING CLOSURES IN THE GOA

[Amounts for incidental catch in other directed fisheries are in metric tons]

Target	Area/component/gear	Incidental catch amount and year (if amounts differ by year)
Pollock	all/offshore	not applicable [1].
Sablefish [2]	all/trawl	2,473 (2021), 3,553 (2022).
Pacific cod	Western, CP, trawl	129 (2021), 209 (2022).
	Central, CP, trawl	426 (2021), 687 (2022).
Shortraker rockfish [2]	all	708.
Rougheye/blackspotted rockfish [2]	all	1,212 (2021), 1,221 (2022).
Thornyhead rockfish [2]	all	1,953.
Other rockfish	all	1,609.
Atka mackerel	all	3,000.
Big skate	all	3,208.
Longnose skate	all	2,587.
Other skates	all	875.
Sharks	all	3,755.
Octopuses	all	980.

[1] Pollock is closed to directed fishing in the GOA by the offshore component under § 679.20(a)(6)(i).

[2] Closures are not applicable to participants in cooperatives conducted under the Central GOA Rockfish Program because cooperatives are prohibited from exceeding their allocations (§ 679.7(n)(6)(viii)).

Consequently, in accordance with § 679.20(d)(1)(i), the Regional Administrator establishes the DFA for the species or species groups listed in Table 29 as zero mt. Therefore, in accordance with § 679.20(d)(1)(iii), NMFS is prohibiting directed fishing for those species, areas, gear types, and components in the GOA listed in Table 29 effective at 1200 hours, A.l.t., February 19, 2021, through 2400 hours, A.l.t., December 31, 2022.

Closures implemented under the 2020 and 2021 GOA harvest specifications for groundfish (85 FR 13802, March 10, 2020) remain effective under authority of these final 2021 and 2022 harvest specifications and until the date specified in those notices. Closures are posted at the following website under the Alaska filter for Management Areas: *https://www.fisheries.noaa.gov/rules-and-announcements/bulletins.*

While these closures are in effect, the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a fishing trip. These closures to directed fishing are in addition to closures and prohibitions found at 50 CFR part 679. NMFS may implement

other closures during the 2021 and 2022 fishing years as necessary for effective conservation and management.

Comments and Responses

NMFS did not receive any comments during the public comment period for the proposed groundfish harvest specifications.

Classification

NMFS has determined that the final harvest specifications are consistent with the FMP and with the Magnuson-Stevens Fishery Conservation and Management Act and other applicable laws.

This final rule is exempt from review under Executive Order 12866.

NMFS prepared an EIS for the Alaska groundfish harvest specifications and alternative harvest strategies (see **ADDRESSES**) and made it available to the public on January 12, 2007 (72 FR 1512). On February 13, 2007, NMFS issued the ROD for the EIS. In January 2021, NMFS prepared a SIR for this action to provide a subsequent assessment of the action and to address the need to prepare a Supplemental EIS (SEIS;40 CFR 1501.11(b); § 1502.9(d)(1)). Copies of the EIS, ROD, and annual SIRs for this action are available from NMFS (see **ADDRESSES**). The Final EIS analyzes the environmental, social, and economic consequences of the groundfish harvest specifications and alternative harvest strategies on resources in the action area. Based on the analysis in the Final EIS, NMFS concluded that the preferred Alternative (Alternative 2) provides the best balance among relevant environmental, social, and economic considerations and allows for continued management of the groundfish fisheries based on the most recent, best scientific information. The preferred alternative is a harvest strategy in which TACs are set at a level within the range of ABCs recommended by the Council's SSC; the sum of the TACs must achieve the OY specified in the FMP. While the specific numbers that the harvest strategy produces may vary from year to year, the methodology used for the preferred harvest strategy remains constant.

The annual SIR evaluates the need to prepare a SEIS for the 2021 and 2022 groundfish harvest specifications. An SEIS should be prepared if (1) the agency makes substantial changes in the proposed action that are relevant to environmental concerns, or (2) significant new circumstances or information exist relevant to environmental concerns and bearing on the proposed action or its impacts (40 CFR 1502.9(d)(1)). After reviewing the information contained in the SIR and SAFE reports, the Regional Administrator has determined that (1) approval of the 2021 and 2022 harvest specifications, which were set according to the preferred harvest strategy in the EIS, does not constitute a substantial change in the action; and (2) there are no significant new circumstances or information relevant to environmental concerns and bearing on the action or its impacts. Additionally, the 2021 and 2022 harvest specifications will result in environmental, social, and economic impacts within the scope of those analyzed and disclosed in the EIS. Therefore, an SEIS is not necessary to implement the 2021 and 2022 harvest specifications.

Section 604 of the Regulatory Flexibility Act (RFA) (5 U.S.C. 604) requires that, when an agency promulgates a final rule under 5 U.S.C. 553, after being required by that section, or any other law, to publish a general notice of proposed rulemaking, the agency shall prepare a final regulatory flexibility analysis (FRFA). The following constitutes the FRFA prepared in the final action.

Section 604 of the RFA describes the required contents of a FRFA: (1) A statement of the need for, and objectives of, the rule; (2) a statement of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis (IRFA), a statement of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments; (3) the response of the agency to any comments filed by the Chief Counsel for Advocacy of the Small Business Administration in response to the proposed rule, and a detailed statement of any change made to the proposed rule in the final rule as a result of the comments; (4) a description of and an estimate of the number of small entities to which the rule will apply or an explanation of why no such estimate is available; (5) a description of the projected reporting, recordkeeping, and other compliance requirements of the rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record; and (6) a description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency that affect the impact on small entities was rejected.

A description of this action, its purpose, and its legal basis are contained at the beginning of the preamble to this final rule and are not repeated here.

NMFS published the proposed rule on December 3, 2020 (85 FR 78076). NMFS prepared an IRFA to accompany the proposed action, and included the IRFA in the proposed rule. The comment period closed on January 4, 2021. No comments were received on the IRFA or on the economic impacts of the rule more generally. The Chief Counsel for Advocacy of the Small Business Administration did not file any comments on the proposed rule.

The entities directly regulated by this action are: (1) Entities operating vessels with groundfish federal fishing permit (FFPs) catching FMP groundfish in Federal waters; (2) all entities operating vessels, regardless of whether they hold groundfish FFPs, catching FMP groundfish in the State-waters parallel fisheries; and (3) all entities operating vessels fishing for halibut inside three miles (5.6 km) of the shore (whether or not they have FFPs).

For RFA purposes only, NMFS has established a small business size standard for businesses, including their affiliates, whose primary industry is commercial fishing (see 50 CFR 200.2). A business primarily engaged in commercial fishing (NAICS code 11411) is classified as a small business if it is independently owned and operated, is not dominant in its field of operation (including its affiliates), and has combined annual gross receipts not in excess of $11 million for all its affiliated operations worldwide.

Using the most recent data available (2019), the estimated number of directly regulated small entities include approximately 871 individual catcher vessel entities with gross revenues meeting small entity criteria. This estimate does not account for corporate affiliations among vessels, and for cooperative affiliations among fishing entities, since some of the fishing vessels operating in the GOA are members of AFA inshore pollock cooperatives, GOA rockfish cooperatives, or BSAI CR Program cooperatives. Vessels that participate in these cooperatives are considered to be large entities within the meaning of the RFA because the aggregate gross receipts of all participating members exceed the $11 million threshold. After accounting for membership in these cooperatives, there are an estimated 812 small CV and 5 small CP entities remaining in the GOA groundfish sector. However, the

estimate of these 817 CVs may be an overstatement of the number of small entities. This latter group of vessels had average gross revenues that varied by gear type. Average gross revenues for hook-and-line CVs, pot gear CVs, trawl gear CVs, and hook-and-line CPs are estimated to be $350,000, $780,000, $1.6 million, and $2.9 million, respectively.

This final rule contains no information collection requirements under the Paperwork Reduction Act of 1995.

This action implements the final 2021 and 2022 harvest specifications, apportionments, and halibut PSC limits for the groundfish fishery of the GOA. This action is necessary to establish harvest limits for groundfish during the 2021 and 2022 fishing years and is taken in accordance with the FMP prepared by the Council pursuant to the Magnuson-Stevens Act. The establishment of the final harvest specifications is governed by the Council's harvest strategy that governs the catch of groundfish in the GOA. The harvest strategy was selected previously from among five alternatives, with the preferred alternative harvest strategy being one in which the TACs fall within the range of ABCs recommended by the SSC. Under this preferred alternative harvest strategy, TACs are set within the range of ABCs recommended by the SSC; the sum of the TACs must achieve the OY specified in the FMP; and while the specific TAC numbers that the harvest strategy produces may vary from year to year, the methodology used for the preferred harvest strategy remains constant. This final action implements the preferred alternative harvest strategy previously chosen by the Council to set TACs that fall within the range of ABCs recommended through the Council harvest specifications process and as recommended by the Council. This is the method for determining TACs that has been used in the past.

The final 2021 and 2022 TACs associated with preferred harvest strategy are those recommended by the Council in December 2020. OFLs and ABCs for the species were based on recommendations prepared by the Council's Plan Team, and reviewed by the Council's SSC. The Council based its TAC recommendations on those of its AP, which were consistent with the SSC's OFL and ABC recommendations. The sum of all TACs remains within the OY for the GOA consistent with § 679.20(a)(1)(i)(B).

The final 2021 and 2022 OFLs and ABCs are based on the best available biological information, including projected biomass trends, information on assumed distribution of stock biomass, and revised technical methods to calculate stock biomass. The final 2021 and 2022 TACs are based on the best available biological and socioeconomic information. The final 2021 and 2022 OFLs, ABCs, and TACs are consistent with the biological condition of groundfish stocks as described in the 2020 SAFE report, which is the most recent, completed SAFE report. Accounting for the most recent biological information to set the final OFLs, ABCs, and TACs is consistent with the objectives for this action, as well as National Standard 2 of the Magnuson-Stevens Act (16 U.S.C. 1851(a)(2)) that actions shall be based on the best scientific information available.

Under this action, the final ABCs reflect harvest amounts that are less than the specified overfishing levels. The final TACs are within the range of final ABCs recommended by the SSC and do not exceed the biological limits recommended by the SSC (the ABCs and overfishing levels). For most species and species groups in the GOA, the Council recommended, and NMFS sets, final TACs equal to final ABCs, which is intended to maximize harvest opportunities in the GOA, unless other conservation or management reasons support setting TAC amounts less than the ABCs.

For these species and species groups, the Council recommended and NMFS sets TACs that are less than the ABCs, including for pollock for the combined W/C/WYK Regulatory Area, Pacific cod, shallow-water flatfish in the Western GOA, arrowtooth flounder in the Western GOA and the West Yakutat and SEO Districts, flathead sole in the Western and Central GOA, Atka mackerel, and ''other rockfish'' in the SEO District. These specific reductions were reviewed and recommended by the Council's AP, and, with the exception of sablefish, the Council in turn adopted the AP's recommendations for the final 2021 and 2022 TACs.

For sablefish, the Council recommended 2021 sablefish TACs that are less than the 2021 ABCs, which is intended to provide an incremental increase from the 2020 TACs to the 2021 TACs rather than the very large increase in the 2021 TACs if they were set equal to final ABCs. Moreover, increasing TACs for some species may not result in increased harvest opportunities for those species. This is due to a variety of reasons. There may be a lack of commercial or market interest in some species. Additionally, there are fixed, and therefore constraining, PSC limits associated with the harvest of the GOA groundfish species that can lead to an underharvest of flatfish TACs. For this reason, the shallow-water flatfish, arrowtooth flounder, and flathead sole TACs are set to allow for increased harvest opportunities for these target species while conserving the halibut PSC limit for use in other fisheries. The Atka mackerel TAC is set to accommodate incidental catch amounts in other fisheries. The ''other rockfish'' TAC in the SEO District is set to reduce the amount of discards of the species in that complex. Finally, the TACs for two species (pollock and Pacific cod) cannot be set equal to ABC, as the TAC must be reduced to account for the State's GHLs in these fisheries. The W/C/WYK Regulatory Area pollock TAC and the GOA Pacific cod TACs are therefore set to account for the State's GHLs for the State water pollock and Pacific cod fisheries so that the ABCs are not exceeded.

Based upon the best available scientific data, and in consideration of the Council's objectives of this action, there are no significant alternatives to the final rule that have the potential to accomplish the stated objectives of the Magnuson-Stevens Act and any other applicable statutes and that have the potential to minimize any significant adverse economic impact of the final rule on small entities. This action is economically beneficial to entities operating in the GOA, including small entities. The action specifies TACs for commercially-valuable species in the GOA and allows for the continued prosecution of the fishery, thereby creating the opportunity for fishery revenue. After public process, during which the Council solicited input from stakeholders, the Council concluded that these final harvest specifications would best accomplish the stated objectives articulated in the preamble for this final rule and in applicable statutes and would minimize to the extent practicable adverse economic impacts on the universe of directly regulated small entities.

Adverse impacts on marine mammals, or endangered or threatened species, resulting from fishing activities conducted under this rule are discussed in the Final EIS and its accompanying annual SIRs (see **ADDRESSES**).

Pursuant to 5 U.S.C. 553(d)(3), the Assistant Administrator for Fisheries, NOAA, finds good cause to waive the 30-day delay in effectiveness for this rule because delaying this rule is contrary to the public interest. The Plan Team review of the 2020 SAFE report occurred in November 2020, and based on the 2020 SAFE report the Council considered and recommended the final harvest specifications in December

2020. Accordingly, NMFS's review of the final 2021 and 2022 harvest specifications could not begin until after the December 2020 Council meeting, and after the public had time to comment on the proposed action.

For all fisheries not currently closed because the TACs established under the final 2020 and 2021 harvest specifications (85 FR 13802, March 10, 2020) were not reached, it is possible that they would be closed prior to the expiration of a 30-day delayed effectiveness period because their TACs could be reached within that period. If implemented immediately, this rule would allow these fisheries to continue fishing because some of the new TACs implemented by this rule are higher than the TACs under which they are currently fishing.

In addition, immediate effectiveness of this action is required to provide consistent management and conservation of fishery resources based on the best available scientific information. This is particularly pertinent for those species that have lower 2021 ABCs and TACs than those established in the 2020 and 2021 harvest specifications (85 FR 13802, March 10, 2020). If implemented immediately, this rule would ensure that NMFS can properly manage those fisheries for which this rule sets lower 2021 ABCs and TACs, which are based on the most recent biological information on the condition of stocks, rather than managing species under the higher TACs set in the previous year's harvest specifications.

Certain fisheries, such as those for pollock, are intensive, fast-paced fisheries. Other fisheries, such as those for sablefish, flatfish, rockfish, Atka mackerel, skates, sharks, and octopuses, are critical as directed fisheries and as incidental catch in other fisheries. U.S. fishing vessels have demonstrated the capacity to catch the TAC allocations in many of these fisheries. If the effectiveness of this rule were delayed 30 days and if a TAC were reached during those 30 days, NMFS would close directed fishing or prohibit retention for the applicable species. Any delay in allocating the final TACs in these fisheries would cause confusion to the industry and potential economic harm through unnecessary discards, thus undermining the intent of this rule. Waiving the 30-day delay allows NMFS to prevent economic loss to fishermen that could otherwise occur should the 2021 TACs (set under the 2020 and 2021 harvest specifications) be reached. Determining which fisheries may close is nearly impossible because these fisheries are affected by several factors that cannot be predicted in advance, including fishing effort, weather, movement of fishery stocks, and market price. Furthermore, the closure of one fishery has a cascading effect on other fisheries by freeing-up fishing vessels, allowing them to move from closed fisheries to open ones, increasing the fishing capacity in those open fisheries, and causing them to close at an accelerated pace.

In fisheries subject to declining sideboard limits, a failure to implement the updated sideboard limits before initial season's end could deny the intended economic protection to the non-sideboarded sectors. Conversely, in fisheries with increasing sideboard limits, economic benefit could be denied to the sideboard-limited sectors.

If the final harvest specifications are not effective by March 6, 2021, which is the start of the 2021 Pacific halibut season as specified by the IPHC, the fixed gear sablefish fishery will not begin concurrently with the Pacific halibut IFQ season. This would result in confusion for the industry and economic harm from unnecessary discard of sablefish that are caught along with Pacific halibut, as both fixed gear sablefish and Pacific halibut are managed under the same IFQ program. Immediate effectiveness of the final 2021 and 2022 harvest specifications will allow the sablefish IFQ fishery to begin concurrently with the Pacific halibut IFQ season.

Finally, immediate effectiveness also would provide the fishing industry the earliest possible opportunity to plan and conduct its fishing operations with respect to new information about TACs. Therefore, NMFS finds good cause to waive the 30-day delay in effectiveness under 5 U.S.C. 553(d)(3).

Small Entity Compliance Guide

This final rule is a plain language guide to assist small entities in complying with this final rule as required by the Small Business Regulatory Enforcement Fairness Act of 1996. This final rule's primary purpose is to announce the final 2021 and 2022 harvest specifications and prohibited species bycatch allowances for the groundfish fisheries of the GOA. This action is necessary to establish harvest limits and associated management measures for groundfish during the 2021 and 2022 fishing years, and to accomplish the goals and objectives of the FMP. This action affects all fishermen who participate in the GOA fisheries. The specific OFL, ABC, TAC, and PSC amounts are provided in tables to assist the reader. NMFS will announce closures of directed fishing in the **Federal Register** and information bulletins released by the Alaska Region. Affected fishermen should keep themselves informed of such closures.

Authority: 16 U.S.C. 773 *et seq.;* 16 U.S.C. 1540 (f), 1801 *et seq.;* 16 U.S.C. 3631 *et seq.;* Pub. L. 105–277; Pub. L. 106–31; Pub. L. 106–554; Pub. L. 108–199; Pub. L. 108–447; Pub. L. 109–241; Pub. L 109–479.

Dated: February 11, 2021.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

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Proposed Rules

Federal Register

Vol. 86, No. 32

Friday, February 19, 2021

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

DEPARTMENT OF ENERGY

10 CFR Parts 430 and 431

[EERE–2020–BT–STD–0004]

Energy Conservation Program: Procedures for Use in New or Revised Energy Conservation Standards and Test Procedures for Consumer Products and Commercial/Industrial Equipment; Prioritization Process

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

ACTION: Request for information; request for comment concerning prioritization of rulemakings.

SUMMARY: The U.S. Department of Energy (DOE or the Department) is initiating an effort to elicit information from stakeholders and the interested public concerning the prioritization of rulemakings pursuant to the Department's rulemaking methodology titled, ''Procedures, Interpretations, and Policies for Consideration of New or Revised Energy Conservation Standards and Test Procedures for Consumer Products and Commercial/Industrial Equipment'' (Process Rule). DOE welcomes written comments as well as the submission of data and other relevant information.

DATES: Written comments and information are requested and will be accepted on or before March 11, 2021.

ADDRESSES: Interested persons are encouraged to submit comments using the Federal eRulemaking Portal at *http://www.regulations.gov*. Follow the instructions for submitting comments. Alternatively, interested persons may submit comments, identified by docket number EERE–2020–BT–STD–0004, by any of the following methods:

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

2. *Email:* to *PrioritySetting2020STD0004@ee.doe.gov*. Include docket number EERE–2020–BT–STD–0004 in the subject line of the message.

No telefacsimilies (faxes) will be accepted. For detailed instructions on submitting comments and additional information on this process, see section III of this document.

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

The docket web page can be found at: *http://www.regulations.gov/docket?D=EERE-2020-BT-STD-0004*. The docket web page contains instructions on how to access all documents, including public comments, in the docket. See section III for information on how to submit comments through *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Mr. John Cymbalsky, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, EE–5B, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 287–1692. Email: *ApplianceStandardsQuestions@ee.doe.gov*.

Ms. Francine Pinto, U.S. Department of Energy, Office of the General Counsel, GC–33, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 586–7432. Email: *Francine.Pinto@hq.doe.gov.*

For further information on how to submit a comment or review other public comments and the docket, contact the Appliance and Equipment Standards Program staff at (202) 287–1445 or by email: *ApplianceStandardsQuestions@ee.doe.gov*.

SUPPLEMENTARY INFORMATION:

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I. Introduction

A. Authority

The Department of Energy's Process Rule was developed to guide implementation of the Appliance Standards Program, which is conducted pursuant to Title III, Part B [1] of the Energy Policy and Conservation Act, as amended (EPCA or the Act),[2] Public Law 94–163 (42 U.S.C. 6291–6309, as codified), establishing the Energy Conservation Program for Consumer Products Other Than Automobiles, which sets forth a variety of provisions designed to improve energy efficiency. In addition, Part C [3] of EPCA, Public Law 94–163 (42 U.S.C. 6311–6317, as codified), added by Public Law 95–619, Title IV, section 441(a), established the Energy Conservation Program for Certain Industrial Equipment, which again sets forth a variety of provisions designed to improve energy efficiency.

The energy conservation program under EPCA consists essentially of four parts: (1) Testing, (2) labeling, (3) Federal energy conservation standards, and (4) certification and enforcement procedures. Relevant provisions of EPCA specifically include definitions (42 U.S.C. 6291; 42 U.S.C. 6311), test procedures (42 U.S.C. 6293; 42 U.S.C. 6314), labeling provisions (42 U.S.C. 6294; 42 U.S.C. 6315), energy conservation standards (42 U.S.C. 6295; 42 U.S.C. 6313), and the authority to require information and reports from manufacturers (42 U.S.C. 6296; 42 U.S.C. 6316). The statute sets forth the criteria, procedures and timeframes DOE must follow when establishing new or amended energy conservation standards for covered products (and at least certain types of equipment). The statute also sets forth the criteria and procedures DOE must follow when prescribing or amending test procedures for covered products.

[1] For editorial reasons, upon codification in the U.S. Code, Part B was redesignated Part A.

[2] All references to EPCA in this document refer to the statute as amended through the Energy Act of 2020, Public Law 116–260 (Dec. 27, 2020).

[3] For editorial reasons, upon codification in the U.S. Code, Part C was redesignated Part A–1.

B. Background on the Process Rule

On July 15, 1996, DOE published a final rule titled, ''Procedures, Interpretations and Policies for Consideration of New or Revised Energy Conservation Standards for Consumer Products.'' 61 FR 36974. This document was codified at 10 CFR part 430, subpart C, appendix A, and became known colloquially as the ''Process Rule.'' The Process Rule was designed to provide guidance to stakeholders as to how DOE would implement its rulemaking responsibilities under EPCA for the Appliance Standards Program.

The Department published a revised Process Rule in the **Federal Register** on February 14, 2020. 85 FR 8626. Section 4(b) of the Rule as revised, includes an opportunity for stakeholders to provide input on the prioritization of the Department's rulemakings as DOE prepares its Spring Regulatory Agenda.

Pursuant to Executive Order 13990 of January 20, 2021 (E.O. 13990; 86 FR 7038, January 25, 2021), DOE was directed to consider ''suspending, revising or rescinding'' certain agency actions, including DOE's Process Rule. (E.O. 13990, Sec. 2(iii)) As directed by E.O. 13990, DOE is in the process of reconsidering the Process Rule but has determined that such reconsideration is not inconsistent with the Process Rule requirement in section 4(b) to seek early stakeholder feedback.

II. The Prioritization Process and Request for Comments

The revised Process Rule provides that stakeholders will have the opportunity to provide input on the prioritization of rulemakings as DOE begins its preparation of the Spring Regulatory Agenda. If stakeholders believe that the Department is pursuing a rule that should not be prioritized as active, for example, the stakeholder comments should reflect such an opinion and inform the Department as to how such rule should be prioritized, if at all, with an explanation for the stakeholder's recommendation. At the same time, if stakeholders believe that DOE should act more quickly on a particular rulemaking, commenters should make such a point with as much specificity as possible to indicate a revised timeline with an explanation for the recommendation. In addition, if stakeholders believe a rulemaking should be initiated and prioritized that is not already underway, the Department would welcome that feedback.

In making its recommendations, stakeholders can utilize the regulatory text in the revised Process Rule, section 4, entitled, Setting Priorities for Rulemaking Activity, that sets forth the factors the Department considers in making its priority-setting decisions.[4]

A. Description of How To Access and Use the Fall 2020 Unified Agenda of Regulatory and Deregulatory Actions

As noted in the revised Process Rule, DOE requests that stakeholders use the previous year's Fall Unified Agenda of Regulatory and Deregulatory Actions (in this case, the 2020 Fall Agenda) as the common frame of reference for stakeholder comments. The 2020 Fall Agenda shows the two basic categories of agency actions: (1) Active rulemakings and (2) long-term actions.

How the rules are ultimately categorized (active versus long-term actions) in the Unified Agenda depends upon the projection date DOE enters into the Regulatory Information Service Center Office of Management and Budget/Office of Information and Regulatory Affairs Consolidated Information System (ROCIS) for the next action in each timetable associated with a specific rule. Generally speaking, those rules with a ''next action'' that is scheduled more than a year away will be categorized as long-term actions; those rules having a ''next action'' within a year are generally categorized as active rules.

The steps to access the active regulatory agenda actions/agency rule list are as follows:

(1) Go to *www.reginfo.gov*.

(2) To access the active actions, go to the box titled, ''Unified Agenda and Regulatory Plan,'' and click on the line item that is titled, ''The Fall Agenda was published on 12/09/2020.''

(3) Go to ''Fall 2020 Unified Agenda of Regulatory and Deregulatory Actions Active Regulatory Actions Listed by Agency.''

(4) Go to ''Select Agency'' and in the drop-down menu select ''Department of Energy'' and click ''Submit.'' What will appear is the Agency Rule list for DOE's portion of the 2020 Fall Agenda. This is the list of all DOE active rulemakings. Rules of the Appliance Standards Program will be included with those DOE rules designated as ''DOE/EERE.'' This agency rule list shows the stage of each rulemaking (*i.e.,* pre-rule, notice of proposed rulemaking, or final rule), the title of the rule, and the regulatory identifier number (RIN). You will need to review the list for those rulemakings specific to the Appliance Program.

Once stakeholders have accessed the list of DOE active rulemakings, they can review the information about each rule, including the timetable, that will be displayed. The timetable itself, which is most critical to this priority-setting review, will list all the actions already taken on that particular rule, as well as the next action DOE is planning to take, along with a projected date for that action.

The steps to access the long-term actions information are as follows:

(1) Go to *www.reginfo.gov*.

(2) To access the long-term actions, go to the box titled, ''Unified Agenda and Regulatory Plan,'' and click on the line item that is titled, ''The Fall Agenda was published on 12/09/2020.''

(3) Click on the line item, ''Current Long Term Actions'' for a list of such actions.

(4) Under the title ''Agenda Agency Regulatory Entries for Long-Term Actions,'' go to ''Select Agency'' and in the drop-down menu select ''Department of Energy'' and click ''Submit.'' What will appear is the Agency Rule list for DOE's portion of the 2020 Fall Agenda. This is the list of all DOE long-term actions. You will need to review the list for those rulemakings specific to the Appliance Program.

Once stakeholders have accessed the list of long-term actions, as with the active rulemakings, stakeholders will find information describing each rule, as well as the timetable for that rule.

B. Request for Comments

As noted previously, the Department is seeking information that will shed light on how it should best prioritize and sequence its rulemaking activities for the Department's Appliance Standards Program. By this notice, and consistent with the revised Process Rule, DOE requests that stakeholders and the interested public review the timetables for all active and long-term appliance rules and comment upon both the timing and categorization of these rules. The Department is also interested in any other rulemaking activities that DOE should initiate and prioritize in the upcoming Spring Agenda.

III. Submission of Comments

DOE invites all interested parties to submit in writing by March 11, 2021, comments and information on matters addressed in this notice and on other

[4] Section 4 reads as follows:

Setting Priorities for Rulemaking Activity

(a) In establishing its priorities for undertaking energy conservation standards and test procedure rulemakings, DOE will consider the following factors, consistent with applicable legal obligations:

(1) Potential energy savings;

(2) Potential social and private, including environmental or energy security, benefits;

(3) Applicable deadlines for rulemakings;

(4) Incremental DOE resources required to complete the rulemaking process;

(5) Other relevant regulatory actions affecting the products/equipment;

(6) Stakeholder recommendations;

(7) Evidence of energy efficiency gains in the market absent new or revised standards;

(8) Status of required changes to test procedures; and

(9) Other relevant factors.

matters relevant to DOE's consideration of the priority-setting process for all upcoming energy conservation standards and test procedure rules. Such comments and information will aid in the development of the rulemaking schedule that will next appear in DOE's Spring Regulatory Agenda.

Submitting comments via http://www.regulations.gov. The *http://www.regulations.gov* web page requires you to provide your name and contact information. Your contact information will be viewable to DOE Building Technologies staff only. Your contact information will not be publicly viewable except for your first and last names, organization name (if any), and submitter representative name (if any). If your comment is not processed properly because of technical difficulties, DOE will use this information to contact you. If DOE cannot read your comment due to technical difficulties and cannot contact you for clarification, DOE may not be able to consider your comment.

However, your contact information will be publicly viewable if you include it in the comment or in any documents attached to your comment. Any information that you do not want to be publicly viewable should not be included in your comment, nor in any document attached to your comment. Persons viewing comments will see only first and last names, organization names, correspondence containing comments, and any documents submitted with the comments.

Do not submit to *http://www.regulations.gov* information for which disclosure is restricted by statute, such as trade secrets and commercial or financial information (hereinafter referred to as Confidential Business Information (CBI)). Comments submitted through *http://www.regulations.gov* cannot be claimed as CBI. Comments received through the website will waive any CBI claims for the information submitted. For information on submitting CBI, see the Confidential Business Information section.

DOE processes submissions made through *http://www.regulations.gov* before posting. Normally, comments will be posted within a few days of being submitted. However, if large volumes of comments are being processed simultaneously, your comment may not be viewable for up to several weeks. Please keep the comment tracking number that *http://www.regulations.gov* provides after you have successfully uploaded your comment.

Submitting comments via email. Comments and documents submitted via email, also will be posted to *http://www.regulations.gov*. If you do not want your personal contact information to be publicly viewable, do not include it in your comment or any accompanying documents. Instead, provide your contact information in a cover letter. Include your first and last names, email address, telephone number, and optional mailing address. The cover letter will not be publicly viewable as long as it does not include any comments.

Include contact information each time you submit comments, data, documents, and other information to DOE. No telefacsimiles (faxes) will be accepted.

Comments, data, and other information submitted to DOE electronically should be provided in PDF (preferred), Microsoft Word or Excel, WordPerfect, or text (ASCII) file format. Provide documents that are not secured, written in English, and free of any defects or viruses. Documents should not contain special characters or any form of encryption and, if possible, they should carry the electronic signature of the author.

Campaign form letters. Please submit campaign form letters by the originating organization in batches of between 50 to 500 form letters per PDF or as one form letter with a list of supporters' names compiled into one or more PDFs. This reduces comment processing and posting time.

Confidential Business Information. Pursuant to 10 CFR 1004.11, any person submitting information that he or she believes to be confidential and exempt by law from public disclosure should submit via email, two well-marked copies: One copy of the document marked ''confidential'' including all the information believed to be confidential, and one copy of the document marked ''non-confidential'' with the information believed to be confidential deleted. Submit these documents via email. DOE will make its own determination about the confidential status of the information and treat it according to its determination.

It is DOE's policy that all comments may be included in the public docket, without change and as received, including any personal information provided in the comments (except information deemed to be exempt from public disclosure).

DOE considers public participation to be a very important part of the process for developing test procedures and energy conservation standards. Interactions with and between members of the public provide a balanced discussion of the issues and assist DOE in the process. Anyone who wishes to be added to the DOE mailing list to receive future notices and information about this process should contact Appliance and Equipment Standards Program staff at (202) 287–1445 or via email at *ApplianceStandardsQuestions@ee.doe.gov*.

Signing Authority

This document of the Department of Energy was signed on February 9, 2021, Kelly Speakes-Backman, Acting Assistant Secretary for Energy Efficiency and Renewable Energy, pursuant to delegated authority from the Acting Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE **Federal Register** Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on February 10, 2021.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2021–03058 Filed 2–18–21; 8:45 am]

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DEPARTMENT OF EDUCATION

34 CFR Chapter III

[Docket ID ED–2020–OSERS–0192]

Proposed Priority—Rehabilitation Short-Term Training-Client Assistance Program (CAP Training)

AGENCY: Office of Special Education and Rehabilitative Services (OSERS), Department of Education.

ACTION: Proposed priority.

SUMMARY: The Department of Education (Department) proposes a priority under the Rehabilitation Short-Term Training program, Assistance Listing Number 84.246K. We may use this priority for competitions in fiscal year (FY) 2021 and later years. We take this action to improve the capacity of Client Assistance Program (CAP) professionals to inform, assist, and advocate for State Vocational Rehabilitation (VR) Services program clients and applicants about expanded education, training, and

employment opportunities under the Rehabilitation Act of 1973, as amended by the Workforce Innovation and Opportunity Act (WIOA). The priority will provide enhanced training and technical assistance on CAP duties and responsibilities under section 112 of the Rehabilitation Act, VR service provision requirements in the Rehabilitation Act, expanded opportunities under WIOA, individual and systems advocacy competencies, and leadership, relationship-building, and outreach skills as well as CAP strategic planning and resources management capacity-building. Also, the priority will promote the use of flexible training delivery methods, including in-person and virtual activities, and state-of-the-art communication tools and platforms, including the latest distance learning and convening technologies.

DATE: We must receive your comments on or before March 22, 2021.

ADDRESSES: Submit your comments through the Federal eRulemaking portal or via postal mail, commercial delivery, or hand delivery. We will not accept comments submitted by fax or by email or those submitted after the comment period. To ensure that we do not receive duplicate copies, please submit your comments only once. In addition, please include the Docket ID at the top of your comments.

- *Federal eRulemaking Portal:* Go to *www.regulations.gov* to submit your comments electronically. Information on using *Regulations.gov*, including instructions for accessing agency documents, submitting comments, and viewing the docket, is available on the site under ''Help.''
- *Postal Mail, Commercial Delivery, or Hand Delivery:* If you mail or deliver your comments, address them to Felipe Lulli, U.S. Department of Education, 400 Maryland Avenue SW, Room 5101, Potomac Center Plaza, Washington, DC 20202–2800.

Privacy Note: The Department's policy is to make all comments received from members of the public available for public viewing in their entirety on the Federal eRulemaking Portal at *www.regulations.gov.* Therefore, commenters should be careful to include in their comments only information that they wish to make publicly available.

FOR FURTHER INFORMATION CONTACT: Felipe Lulli, U.S. Department of Education, 400 Maryland Avenue SW, Room 5101, Potomac Center Plaza, Washington, DC 20202–2800. Telephone: (202) 245–7425. Email: *84.246K@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: *Invitation to Comment:* We invite you to submit comments regarding this proposed priority. To ensure that your comments have maximum effect in developing the notice of final priority, we urge you to clearly identify the proposed priority and specific requirement that each comment addresses.

We invite you to assist us in complying with the specific requirements of Executive Orders 12866, 13563, and 13771 and their overall requirement of reducing regulatory burden that might result from the proposed priority. Please let us know of any ways we could reduce potential costs or increase potential benefits while preserving the effective and efficient administration of the program.

During and after the comment period, you may inspect all public comments about this proposed priority by accessing *Regulations.gov.* Due to the COVID–19 pandemic, the Department buildings are currently not open. However, upon reopening, you may also inspect the comments in person in Room 5051, 550 12th Street SW, Washington, DC, between the hours of 9:30 a.m. and 4:00 p.m., Eastern time, Monday through Friday of each week except Federal holidays.

Assistance to Individuals with Disabilities in Reviewing the Rulemaking Record: On request, we will provide an appropriate accommodation or auxiliary aid to an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record for this proposed priority. If you want to schedule an appointment for this type of accommodation or auxiliary aid, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

Purpose of Program: The Rehabilitation Short-Term Training program is designed to provide short-term training and technical instruction in areas of special significance to the vocational, medical, social, and psychological rehabilitation programs, supported employment programs, independent living services programs, and client assistance programs, including special seminars, institutes, workshops, and other short-term courses. Short-term training projects may be of regional or national scope.

Program Authority: 29 U.S.C. 772(a)(1).

Applicable Program Regulations: 34 CFR part 385 and 390.

Proposed Priority

This notice contains one proposed priority.

Background

The CAP is a formula program authorized by section 112 of the Rehabilitation Act. The purpose of the CAP is to inform and advise VR clients and applicants about all the benefits available under the Rehabilitation Act, including under sections 113 and 511 regarding pre-employment transition services and limitations on use of subminimum wages, respectively. Upon the client's or applicant's request, the CAP program will provide assistance and advocacy in pursuing legal, administrative, or other appropriate remedies to ensure the protection of the rights of such individuals under the Rehabilitation Act and to facilitate access to the services funded under the Rehabilitation Act through individual and systemic advocacy. The CAP program's assistance and advocacy services may be directly related to facilitating the employment of the individual. The CAP program also provides information on available services and benefits under title I of the Americans with Disabilities Act of 1990 as well as the Rehabilitation Act, especially with regard to individuals with disabilities who have traditionally been unserved or underserved by VR programs. According to the Annual Client Assistance Program Report (RSA–227), CAP offices responded to 28,709 requests for information and referral in FY 2019. They also provided direct services, including assistance and advocacy, to 4,359 individuals with disabilities that year.

The WIOA amendments to the Rehabilitation Act placed heightened emphasis on expanding quality employment and career advancement opportunities for individuals with disabilities, with a focus on competitive integrated employment as defined in the Rehabilitation Act. Consistent with WIOA's amendments to the Rehabilitation Act, the State VR program operates under the principle that individuals with disabilities, including those with significant and the most significant disabilities, are capable of quality employment outcomes when provided appropriate services, skills, and supports. WIOA places certain limitations on subminimum wage employment. WIOA also emphasizes pre-employment transition services for

students with disabilities, supported employment for individuals with the most significant disabilities, customized employment, and coordinated strategies such as career pathways and apprenticeships to help individuals with disabilities realize employment goals consistent with their strengths, resources, priorities, concerns, abilities, capabilities, interests, and informed choice. At the same time, WIOA recognizes the need to reach traditionally unserved or underserved groups and individuals.

Many of the WIOA provisions and priorities are reflected in the Combined and Unified State Plans developed in coordination with State and local workforce development boards. Some States are also implementing innovative approaches, including rapid engagement and progressive employment, to help individuals with disabilities to pursue quality employment outcomes.

State VR agency personnel have experienced several challenges in implementing the WIOA expanded provisions. As of November 13, 2020, 25 of 78 VR agencies were unable to serve all eligible individuals due to a lack of financial and staff resources and have thus introduced orders of selection, closed one or more priority categories, and limited the provision of services to eligible individuals based on the significance of their disabilities. Five of these VR agencies have closed all priority categories, meaning that they are not providing services to new applicants for the VR program. VR agencies are implementing orders of selection for two main reasons, one being the inability to provide the non-Federal share required as match for the VR program, which prevents them from accessing all available Federal VR program funds, and the other being the requirement to reserve at least 15 percent of Federal VR program funds for providing pre-employment transition services to eligible and potentially eligible students with disabilities, which restricts the amount of VR program funds available to serve all other eligible individuals with disabilities. These trends may be impacting the nature, scope, and timeliness of the VR services as well as the number of eligible individuals served.

The CAP professionals play a vital role in helping VR clients and applicants to access the expanded opportunities under WIOA, even in the midst of the challenges the State VR agencies face, through individual information and advocacy services, systems change activities, and outreach to traditionally unserved or underserved populations. To fulfill their role effectively, CAP professionals must be knowledgeable about the enhanced opportunities, VR service-provision requirements, and CAP program's roles and responsibilities under the Rehabilitation Act. Also, CAP professionals must understand the specific needs of individuals with disabilities, the challenges State VR agencies face, and the roles of the State Rehabilitation Council, community rehabilitation programs, and workforce development partners in their States. Further, CAP professionals must possess effective individual and systems advocacy, leadership, relationship-building, and outreach skills. Finally, the CAP programs require strong strategic planning and resource management capabilities.

The purpose of this priority is to provide high-quality and relevant training and technical assistance to increase CAP professionals' knowledge, skills, competencies, and capabilities in these critical areas.

The project must be awarded and operated in a manner consistent with the nondiscrimination requirements mandated by the U.S. Constitution and Federal civil rights laws.

Proposed Priority

Rehabilitation Short-Term Training—Client Assistance Program (CAP Training).

The Department proposes to establish this Rehabilitation Short-Term Training-Client Assistance Program (CAP Training) priority to provide CAP professionals the necessary knowledge, competencies, and skills to help VR clients and applicants access expanded education, training, and employment opportunities under WIOA, and to address obstacles or barriers that VR clients and applicants may encounter.

Under this priority, grantees must provide comprehensive and in-depth training and technical assistance activities that provide updated information about CAP program duties and responsibilities under the Rehabilitation Act; expanded VR service provisions in the Rehabilitation Act, including section 113 on pre-employment transition services and section 511 regarding limitations on subminimum wages; and on other education, training, and employment opportunities under WIOA, including career pathways, apprenticeships, and customized employment. In providing the training and technical assistance, grantees must consider the challenges that State VR agencies face in implementing WIOA's expanded provisions and opportunities and the roles of the State Rehabilitation Council, community rehabilitation programs, workforce development partners, and other stakeholders, as reflected in the Unified or Combined State Plans. The training and technical assistance must enhance CAP professionals' individual and systems advocacy competencies and their leadership, relationship-building, and outreach skills. In addition, the training and technical assistance must strengthen the institutional effectiveness of the CAP programs in the individual States through strategic planning and resource management capacity-building activities.

Under this priority, the Secretary will fund only applications that meet the project requirements outlined below. Applicants must describe major implementation activities, timelines, and milestones for each of the following project requirements:

(1) Training and technical assistance to increase CAP professionals' knowledge, skills, and competencies in the four broad subject areas and related topics, including, but not limited to:

(a) Rehabilitation Act in the context of WIOA

(i) CAP program duties and responsibilities under section 112(a) of the Rehabilitation Act;

(ii) VR service provision requirements in the Rehabilitation Act and related regulations, policy guidance, and legal decisions, including those regarding section 113 on pre-employment transition services and section 511 regarding limitations on subminimum wages;

(iii) Expanded training, education, and employment opportunities under WIOA, including but not limited to pre-employment transition services, work-based learning, apprenticeships, customized employment, career pathways, and focus on postsecondary credential attainment, including advanced degrees;

(iv) Challenges and successes that VR agencies experience in making the opportunities under WIOA available to individuals with disabilities in their States;

(v) Obstacles that individuals with disabilities experience in accessing VR services, including the new and expanded services available through the VR program as a result of WIOA, particularly individuals with the most significant disabilities, students and youth with disabilities, members of traditionally unserved or underserved groups, and individuals in economically disadvantaged communities; and

(vi) Key stakeholder roles, including State Rehabilitation Councils (SRC),

community rehabilitation programs, and workforce development boards, as reflected in the Unified or Combined State Plans.

(b) Discrete skills related to CAP duties and responsibilities

(i) Individual advocacy;

(ii) Systems advocacy;

(iii) Alternate dispute resolution; and

(iv) Leadership, relationship building, and outreach.

(c) Strategic planning

(i) Assessments of VR program challenges, needs, and opportunities in the State, including the State VR agency's own innovative approaches as well as the expanded provisions under WIOA. Strategic assessments include targeted reviews of the RSA–227, Unified or Combined State Plans, RSA monitoring reports, and feedback from VR clients, applicants, and other key stakeholders;

(ii) Development of the individual CAP programs' strategic goals and action plans (including their particular training or technical assistance needs, based on their identified State VR program challenges, needs, and opportunities; and

(iii) Strategic outreach and engagement with State VR agencies, the SRC, and workforce development partners, among others.

(d) Resource management

(i) Budgeting and financial oversight practices in support of strategic goals and objectives, consistent with Generally Accepted Accounting Practices; and

(ii) Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, at 2 CFR part 200, pertinent to CAP and VR program operations.

(2) Comprehensive plan for the delivery of training and technical assistance on the required subject areas and topics. The plan must describe the following:

(a) Subject areas and topics, specifically, how they will be prioritized and made available in the initial year and subsequent years of the project;

(b) Training activities, consisting of both established training modules and ad hoc training responsive to emerging circumstances or trends;

(c) Technical assistance, consisting of individualized information on identified subject areas and topics, as well as consultation on options for applying existing law, regulations, and RSA-issued guidance to specific factual circumstances that arise in the course of CAP professionals' individual or systems advocacy efforts;

(d) Training and technical assistance curricula, materials, and tools, which may include resources developed by RSA VR technical assistance centers and demonstration projects, available at the National Clearinghouse of Rehabilitation Training Materials;

(e) Information delivery methods, including in-person and virtual activities, communities of practice, social media, and searchable databases; and

(f) State-of-the-art communication tools and platforms, including an interactive project website, distance learning and convening technologies, and searchable databases.

The training and technical assistance plan must be based on a comprehensive review of CAP professionals' needs with respect to the required subject areas and topics outlined above. The comprehensive needs assessment may comprise reviews of the RSA–227, Unified or Combined State Plans, and RSA State monitoring reports as well as questionnaires, surveys, and interviews with CAP professionals and key stakeholders, among others.

(3) Quality control processes to ensure that training and technical assistance activities and materials are updated to reflect the statutory and regulatory changes in the Rehabilitation Act as amended by title IV of WIOA, the RSA policy guidance updates, and future reauthorizations of the Rehabilitation Act;

(4) Coordination with and leveraging the resources of RSA's vocational rehabilitation technical assistance centers and other Federal or non-Federal programs, including the recently funded RSA technical assistance centers on Quality Employment and Quality Management and the National Technical Assistance Center on Transition, in the development of CAP Training project activities, curriculum, materials, and tools;

(5) Coordination with the entity providing training and technical assistance to the Protection and Advocacy of Individual Rights program, consistent with section 509 of the Rehabilitation Act; and

(6) Project evaluation based on performance measures to be established in the notice inviting applications, consistent with the Government Performance and Results Act.

CAP Training performance will be assessed based on the following considerations:

(a) Quality, relevance, and usefulness of the training and technical assistance;

(b) Trends in pertinent CAP program services, including individual and systems advocacy; and

(c) Relationship between the observed CAP services trends and the training and technical assistance provided under this priority.

The performance assessment will be based on a variety of quantitative and qualitative data sources, including, but not limited to:

(a) RSA–227;

(b) Pre- and post-training assessments;

(c) Questionnaires, surveys, and focus groups;

(d) Success stories; and

(e) Peer reviews.

The foregoing performance considerations and data sources must be incorporated in a comprehensive evaluation plan. The evaluation plan will include a logic model that outlines the proposed project activities, outputs, outcomes, baselines, and targets. The plan also will describe how the evaluation results will be used to promote continuous program improvement throughout the grant's period of performance.

Types of Priorities

When inviting applications for a competition using one or more priorities, we designate the type of each priority as absolute, competitive preference, or invitational through a notice in the **Federal Register**. The effect of each type of priority follows:

Absolute priority: Under an absolute priority, we consider only applications that meet the priority (34 CFR 75.105(c)(3)).

Competitive preference priority: Under a competitive preference priority, we give competitive preference to an application by (1) awarding additional points, depending on the extent to which the application meets the priority (34 CFR 75.105(c)(2)(a)); or (2) selecting an application that meets the priority over an application of comparable merit that does not meet the priority (34 CFR 75.105(c)(2)(ii)).

Invitational priority: Under an invitational priority, we are particularly interested in applications that meet the priority. However, we do not give an application that meets the priority a preference over other applications (34 CFR 75.105(c)(1)).

Final Priority: We will announce the final priority in a notice in the **Federal Register**. We will determine the final priority after considering responses to the proposed priority and other information available to the Department. This document does not preclude us from proposing additional priorities, requirements, definitions, or selection criteria, subject to meeting applicable rulemaking requirements.

Note: This notice does *not* solicit applications. In any year in which we choose to use this priority, we invite applications through a notice in the **Federal Register**.

Executive Orders 12866, 13563, and 13771

Regulatory Impact Analysis

Under Executive Order 12866, the Office of Management and Budget (OMB) determines whether this regulatory action is ''significant'' and, therefore, subject to the requirements of the Executive order and subject to review by OMB. Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action likely to result in a rule that may—

(1) Have an annual effect on the economy of $100 million or more, or adversely affect a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities in a material way (also referred to as an ''economically significant'' rule);

(2) Create serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles stated in the Executive order.

OMB has determined that this proposed regulatory action is not a significant regulatory action subject to review by OMB under section 3(f) of Executive Order 12866.

Under Executive Order 13771, for each new rule that the Department proposes for notice and comment or otherwise promulgates that is a significant regulatory action under Executive Order 12866 and that imposes total costs greater than zero, it must identify two deregulatory actions. For FY 2021, any new incremental costs associated with a new rule must be fully offset by the elimination of existing costs through deregulatory actions. However, Executive Order 13771 does not apply to ''transfer rules'' that cause only income transfers between taxpayers and program beneficiaries, such as those regarding discretionary grant programs. Because the proposed priority would be used in connection with a discretionary grant program, Executive Order 13771 does not apply.

We have also reviewed this proposed regulatory action under Executive Order 13563, which supplements and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866. To the extent permitted by law, Executive Order 13563 requires that an agency—

(1) Propose or adopt regulations only upon a reasoned determination that their benefits justify their costs (recognizing that some benefits and costs are difficult to quantify);

(2) Tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives and taking into account—among other things and to the extent practicable—the costs of cumulative regulations;

(3) In choosing among alternative regulatory approaches, select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity);

(4) To the extent feasible, specify performance objectives, rather than the behavior or manner of compliance a regulated entity must adopt; and

(5) Identify and assess available alternatives to direct regulation, including economic incentives—such as user fees or marketable permits—to encourage the desired behavior or provide information that enables the public to make choices.

Executive Order 13563 also requires an agency ''to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible.'' The OMB Office of Information and Regulatory Affairs has emphasized that these techniques may include ''identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes.''

We are issuing the proposed priority only on a reasoned determination that their benefits justify their costs. In choosing among alternative regulatory approaches, we selected those approaches that maximize net benefits. Based on the analysis that follows, the Department believes that this regulatory action is consistent with the principles in Executive Order 13563.

We have also determined that this regulatory action does not unduly interfere with State, local, and Tribal governments in the exercise of their governmental functions.

In accordance with these Executive orders, the Department has assessed the potential costs and benefits, both quantitative and qualitative, of this regulatory action. The potential costs are those resulting from statutory requirements and those we have determined as necessary for administering the Department's programs and activities. The costs would include the time and effort in responding to the priority for entities that choose to respond.

In addition, we have considered the potential benefits of this regulatory action and have noted these benefits in the Background section of this document. The benefits include receiving comments regarding the best way to provide training to CAP professionals.

Clarity of the Regulations

Executive Order 12866 and the Presidential memorandum ''Plain Language in Government Writing'' require each agency to write regulations that are easy to understand. The Secretary invites comments on how to make these proposed priorities easier to understand, including answers to questions such as the following:

- Are the requirements in the proposed regulations clearly stated?
- Do the proposed regulations contain technical terms or other wording that interferes with their clarity?
- Does the format of the proposed regulations (grouping and order of sections, use of headings, paragraphing, etc.) aid or reduce their clarity?
- Would the proposed regulations be easier to understand if we divided them into more (but shorter) sections?
- Could the description of the proposed regulations in the **SUPPLEMENTARY INFORMATION** section of the preamble be more helpful in making the proposed regulations easier to understand? If so, how?
- What else could we do to make the proposed regulations easier to understand?

To send any comments that concern how the Department could make these proposed regulations easier to understand, see the instructions in the **ADDRESSES** section.

Regulatory Flexibility Act Certification: The Secretary certifies that this proposed regulatory action would not have a significant economic impact on a substantial number of small entities. The U.S. Small Business Administration Size Standards define proprietary institutions as small businesses if they are independently owned and operated, are not dominant in their field of operation, and have total annual revenue below $7,000,000. Nonprofit institutions are defined as small entities if they are independently owned and operated and not dominant in their field of operation. Public institutions are defined as small organizations if they are operated by a

government overseeing a population below 50,000.

The small entities that this proposed regulatory action would affect are public or private nonprofit agencies and organizations, including Indian Tribes and institutions of higher education, that may apply. We believe that the costs imposed on an applicant by the proposed priority would be limited to paperwork burden related to preparing an application and that the benefits of this proposed priority would outweigh any costs incurred by the applicant. There are very few entities who could provide the type of training and technical assistance required under the proposed priority. For these reasons, the proposed priority would not impose a burden on a significant number of small entities.

Paperwork Reduction Act of 1995: The proposed priority contains information collection requirements that are approved by OMB under OMB control number 1820–0018.

Intergovernmental Review: This program is subject to Executive Order 12372 and the regulations in 34 CFR part 385. One of the objectives of the Executive order is to foster an intergovernmental partnership and a strengthened federalism. The Executive order relies on processes developed by State and local governments for coordination and review of proposed Federal financial assistance.

This document provides early notification of our specific plans and actions for this program.

Assessment of Educational Impact

In accordance with section 411 of the General Education Provisions Act, 20 U.S.C. 1221e–4, the Secretary particularly requests comments on whether these proposed regulations would require transmission of information that any other agency or authority of the United States gathers or makes available.

Accessible Format: On request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document and a copy of the application package in an accessible format. The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF) or text format (txt), a thumb drive, an MP3 file, braille, large print, audiotape, or compact disc, or other accessible format.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at *www.govinfo.gov.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF, you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

David Cantrell,

Deputy Commissioner, Office of Special Education Programs. Delegated the authority to perform the functions and duties of the Assistant Secretary for the Office of Special Education and Rehabilitative Services.

[FR Doc. 2021–03422 Filed 2–18–21; 8:45 am]

BILLING CODE 4000–01–P

POSTAL SERVICE

39 CFR Part 113

Treatment of E-Cigarettes in the Mail

AGENCY: Postal Service™.

ACTION: Proposed revision, invitation for comment.

SUMMARY: The Postal Service proposes to revise Publication 52, *Hazardous, Restricted, and Perishable Mail,* to incorporate new statutory restrictions on the mailing of electronic nicotine delivery systems. Such items would be subject to the same prohibition as cigarettes and smokeless tobacco, subject to many of the same exceptions.

DATE: We must receive your comments on or before March 22, 2021.

ADDRESSES: Mail or deliver written comments to the Manager, Product Classification, U.S. Postal Service, 475 L'Enfant Plaza SW, Room 4446, Washington, DC 20260–3436. Email comments, containing the name and address of the Commenter, may be sent to: *PCFederalRegister@usps.gov,* with a subject line of ''E-Cigarette Restrictions.'' Faxed comments are not accepted. All submitted comments and attachments are part of the public record and subject to disclosure. Do not enclose any material in your comments that you consider to be confidential or inappropriate for public disclosure.

You may inspect and photocopy all written comments, by appointment only, at USPS® Headquarters Library, 475 L'Enfant Plaza SW, 11th Floor North, Washington, DC 20260. These records are available for review Monday through Friday, 9 a.m. and 4 p.m. by calling 202–268–2906.

FOR FURTHER INFORMATION CONTACT: Dale E. Kennedy, 202–268–6592.

SUPPLEMENTARY INFORMATION: The Postal Service is proposing to amend Publication 52 with the provisions described below and, once adopted, will incorporate the revised Publication 52 by reference into 39 CFR part 113. You may view the text of the proposed edits to Publication 52 at *https://pe.usps.com.*

On December 27, 2020, the Preventing Online Sales of E-Cigarettes to Children Act (''Act''), Public Law 116–160, div. FF, title VI (2020), was enacted. Effective 90 days after enactment, Section 602 of the Act adds ''electronic nicotine delivery systems'' (ENDS) to the definition of ''cigarettes'' subject to regulation under the Jenkins Act, 15 U.S.C. 375 *et seq.* Consequently, ENDS will also become subject to the mailability restrictions and exceptions in 18 U.S.C. 1716E, which rely on the Jenkins Act definition of ''cigarettes.'' 18 U.S.C. 1716E(a)(1). Section 603 of the Act requires the Postal Service to promulgate implementing regulations not later than 120 days after enactment and provides that the prohibition on mailing ENDS will apply immediately ''on and after'' the date of the final rule.

Current Mailing Restrictions on Cigarettes and Smokeless Tobacco

Currently, 18 U.S.C. 1716E bans the mailing of cigarettes and smokeless tobacco except in narrowly defined circumstances, as described below.

- Noncontiguous States: Intrastate shipments within Alaska or Hawaii;
- Business/Regulatory Purposes: Shipments transmitted between verified and authorized tobacco industry businesses for business purposes, or between such businesses and federal or state agencies for regulatory purposes;
- Certain Individuals: Lightweight shipments mailed between adult individuals, limited to 10 per 30-day period;
- Consumer Testing: Limited shipments of cigarettes sent by verified and authorized manufacturers to adult smokers for consumer testing purposes; and
- Public Health: Limited shipments by federal agencies for public health purposes under similar rules applied to manufacturers conducting consumer testing.

18 U.S.C. 1716E(b)(2)–(6). Outside of these exceptions, the Postal Service cannot accept or transmit any package that it knows, or has reasonable cause to believe, contains nonmailable smokeless tobacco or cigarettes. *Id.* at (a)(1).

The Postal Service has determined that the exceptions above cannot feasibly be applied to inbound or outbound international mail, mail to or from the Freely Associated States, or mail presented at overseas Army Post Office (APO), Fleet Post Office (FPO), or Diplomatic Post Office (DPO) locations and destined to addresses in the United States. Publication 52, *Hazardous, Restricted and Perishable Mail* 472.2. As such, all cigarettes and smokeless tobacco in such mail are nonmailable, without exception.

Nonmailable cigarettes and smokeless tobacco deposited in the mail are subject to seizure and forfeiture. 18 U.S.C. 1716E(c). Senders of nonmailable cigarettes or smokeless tobacco are subject to criminal fines, imprisonment, and civil penalties, in addition to enforcement under other federal, state, and local laws. *Id.* at (d), (e), (h).

Definition of ENDS

The proposed rule uses the definition of ENDS contained in 15 U.S.C. 375(7), as amended by section 602(a)(1)(C) of the Act. Under this definition, an ENDS is any electronic device that, through an aerosolized solution, delivers nicotine, flavor, or any other substance to the user inhaling from the device. Examples include e-cigarettes, e-hookahs, e-cigars, vape pens, advanced refillable personal vaporizers, and electronic pipes. Provisions relating to ENDS also extend to any component, liquid, part, or accessory of an ENDS, regardless of whether sold separately from the device. Despite the name, an item can qualify as an ENDS without regard to whether it contains or is intended to be used to deliver nicotine; liquids that do not actually contain nicotine can still qualify as ENDS, as can devices, parts, components, and accessories capable of or intended for use with non-nicotine-containing liquids.

Excluded from the statutory definition are products approved by the Food and Drug Administration for sale as tobacco cessation products or for other therapeutic purposes and marketed and sold solely for such purposes. Accordingly, the proposed rule excludes such items from the definition of ENDS. Approved tobacco cessation and therapeutic products thus remain mailable in domestic mail, international mail, mail treated as domestic, and mail from overseas APO/FPO/DPO addresses to United States destination addresses.

Extension of Existing Provisions to ENDS in General; Terminology

In general, the proposed rule would extend the current treatment of cigarettes and smokeless tobacco to ENDS. This is consistent with how the Act formally includes ENDS within the definition of ''cigarettes'' in 15 U.S.C. 375(2)(A)(ii), which is used in 18 U.S.C. 1716E. Consequently, all existing restrictions on and exceptions for ''cigarettes'' apply to ENDS, except where context indicates otherwise.

It is not intuitive that ENDS should be understood as a form of ''cigarette.'' In general parlance, ''cigarettes'' most commonly consist of ground leaf tobacco wrapped in paper, which deliver nicotine to a smoker when solid matter is combusted, and the resulting smoke inhaled. ENDS are electronic devices and their components and fillers, which deliver either nicotine or non-nicotine substances to a user when a liquid is vaporized, and the resulting vapor inhaled. To facilitate understanding by readers not versed in the statute, we propose to treat ENDS as a standalone category, albeit one generally subject to the same restrictions and exceptions as cigarettes, consistent with the statute.

We have considered two ways in which to express this generally equivalent treatment. First, cigarettes, ENDS, and smokeless tobacco could be listed serially in every applicable instance; however, this option appears to unduly clutter the rules' text. Second, we could employ a shorthand term to encompass all three types of items. Indeed, the statute itself appears to take this approach. Although the term is not defined in either 18 U.S.C. 1716E or 15 U.S.C. 375, ''tobacco product'' is used in the title of 18 U.S.C. 1716E and throughout its text as apparent shorthand for the products made nonmailable by that section (*i.e.,* cigarettes and smokeless tobacco). Because ENDS now fall within that scope through their inclusion in the pertinent statutory definition of ''cigarettes,'' it seems reasonable to use the umbrella term ''tobacco product'' to refer to ENDS as well as cigarettes and smokeless tobacco. Hence, we propose to add a definition of ''tobacco products'' and to replace numerous instances of ''cigarettes and smokeless tobacco'' with ''tobacco products.''

This proposed solution admittedly shares some of the same conceptual difficulty discussed above in relation to cigarettes: Technically speaking, ENDS are not products derived from tobacco. In this instance, however, the general conceptual alignment, together with the benefits of a shorthand term and consistency with the statute's use of the term, appear to weigh in favor of ''tobacco product'' in reference to all products nonmailable under 18 U.S.C. 1716E. Commenters are invited to propose alternative terminological approaches and to discuss the relative merits of their proposals.

Standards for Determining Nonmailability

Current law requires the Postal Service to treat shipments of cigarettes and smokeless tobacco as nonmailable not only where Postal Service personnel have actual knowledge that a shipment contains such items, but also where Postal Service personnel have ''reasonable cause to believe'' that such contents are present. 18 U.S.C. 1716E(a)(1). ''Reasonable cause'' exists where a party is on the U.S. Attorney General's List of Unregistered or Noncompliant Delivery Sellers, and where public statements or advertisements indicate an intent to mail nonmailable cigarettes or smokeless tobacco for payment. *Id.* at (a)(2). The statute's use of ''includes'' before these enumerations of ''reasonable cause'' plainly indicates that the list is illustrative, rather than exhaustive, but it is silent on what else constitutes ''reasonable cause.'' Beyond those enumerated indicia of suspicion, other circumstances pertaining to a mailpiece may give rise to a reasonable suspicion that a package contains nonmailable cigarettes, smokeless tobacco, or ENDS. Where Postal Service personnel observe such circumstances and determine that reasonable cause exists, they may treat a package as nonmailable. The proposed rule would make this explicit.

In the specific context of ENDS, the new statutory definition conditions mailability on factors that are extrinsic to the physical item: Namely, whether a product is FDA-approved for therapeutic or tobacco-cessation use, and whether it is marketed and sold exclusively for such purposes. These circumstances are known or knowable by a mailer, but they are not necessarily apparent to Postal Service personnel reviewing a package. If the possessor of an FDA-approved and exclusively marketed therapeutic or tobacco-cessation product wishes to mail it, then that person has the unique means and incentive to provide adequate information with the package so that Postal Service personnel can identify the otherwise nonmailable item as, in fact, mailable. If a mailer does not do so, then the Postal Service has no basis to disbelieve indicia indicating the presence of a nonmailable ENDS.

In expecting the mailer to supply such information, the Postal Service must be able to verify that the mailer is acting in good faith and not illegitimately treating the therapeutic/tobacco-cessation

exclusion as an opportunity to evade the general mailing ban. If the mailer's claim to the exclusion is not appropriately credible or verifiable, then that claim may not be sufficient to deprive the Postal Service of reasonable cause to believe that the item is a nonmailable ENDS. Therefore, the proposed rule would authorize Postal Service personnel, upon reasonable cause to believe that a package contains cigarettes, smokeless tobacco, or ENDS, to treat the package as nonmailable unless the customer has affirmatively, credibly, and verifiably indicated that the relevant contents are, in fact, mailable.

Commenters are invited to offer their views on this proposed standard for reasonable cause in connection with ENDS-type items (or any other tobacco products). To the extent that commenters might propose alternative standards, commenters are advised to account specifically for the need to prevent abuse of the narrow exclusion of therapeutic and tobacco-cessation products; the asymmetry between mailers' and the Postal Service's access to information about the FDA-approval status and marketing of particular products; the Postal Service's limited resources; and its limited legal authority to open mailpieces that are sent in sealed mail classes without a warrant. 39 U.S.C. 404(c); 39 CFR 233.3(c)(3)–(4), (g)(1)–(2).

Applicability of Exceptions

The existing Noncontiguous States, Business/Regulatory Purposes, and Certain Individuals exceptions appear to be articulated in terms that can apply to ENDS as well as to cigarettes and smokeless tobacco. As such, the proposed use of the umbrella term ''tobacco products'' in the rules for each exception would automatically apply all such existing rules to ENDS. Commenters are nonetheless invited to identify any potential anomalies or other problems that this approach might create and to recommend solutions for such problems.

The Consumer Testing and Public Health exceptions apply only to ''cigarettes,'' and not to smokeless tobacco. 18 U.S.C. 1716E(b)(5)–(6). As noted earlier, the Act technically includes ENDS within the relevant definition of ''cigarettes.'' Without more, this would ordinarily indicate that these exceptions should apply to ENDS as well as other forms of ''cigarettes.'' However, 18 U.S.C. 1716E(b)(5)(A)(ii) or (C)(ii)(III) confine the exceptions to packages containing ''not more than 12 packs of cigarettes (240 cigarettes).'' Congress did not amend these provisions when it included ENDS, broadly defined, in the definition of ''cigarettes,'' and neither the text of the Act nor its legislative history contains any guidance as to how these conditions should apply to ENDS.

ENDS are not packaged in such standard quantities as traditional cigarettes. ENDS rely on devices that can be used in an open-ended fashion, with potentially limitless quantities of liquid filled cartridges, whereas traditional cigarettes are self-contained, single-use items. Moreover, ENDS filler liquids can contain varying quantities of nicotine, or even no nicotine, whereas cigarettes uniformly contain nicotine. As such, it does not appear possible even to devise an administrable standard of equivalence that would allow ''12 packs of cigarettes (240 cigarettes)'' to be translated into some quantity of ENDS filler liquid, let alone ENDS products other than filler liquid.

Given the Act's broad definition of ENDS and the material differences between ENDS products and the types of products originally encompassed by the Consumer Testing and Public Health exceptions, it appears reasonable to construe the lack of accommodation for ENDS in the relevant statutory text to render those exceptions inapplicable to ENDS. To the extent that commenters believe that the Consumer Testing and Public Health exceptions should apply to ENDS, commenters are invited to recommend alternative standards consistent with Congress's apparent intent to limit the quantity of items mailed in packages under the exceptions. Commenters should explain in detail how any proposed alternative quantity limits are analogous to or otherwise consistent with those in 18 U.S.C. 1716E(b)(5)(A)(ii) or (C)(ii)(III), or why such consistency is not necessary. Commenters are also invited to furnish any relevant documentation or supporting information that may aid the Postal Service in evaluating their recommendations.

Effective Date of Eventual Final Rule

Particularities here merit a brief discussion of the timing of the eventual final rule, in the interest of providing stakeholders with advance information. Section 603(a) of the Act requires the Postal Service ''promulgate regulations to clarify the applicability of the prohibition on mailing of cigarettes'' to ENDS not later than 120 days after enactment (*i.e.,* April 26, 2021). Section 603(b) provides that the prohibition will apply to mailings of ENDS ''on and after'' the publication date of the final rule. In specifying this immediate effective date, Congress expressly abrogated the standard 30-day notice period for a final rule under the Administrative Procedure Act (APA), which would otherwise apply to rulemakings concerning the mailability statute here. 5 U.S.C. 553(d), 559; 39 U.S.C. 3001(m). To the extent that this rulemaking concerns not only the mailing prohibition referenced in the Act, but also the application of exemptions from that prohibition, the APA permits those aspects of the eventual final rule likewise to take effect with less than 30 days' notice (*e.g.,* immediately upon publication). 5 U.S.C. 553(d)(1).

Joshua J. Hofer,

Attorney, Ethics and Legal Compliance.

[FR Doc. 2021–03393 Filed 2–17–21; 11:15 am]

BILLING CODE 7710–12–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R10–OAR–2019–0599, FRL–10019–38–Region 10]

Air Plan Approval; OR; Smoke Management Revision

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: Environmental Protection Agency (EPA) is proposing to approve Oregon State Implementation Plan (SIP) revisions submitted on November 3, 2014 and September 27, 2019. The submitted revisions incorporate by reference the most recent updates to Oregon's Smoke Management Plan. EPA is acting only on the most recent version of such regulations as the previous versions are no longer in effect as a matter of state law. EPA is also making technical corrections related to previous approvals of components of Oregon's SIP. EPA is proposing to determine that the changes are consistent with Clean Air Act requirements.

DATES: Comments must be received on or before March 22, 2021.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R10–OAR–2019–0599, at *https://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *https://www.regulations.gov.* EPA may publish any comment received to its public docket. Do not electronically submit any information you consider to be Confidential Business Information (CBI) or other information the disclosure of

which is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Randall Ruddick, EPA Region 10, 1200 Sixth Avenue, Suite 155, Seattle, WA 98101, at (206) 553–1999, or *ruddick.randall@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, wherever ''we,'' ''us,'' or ''our'' is used, it means EPA.

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I. Background

Each state has a State Implementation Plan (SIP) containing the control measures and strategies used to attain and maintain the national ambient air quality standards (NAAQS) established by the Environmental Protection Agency (EPA) for the criteria pollutants (carbon monoxide, lead, nitrogen dioxide, ozone, particulate matter, sulfur dioxide). The SIP contains such elements as air pollution control regulations, emission inventories, attainment demonstrations, and enforcement mechanisms. Oregon, and some other states, have adopted Smoke Management Plan SIPs to reduce emissions that contribute to visibility impairment. Wildfire has had a serious impact on Oregon during the past decade with many large-scale wildfires impacting the summer air quality in Oregon. The state anticipates that the Oregon Department of Forestry (ODF) will increase the use of prescribed fire to minimize the impacts of wildfire on air quality in response to this trend. Through the SMP, Oregon carefully manages prescribed fires to minimize smoke impacts to populated areas while maximizing the use of prescribed fire as a forest management tool.

EPA first approved Oregon's Smoke Management Plan and associated rules into the SIP in 1988 and has approved numerous revisions to the Plan over time.[1] Oregon requested additional revisions to smoke management rules contained in OAR Chapter 629–048, and ODF Directive 1–4–1–601 in a SIP submittal dated October 31, 2014 (received November 3, 2014, hereafter ''2014 Submittal''). Before EPA took action on the 2014 Submittal, Oregon began additional rulemaking to revise portions of its smoke management rules. Oregon submitted those additional revisions to OAR 629–048 for SIP approval on September 24, 2019 (hereafter ''2019 Submittal''). The 2019 Submittal includes revisions to regulations in Oregon's 2014 Submittal on which the EPA has not yet taken action. In this action, EPA is proposing to approve only the most recent submitted version of such regulations because the previous versions of the regulations included in the 2014 Submittal are no longer in effect as a matter of state law.

II. Oregon's Smoke Management Program

The ODF oversees prescribed forest burning in Oregon forest lands to decrease forest fuels and debris that pose increased fire risk, restore forest health and reduce the potential for major wildfires. ORS 477.013 directs ODF to develop and implement a Smoke Management Plan for prescribed forestry burning. To carry out this directive, ODF developed a Smoke Management Plan, which currently consists of rules under OAR 629–048 (previously under OAR 629–043) and the Operational Guidance for the Oregon Smoke Management Program in Directive 1–4–1–601. Oregon's Smoke Management Plan applies to prescribed burning on federal, state and private forestland. The objectives of the Oregon Smoke Management Plan (629–048–0010(4)) are to:

(a) Minimize smoke emissions resulting from prescribed burning as described by ORS 477.552;
(b) Provide maximum opportunity for essential forestland burning;
(c) Protect public health by avoiding smoke intrusions;
(d) Coordinate with other state smoke management programs;
(e) Comply with state and federal air quality and visibility requirements; and
(f) Promote the further development of techniques to minimize or reduce emissions by encouraging cost-effective utilization of forestland biomass, alternatives to burning and emission reduction techniques.

A. 2014 Submittal Summary

As discussed above, in 2014 Oregon revised its Smoke Management Plan and submitted it to EPA for approval into the SIP. Among the 2014 revisions, OAR 629–048–0130, Visibility Objectives, was strengthened by extending applicability to the full calendar year, as it was previously only applicable from July 1 to September 15. OAR 629–048–0130 is the only provision in the 2014 Submittal that remains in effect. All other portions of OAR 629–048 submitted in 2014 were further revised and included in the state's subsequent 2019 Submittal. Since the remainder of the 2014 Submittal is no longer in effect as a matter of state law, EPA is not proposing to take action on any other component of Oregon's 2014 Submittal.

B. 2019 Submittal Summary

In the 2019 Submittal, Oregon's process for approving prescribed fires focuses heavily on forecasting weather conditions and their effects on smoke dispersal with new NAAQS-related considerations. Oregon's previous approach included making single decisions for large tracts (approximately 150,000 contiguous acres, roughly the size of a ranger district) even though these large tracts can contain multiple airsheds and vastly different smoke dispersion conditions. The approach in the 2019 Submittal is more protective because ODF tailors burn decisions based on air quality and meteorological conditions within airsheds allowing for more accurate forecasts of smoke dispersion overall.

Oregon's prescribed fires and resulting smoke are managed under the 2019 Submittal with no burning allowed within 35 miles of a smoke sensitive receptor area[2] (SSRA), if smoke or

[1] On November 22, 1988, (53 FR 47188) EPA approved the Oregon Smoke Management Plan at Oregon Administrative Rule (OAR) Chapter 629, Division 43–043, and the Oregon Department of Forestry (ODF) ''Operational Guidance for the Oregon Smoke Management Program'' (Directive 1–4–1–601), into the Oregon SIP. On November 1, 2001, (66 FR 55105) EPA approved revisions to the Smoke Management Plan at OAR 629–43–043, and approved modifications to the ODF directive ''Operational Guidance for the Oregon Smoke Management Program'' into the Oregon SIP. Oregon requested EPA approve further changes to the Smoke Management Rule in a December 20, 2010, SIP submittal. In the 2010 submittal, OAR 629–048 (''Smoke Management'') replaced OAR 629–043 (''Smoke Management Plan''). EPA approved the 2010 submission on August 22, 2012 (77 FR 50611).

[2] SSRAs are defined in OAR 629–048–0005(26) as areas designated for the highest level of protection under the Smoke Management Plan. They are designated by the State Board of Forestry, in

Continued

down-slope drainage is likely to impact the SSRA due to forecasted wind direction. Forecasts are produced 6 days a week by ODF during the prescribed fire season and provide instructions for burners to prevent smoke impacts such as wind-direction related limitations on burning near SSRAs. Oregon's stated main goal of burn instructions is to move smoke up and away from ground levels, which is why individual burn plan instructions are customized for the burn area and are subject to changes based on forecast meteorology and field conditions. ODF also communicates directly with individual burn bosses about fires planned near SSRAs.

The 2019 Submittal's SIP revisions do not increase prescribed fire authorization levels. The 2019 Submittal also retains the five program elements in Oregon's currently approved SIP: (1) Taking actions to minimize smoke emissions, (2) burning only during appropriate weather conditions in order to avoid smoke impacts in urban areas, (3) encouraging use of alternatives to fire, including a comprehensive reference manual of alternatives to prescribed fire, (4) requiring permits be obtained prior to burning, and (5) including a burn authorization process that involves the issuance of smoke management forecasts and burning instructions.[3]

Oregon's 2019 Submittal includes additional controls and contingencies to protect against impacts on air quality from prescribed burning to nonattainment areas, maintenance areas, and areas at risk for becoming nonattainment. The 2019 Submittal provisions call for consideration of all particulate matter (PM) emissions in the air when planning for prescribed burns whereas the current federally approved requirements only consider the PM emissions attributable to prescribed fires. The 2019 Submittal adds a definition for a ''smoke incident'' and re-defines a ''smoke intrusion'' in order to establish sub-NAAQS intrusion thresholds and a burn approval target not to exceed approximately 75% of the 24-hour $PM_{2.5}$ NAAQS. The 2019 SIP Submittal also establishes a NAAQS protective criterion for burn approvals through use of a one-hour threshold even though there is no NAAQS one-hour limit. The one-hour intrusion level, set at 70 μg/m3, and a 24-hour intrusion level set at 26 μg/m3 level (OAR 629–048–0005 (27)) are designed to protect the NAAQS ($PM_{2.5}$). These criteria collectively enable ODF to dictate necessary modifications to burn volume or tonnage, or to withhold approval to burn considering weather conditions. Considered as a whole, the revisions contained in the 2019 Submittal strengthen the currently SIP-approved smoke management requirements.

Other notable modifications to the State's Smoke Management SIP include a process for developing community response plans and exemption requests, updates to Special Protection Zone[4] (SPZ) requirements that provide extra smoke management protection during winter months to communities with histories of exceeding federal air quality standards, and allowing the use of polyyethylene sheeting on burn piles to facilitate rapid ignition and combustion of burn piles.

III. Evaluation of Oregon's SIP Submittals

Approvals to revisions of SIPs are subject to the requirements of CAA section 110(l). Under CAA section 110(l), the Administrator may not approve a SIP revision ''if the revision would interfere with any applicable requirements concerning attainment and reasonable further progress, or any other applicable requirement of [the Act].''

The 2019 Submittal contains a 'weight of evidence' analysis[5] focused primarily on particulate matter impacts of the SMP revisions, as well as the implications of the revisions to the SMP on other NAAQS pollutants. The most relevant pollutants for this analysis are $PM_{2.5}$, PM_{10}, and ozone due to the nature of prescribed fire emissions and because EPA recently revised the $PM_{2.5}$ and Ozone NAAQS resulting in more stringent standards (78 FR 3085, January 15, 2013, and 80 FR 65292, October 26, 2015). EPA expects that attainment and maintenance related to criteria pollutants other than PM and ozone are unlikely to be impacted by the State's prescribed burning program. In addition, there are no nonattainment areas for ozone, carbon monoxide, sulfur dioxide, nitrogen dioxide, or lead in Oregon, nor has Oregon submitted any changes to regulatory limits in its smoke management SIP provisions for these pollutants.

Prescribed burning does not generally occur in Oregon in summer months, the season when ozone values are expected to be the highest due to increased temperature and solar radiation, because those months generally have unfavorable smoke dispersion conditions[6] and fire safety concerns. For these reasons, we are proposing to find that attainment and maintenance of the Ozone NAAQS are unlikely to be affected by the provision submitted for approval.

We are also proposing to find that attainment and maintenance of the PM NAAQS are unlikely to be affected by the provisions in the 2019 Submittal for reasons discussed below. There are currently three PM nonattainment areas in Oregon: Klamath Falls for 2006 $PM_{2.5}$ and Oakridge for the 2006 $PM_{2.5}$ and 1987 PM_{10} NAAQS. Determinations of Attainment by the Attainment Date and a Clean Data Determinations were published by EPA for these areas.[7] All areas in Oregon fall far below the PM_{10} standard of 150 μg/m^3 and are attaining the PM_{10} NAAQS. As discussed in the proposed findings of attainment for Klamath Falls (81 FR 36176, June 6, 2016) and Oakridge (82 FR 52686, November 14, 2017), residential wood combustion (RWC) in the cold, winter months during atmospheric inversions is the most significant source of $PM_{2.5}$ emissions responsible for elevated particulate matter in these areas. RWC emissions from certified and non-certified wood stoves, fireplaces, and pellet stoves are the most significant source of $PM_{2.5}$ emissions. In the Oakridge area, RWC accounts for about 86% of the base year direct $PM_{2.5}$ emissions and 84% of the projected emissions on worst case winter days. The primary control strategy for these areas is reducing emissions from residential wood combustion through a program to change-out uncertified woodstoves and an episodic woodstove curtailment program. The curtailment program restricts wood burning on ''Red'' advisory days. ''Red'' days are generally declared when $PM_{2.5}$ concentration is expected to be 25μg/m^3 (approx. 72% of the NAAQS) or higher.

Oregon established SPZs around Klamath Falls and Oakridge to provide additional protection from smoke in these areas. The Oregon Smoke Management Plan designates SPZs to

consultation with DEQ under OAR 629–048–0140, due to past history of smoke incidents, density of population or other special legal status related to visibility such as the Columbia River Gorge Scenic Area.

[3] EPA finalized the 2012 proposed approval on August 22, 2012, (77 FR 50611).

[4] Special Protection Zones have been established around certain communities requiring additional protection from particulates such as nonattainment or maintenance. Maps identifying these areas are identified in maps located within Department Directive 1–4–1–601, which is included in the docket. See OAR 629–048–0135 for details on requirements for these areas.

[5] A copy of the study is included in the Docket materials for this action. See: *Oregon SMP 110 Discussion.*

[6] See Section 2.6 of *Oregon SMP 110 Discussion,* which is included in the docket for this action.

[7] Klamath Falls 2006 $PM_{2.5}$, 81 FR 36176, 6/6/2016; and Oakridge 2006 $PM_{2.5}$, 85 FR 5537, 2/8/2018; Oakridge 1987 $p.m._{10}$, 66 FR 38947, 7/26/2001.

include extra restrictions regarding the use of prescribed fire during the problematic cold weather season when these areas can experience air stagnation events. Specifically, the Oregon SMP at OAR 629–048–0135 prohibits prescribed burning on ''Red'' woodstove days in the SPZ from December 1 through February 15 and provides additional cautionary requirements for prescribed burning in SPZs on non ''Red'' woodstove days from November 15 through February 15.

The 2014 and 2019 submittals establish more protective burn authorization levels than those in the previously SIP-approved SMP through the establishment of sub-NAAQS intrusion thresholds at OAR 629–048–0005(27).[8] For example, although there is no one hour NAAQS for $PM_{2.5}$, ODEQ has established a 1-hr threshold of 70 μg/m^3, further bound by the 24-hr threshold of 26 μg/m^3 (approximately 75% of the NAAQS) for determining whether or not a burn will be permitted. If $PM_{2.5}$ is at or above the sub-NAAQS thresholds, the 2019 Submittal provides that a prescribed burn would not be approved. Likewise, if the $PM_{2.5}$ is lower than the $PM_{2.5}$ thresholds, but additional smoke would likely cause an exceedance of the thresholds, the burn would also not be approved. The submitted revisions contain an exemption process from the 1-hr $PM_{2.5}$ intrusion threshold but the exemption imposes additional requirements and conditions (OAR 629–048–0180). The revised Smoke Management Plan also includes provisions for removing a community's exemption from the 1-hour intrusion threshold if an area has had three or more 24-hour threshold exceedances in five years.[9] The revised plan also includes a provision for revoking the exemption if the SSRA is within one exceedance of a NAAQS violation. Also, SSRAs that are in a non-attainment with the NAAQS will not be eligible for an exemption (see 629–048–0180 (3)(e) and (f)). There is not an exemption process for the 24-hr $PM_{2.5}$ threshold of 26 μg/m^3, therefore the revised Smoke Management Plan is more protective than the 24-hr $PM_{2.5}$ NAAQS.

The proposed revisions also include new best burn practices and emissions reduction techniques at OAR 629–048–0210 allowing the burning of polyethylene coverings used to keep piles of slash and thinning debris dry. To determine the efficacy of polyethylene coverings, ODF and EPA's Office of Research and Development contracted with a testing firm to conduct a study[10] of emissions from wet versus dry (covered and uncovered) piles. The study showed that wet piles burn slower and produce more emissions on a mass basis due to incomplete combustion than dry piles. In general, burning dry piles, even with polyethylene still in place, produces less criteria pollutant emissions than burning uncovered wet piles. Therefore, the revisions allowing for burning polyethylene to facilitate a reduction in emissions are more protective of the NAAQS.

Some additional changes in the 2014 and 2019 Submittals that EPA proposes to determine are either more protective than current SIP requirements or not expected to result in significant NAAQS impacts include expanding SPZ boundaries[11] to include the areas from which prescribed burning could cause an impact and changing SSRA[12] boundaries to better align with airshed boundaries. Prescribed burning is generally not expected to make significant contributions to the remaining criteria pollutants (Lead, CO, NO_X, and SO_2) due to a combination of factors. Monitored values in Oregon for these pollutants are well below the level of the NAAQS; wildfires are not known to be significant contributors of airborne Lead or SO_2, and finally, prescribed burning in any one geographic area will be infrequent enough that it is not expected to create elevated concentrations that violate the NAAQS for any of these criteria pollutants. For additional information regarding these pollutants see *Oregon SMP 110 Discussion,* which is included in the docket materials for this action.

Oregon's Smoke Management Plan revisions include OAR 629–048–0130 Visibility Objectives, which clearly state that it is the intent under the Smoke Management Plan to comply with Regional Haze requirements as identified in the Oregon Regional Haze Plan. The revised Smoke Management Plan also enhances the Regional Haze Plan by incorporating practices to minimize visibility impacts to the Kalmiopsis Wilderness and Crater Lake National Park into the Smoke Management Plan.[13] Oregon's 5-Year Progress Report approved May 17, 2019 (83 FR 22853), demonstrates that the long-term strategy and emission control measures in the existing Regional Haze SIP are sufficient to enable Oregon to meet all established reasonable progress goals. EPA proposes to find that Oregon's smoke management revisions do not constitute a relaxation in Oregon's Regional Haze SIP approved August 22, 2012 (77 FR 50611) because Oregon's revisions do not alter limits on the quantity of light impairing pollutants emitted from prescribed burning and OAR 629–048(2) clearly states it is Oregon's intent to operate their Smoke Management Plan in a manner consistent with the Oregon Regional Haze Plan.

IV. Technical Corrections

EPA is making technical corrections to provisions previously approved as revisions to the Oregon SIP pursuant to CAA 110(k)(6). In 2012 we approved (77 FR 50611) Oregon's revised Smoke Management Plan at OAR 629–048–0001 through –0500 which replaced OAR 629–043–0043 but we failed to update 40 CFR 52.1970(c), Table 2. We are correcting Table 2 to reflect the 2012 approval by removing ''OAR 629–43–043'' and adding the portions of OAR 629–048 (state effective January 1, 2008) that were not revised by Oregon's 2014 or 2019 Submittals.

We are correcting the identification of the Oregon SIP at 40 CFR part 52.1970(c), Table 2 by adding:

- OAR 629–048–0100, Regulated Areas (state effective 1/1/2008);
- OAR 629–048–0160, Bear Creek/Rogue River Valley SSRA (state effective 1/1/2008);
- OAR 629–048–0300, Registration of Intent to Burn (state effective 1/1/2008);
- OAR 629–048–0330, Emission Inventories (state effective 1/1/2008);
- OAR 629–048–0400, Coordination with Other Regulating Jurisdictions and for Other Pollutants (state effective 1/1/2008).

We are also making technical corrections to the Oregon SIP at 40 CFR part 52.1970(e), Table 5, Section 3, by revising the reference to Oregon's

[8] In its response to comments during the state public process, Oregon acknowledged that the proposed 2019 SIP amendments have the effect of allowing for an estimated increase of prescribed fire use by 80%. However, EPA proposes to conclude the burn-specific authorization criteria based on ambient monitoring data, included in the proposed SIP amendment, are sufficient to ensure continued protection of the NAAQS.

[9] From 629–048–0180 (3)(d), ''ODF and DEQ may revoke the exemption if there are repeated (three or more in five years) smoke intrusions that exceed the 24-hour average threshold or prescribed burning contributes to two or more NAAQS exceedances.''

[10] A copy of the study is included in the Docket materials for this action. See: Attachment G of *Oregon SMP 110 Discussion.*

[11] As described in OAR 629–048–0137 SPZ Contingency Plan Requirements.

[12] SSRAs are areas designated for the highest level of protection under the Smoke Management Plan (OAR 629–048–0005(26).

[13] See our proposed approval of Oregon's Regional Haze Progress Report (83 FR 11927, March 19, 2018) which was finalized May 17, 2018 (83 FR 33853).

Smoke Management Plan Administrative Rule to reflect the 2012 approval of OAR 629–048 and by removing the reference to OAR ''629 43–043''.

V. EPA's Proposed Action

We have reviewed Oregon's demonstration and propose to find that the revisions discussed above meet the requirements of the CAA. Based on our review of Oregon's demonstration, we propose to conclude that the revisions to Oregon's SIP will not interfere with any applicable requirement concerning attainment, reasonable further progress, or any other applicable requirement of the Clean Air Act.

Under CAA section 110(k), EPA is proposing to approve, and incorporate by reference, the 2014 and 2019 submitted revisions into the Oregon SIP at 40 CFR part 52, subpart MM. As discussed above, Oregon's 2014 and 2019 Submittals revised portions of OAR 629–048 and we are proposing to approve only the most recently submitted version of such regulations as previous versions are no longer in effect as a matter of state law.

Upon final approval, the Oregon SIP will include the addition of the following:

- OAR 629–048–0001, Title, Scope and Effective Dates (state effective 3/1/2019);
- OAR 629–048–0005, Definitions (state effective 3/1/2019);
- OAR 629–048–0010, Purpose (state effective 3/1/2019);
- OAR 629–048–0020, Necessity of Prescribed Burning (state effective 3/1/2019);
- OAR 629–048–0021, Necessity of Safeguarding Public Health (state effective 3/1/2019);
- OAR 629–048–0100, Regulated Areas (state effective 1/1/2008);
- OAR 629–048–0110, Characterization and Response to Smoke Incidents, Smoke Intrusions, and National Ambient Air Quality Standards (NAAQS) Exceedances (state effective 3/1/2019);
- OAR 629–048–0120, Air Quality Maintenance Objectives (state effective 3/1/2019);
- OAR 629–048–0130, Visibility Objectives (state effective 7/11/2014);
- OAR 629–048–0135, Special Protection Zone Requirements (state effective 3/1/2019);
- OAR 629–048–0137, SPZ Contingency Plan Requirements (state effective 3/1/2019);
- OAR 629–048–0140, Smoke Sensitive Receptor Areas (state effective 3/1/2019);
- OAR 629–048–0150, Criteria for Future Listing of Smoke Sensitive Receptor Areas (state effective 3/1/2019);
- OAR 629–048–0160, Bear Creek/Rogue River Valley SSRA (state effective 1/1/2008);
- OAR 629–048–0180, Communication, Community Response Plans, and Exemption Requests (state effective 3/1/2019);
- OAR 629–048–0200, Regulated Areas (state effective 3/1/2019);
- OAR 629–048–0210, Best Burn Practices; Emission Reduction Techniques (state effective 3/1/2019);
- OAR 629–048–0220, Forecast Procedures (state effective 3/1/2019);
- OAR 629–048–0230, Burn Procedures (state effective 3/1/2019);
- OAR 629–048–0300, Registration of Intent to Burn (state effective 1/1/2008);
- OAR 629–048–0310, Fees for Prescribed burning (state effective 3/1/2019);
- OAR 629–048–0320, Reporting of Accomplishments (state effective 3/1/2019);
- OAR 629–048–0330, Emission Inventories (state effective 1/1/2008);
- OAR 629–048–0400, Coordination with Other Regulating Jurisdictions and for Other Pollutants (state effective 1/1/2008);
- OAR 629–048–0450, Periodic Evaluation and Adaptive Management (state effective 3/1/2019);
- OAR 629–048–0500, Enforcement (state effective 3/1/2019);
- ORS 477.013, Smoke Management Plan; rules (state effective 3/1/2019); and
- Oregon Department of Forestry Directive 1–4–1–601, Operational Guidance for the Oregon Smoke Management Program (state effective 3/1/2019).

Pursuant to 110(k)(6), we are also making corrections to the regulatory text that includes incorporation by reference by removing ''OAR 629–43–043'' as discussed in Section IV. Upon final approval, the following regulations will be removed from 40 CFR 52.1970(c), Table 2:

- OAR 629–043–0043, Smoke Management Plan (state effective 4/13/1987); and the corresponding cross-reference will be removed from 40 CFR 52.1970(e), Table 5, Section 3.

VI. Incorporation by Reference

In this document, EPA is proposing to include in a final rule, regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is proposing to incorporate by reference the provisions described in Section V of this preamble. Also, in this document, EPA is proposing to remove the incorporation by reference of ''OAR 629–43–043'' as described in Section IV. EPA has made, and will continue to make, these documents generally available through *https://www.regulations.gov* and at EPA Region 10 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

VII. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Clean Air Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this proposed 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 proposed 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);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of the requirements would be inconsistent with the Clean Air Act; and
- Does not provide EPA with the discretionary authority to address, as

appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this proposed action does not apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Ozone, Particulate matter.

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

Dated: February 9, 2021.

Michelle L. Pirzadeh,

Acting Regional Administrator, Region 10.

[FR Doc. 2021–03036 Filed 2–18–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2020–0477; FRL–10016–38–Region 9]

Air Plan Approval; California; Placer County Air Pollution Control District; Open Burning Rules

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve revisions to the Placer County Air Pollution Control District (PCAPCD) portion of the California State Implementation Plan (SIP). These revisions concern emissions of oxides of nitrogen (NO_X) and particulate matter (PM) from open burning. We are proposing to approve local rules to regulate these emission sources under the Clean Air Act (CAA or the Act). We are taking comments on this proposal and plan to follow with a final action.

DATES: Comments must be received on or before March 22, 2021.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R09–OAR–2020–0477 at *https://www.regulations.gov.* For comments submitted at *Regulations.gov,* follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.* If you need assistance in a language other than English or if you are a person with disabilities who needs a reasonable accommodation at no cost to you, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Kevin Gong, EPA Region IX, 75 Hawthorne St., San Francisco, CA 94105. By phone: (415) 972–3073 or by email at *Gong.Kevin@epa.gov.*

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

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I. The State's Submittal

A. What rules did the State submit?

Table 1 lists the rules addressed by this proposal with the dates that they were adopted by the local air agency and submitted by the California Air Resources Board.

TABLE 1—SUBMITTED RULES

Local agency	Rule No.	Rule title	Amended	Submitted
PCAPCD	301	Nonagricultural Burning Smoke Management	08/09/2018	11/21/2018
PCAPCD	302	Agricultural Waste Burning Smoke Management	08/09/2018	11/21/2018
PCAPCD	305	Residential Allowable Burning	10/11/2018	01/31/2019

On May 21, 2019, the submittal for PCAPCD Rules 301 and 302 was deemed by operation of law to meet the completeness criteria in 40 CFR part 51 Appendix V, which must be met before formal EPA review. On July 31, 2019, the submittal for PCAPCD Rule 305 was also deemed by operation of law to meet the criteria.

B. Are there other versions of these rules?

We approved earlier versions of Rules 301, 302, and 305 into the SIP on January 31, 2013 (78 FR 6736). If we take final action to approve the submitted versions of Rules 301, 302, and 305 that are the subject of this rulemaking, they will replace the previously approved versions of these rules in the SIP.

C. What is the purpose of the rule revisions?

Emissions of NO_X contribute to the production of ground-level ozone, smog and PM, which harm human health and the environment. Section 110(a) of the CAA requires states to submit regulations that control NO_X emissions. Emissions of PM, including PM equal to or less than 2.5 microns in diameter ($PM_{2.5}$) and PM equal to or less than 10 microns in diameter (PM_{10}), contribute to effects that are harmful to human health and the environment, including premature mortality, aggravation of respiratory and cardiovascular disease, decreased lung function, visibility impairment, and damage to vegetation and ecosystems. Section 110(a) of the CAA requires states to submit

regulations that control PM emissions. Rules 301, 302, and 305 address open burning regulations for agricultural and non-agricultural smoke management and allowable residential burning to reduce emissions of particulates and NO_X from such burning. The EPA's technical support document (TSD) has more information about these rules.

II. The EPA's Evaluation and Action

A. How is the EPA evaluating the rules?

Rules in the SIP must be enforceable (see CAA section 110(a)(2)), must not interfere with applicable requirements concerning attainment and reasonable further progress or other CAA requirements (see CAA section 110(l)), and must not modify certain SIP control requirements in nonattainment areas without ensuring equivalent or greater emissions reductions (see CAA section 193).

Generally, SIP rules must implement reasonably available control measures (RACM), including reasonably available control technology (RACT) in Moderate $PM_{2.5}$ nonattainment areas (see CAA sections 172(c)(1) and 189(a)(1)(C)). The PCAPCD regulates a $PM_{2.5}$ nonattainment area classified as Moderate for the 2006 $PM_{2.5}$ national ambient air quality standard (NAAQS) (40 CFR 81.305). A RACM and RACT evaluation is generally performed in the context of a broader plan.

Guidance and policy documents that we used to evaluate enforceability, revision/relaxation and rule stringency requirements for the applicable criteria pollutants include the following:

1. ''State Implementation Plans; General Preamble for the Implementation of Title I of the Clean Air Act Amendments of 1990,'' 57 FR 13498 (April 16, 1992); 57 FR 18070 (April 28, 1992).
2. ''Issues Relating to VOC Regulation Cutpoints, Deficiencies, and Deviations,'' EPA, May 25, 1988 (the Bluebook, revised January 11, 1990).
3. ''Guidance Document for Correcting Common VOC & Other Rule Deficiencies,'' EPA Region 9, August 21, 2001 (the Little Bluebook).
4. ''State Implementation Plans; Nitrogen Oxides Supplement to the General Preamble; Clean Air Act Amendments of 1990 Implementation of Title I; Proposed Rule,'' (the NO_X Supplement), 57 FR 55620, November 25, 1992.
5. ''Airborne Toxic Control Measure to Reduce Emissions of Toxic Air Contaminants from Outdoor Residential Waste Burning'', California Code of Regulations (CCR 93113), February 3, 2003

B. Do the rules meet the evaluation criteria?

These rules meet CAA requirements and are consistent with relevant guidance regarding enforceability, stringency, and SIP revisions. The TSD has more information on our evaluation.

C. EPA Recommendations To Further Improve the Rules

The TSD includes recommendations for the next time the local agency modifies the rules.

D. Public Comment and Proposed Action

As authorized in section 110(k)(3) of the Act, the EPA proposes to fully approve the submitted rules because they fulfill all relevant requirements. We will accept comments from the public on this proposal until March 22, 2021. If we take final action to approve the submitted rules, our final action will incorporate these rules into the federally enforceable SIP.

III. Incorporation by Reference

In this rule, the EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with the requirements of 1 CFR 51.5, the EPA is proposing to incorporate by reference the PCAPCD rules described in Table 1 of this preamble. The EPA has made, and will continue to make, these materials available through *https://www.regulations.gov* and at the EPA Region IX Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

IV. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this proposed action merely proposes to approve state law as meeting federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed 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);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- Does not provide the EPA with the discretionary authority to address disproportionate human health or environmental effects with practical, appropriate, 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).

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.

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

Dated: February 5, 2021.

Deborah Jordan,

Acting Regional Administrator, Region IX.

[FR Doc. 2021–02907 Filed 2–18–21; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R02–OAR–2020–0438; FRL10017–48–Region 2]

Approval and Promulgation of Implementation Plans; United States Virgin Islands; Regional Haze Federal Implementation Plan; Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: On October 22, 2012, the EPA published a final rule in the **Federal Register** promulgating a Federal Implementation Plan (FIP) intended to address regional haze obligations for the Territory of the United States Virgin Islands. However, at that time EPA erroneously failed to incorporate into the Code of Federal Regulations (CFR) certain emission limits that had been determined to be necessary to satisfy those obligations and that had been proposed and included in the docket for the action. EPA is proposing to correct this inadvertent error by incorporating the previously noticed limits into the CFR. EPA is not reopening any of its previous determinations here.

DATES: Written comments must be received on or before March 22, 2021.

ADDRESSES: Submit your comments, identified by Docket Number EPA–R02–OAR–2020–0438, at *http://www.regulations.gov*. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or withdrawn. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, such as the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets*.

FOR FURTHER INFORMATION CONTACT: Omar Hammad, Air Planning Section, Environmental Protection Agency, 290 Broadway, 25th Floor, New York, New York 10007–1866, (212) 637–3347.

SUPPLEMENTARY INFORMATION: EPA published a final rule on October 22, 2012 (77 FR 64414). In that document, EPA promulgated a Federal Implementation Plan (FIP) to address regional haze obligations for the Territory of the United States Virgin Islands. EPA determined that certain emission limits for sources of visibility impairing pollutants in the Virgin Islands were necessary to satisfy the requirements of the Clean Air Act and EPA's rules concerning making reasonable progress towards the national goal of preventing any future and remedying any existing man-made impairment of visibility in mandatory Class I areas (also referred to as the ''regional haze program''). In that action, however, EPA erroneously failed to incorporate into the Code of Federal Regulations those limits, which had been noticed in the proposed rule (77 FR 37842, June 25, 2012) and which were included in docket EPA–R02–OAR–2012–0457, accompanying that proposed rule.[1] EPA determined in the 2012 final rule that those potential-to-emit (PTE) limits constituted the best-available retrofit technology (BART) emission limits for sources that had been determined to be subject-to-BART. EPA is now proposing a technical correction to incorporate the table containing the PTE limits necessary to satisfy the Virgin Islands' BART obligation into the CFR.

While EPA would not ordinarily request comment on a technical correction of this nature, we are doing so here because under the circumstances we believe maximum transparency is in the public interest. We are requesting comment on the narrow issue of whether the limits in the table that follows are the limits EPA determined to be BART in the 2012 action. Comments received on any other issues, including other aspects of the 2012 final rule, will be deemed beyond the scope of this action. This proposed rule does not reopen the previous determination that the PTE limits contained in the docket for the 2012 final rule represent BART for the units determined to be subject-to-BART; this action merely corrects an inadvertent omission in a previous rulemaking. This proposal does not address current circumstances, but merely clarifies what was intended to be included in the CFR pursuant to the 2012 FIP. The already approved BART limits are summarized in the following table:

Facility	BART unit	BART controls/limits			
		Control	SO_2 (tons/year)	NO_2 (tons/year)	PM (tons/year)
HOVENSA	Boilers:				
	1 (B–1151)		330.1	450.6	40.6
	3 (B–1153)		330.1	450.6	40.6
	4 (B–1154)		322.5	443.5	39.7
	5 (B–1155)		484.9	676.9	60.7
	6 (B–3301)		330.8	435.3	40.6
	7 (B–3302)		330.8	435.3	40.6
	8 (B–3303)		640.1	559.8	78.6
	9 (B–3304)		640.1	559.8	78.6
	Turbines:				
	GT1 (G–1101E)		135.5	805.7	12.2
	GT2 (G–1101F)		135.5	805.7	12.2
	GT3 (G–1101G)		135.5	805.7	12.2

[1] Document ID EPA–R02–OAR–2012–0457–0007 and EPA–R02–OAR–2012–0457–0008 in docket EPA–R02–OAR–2012–0457.

Facility	BART unit	BART controls/limits			
		Control	SO_2 (tons/year)	NO_2 (tons/year)	PM (tons/year)
	GT4 (G–3404)		161.0	809.5	12.9
	GT5 (G–3405)		161.0	766.5	12.9
	GT6 (G–3406)		161.0	766.5	12.9
	GT7 (G–3407)		161.0	766.5	12.9
	GT8 (G–3408)		167.6	1002.1	15.1
	GT9 (G–3409)	Steam Injection for NO_X Control	52.2	150.2	14.0
	Process Heaters:				
	H–101		155.5	232.5	19.3
	H–104		115.5	172.8	17.2
	H–200		8.1	16.0	1.2
	H–201		8.2	16.1	1.2
	H–202		26.6	146.5	4.0
	H–401A		197.6	279.1	24.4
	H–401B		197.6	279.1	24.4
	H–401C		197.6	279.1	24.4
	H–1401A		163.1	388.7	21.1
	H–1401B		155.4	370.2	20.1
	H–1500		13.0	25.5	2.0
	H–1501		13.7	26.8	2.0
	H–160		29.6	163.0	4.4
	H–600		11.5	22.5	1.7
	H–601		7.8	15.2	1.2
	H–602		62.6	344.4	9.4
	H–603		17.2	33.7	2.6
	H–604		8.1	15.9	1.2
	H–605		3.4	6.6	0.5
	H–606		11.8	23.1	1.8
	H–800A		9.4	18.4	1.4
	H–800B		9.4	18.4	1.4
	H–801		22.0	121.1	3.3
	H–2101		116.4	283.2	15.1
	H–2102		112.7	274.1	14.6
	H–2201A		13.4	26.3	2.0
	H–2201B		13.4	26.3	2.0
	H–2202		26.1	143.7	3.9
	H–2400		7.2	14.2	1.1
	H–2401		24.1	132.5	3.6
	H–2501		44.5	244.5	6.7
	H–4502		32.5	178.9	4.9
	H–4503		30.8	169.6	4.6
	H–4504		27.6	151.9	4.1
	H–4505		23.9	131.3	3.6
	H–3101A		356.7	507.1	48.1
	H–3101B		356.7	507.1	48.1
	H–4101A		356.7	507.1	48.1
	H–4101B		356.7	507.1	48.1
	H–4401		29.4	161.5	4.4
	H–4402		28.0	153.8	4.2
	H–4451		83.4	458.7	12.5
	H–4452		54.3	298.6	8.1
	H–4453		54.3	298.6	8.1
	H–4454		16.9	33.1	2.5
	H–4455		30.3	166.6	4.5
	H–4201		367.7	448.1	44.9
	H–4202		355.7	433.6	43.4
	H–5401		29.4	161.5	4.4
	H–5402		28	153.8	4.2
	H–5451		83.4	458.7	12.5
	H–5452		54.3	298.6	8.1
	H–5453		54.3	298.6	8.1
	H–5454		16.9	33.1	2.5
	H–5455		30.3	166.6	4.5
	H–4601A		13.4	26.3	2
	H–4601B		13.4	26.3	2
	H–4602		26.1	143.7	3.9
	H–4301A		14.6	28.7	2.2
	H–4301B		14.6	28.7	2.2
	H–4302		26.7	147.1	4
	H–5301A		14.6	28.7	2.2

Facility	BART unit	BART controls/limits			
		Control	SO_2 (tons/year)	NO_2 (tons/year)	PM (tons/year)
	H–5301B		14.6	28.7	2.2
	H–5302		26.7	147.1	4
	TGT unit No. 2 Beavo:				
	H–4761 & T–4761		2.0	4.0	1.0
	TGI units:				
	H–1032		1.6	3.1	0.2
	H–1042		3.3	6.5	0.5
	H–4745		900.0	28.0	3.0
	Compressors:				
	C–200A	Catalytic Converters for NO_X and CO control	0.0	33.1	0.2
	C–200B	Catalytic Converters for NO_X and CO control	0.0	33.1	0.2
	C–200C	Catalytic Converters for NO_X and CO control	0.0	33.1	0.2
	C–1500A		0.0	40.0	0.1
	C–1500B		0.0	40.0	0.1
	C–1500C		0.0	40.0	0.1
	C–2400A	Catalytic Converters for NO_X and CO control	0.0	19.4	0.3
	C–2400B	Catalytic Converters for NO_X and CO control	0.0	19.4	0.3
	C–4601A		0.0	380.6	0.9
	C–4601B		0.0	380.6	0.9
	C–4601C		0.0	380.6	0.9
	Flares:				
	#2 Flare (H–1105)		150.0	237.0	negligible
	#3 Flare (H–1104)		150.0	237.0	negligible
	#5 Flare (H–3351)		150.0	237.0	negligible
	#6 Flare (H–3352)		150.0	237.0	negligible
	#7 Flare (H–3301)		150.0	237.0	negligible
	Water Pumps:				
	PD–1602		1.9	40.6	2.9
	PD–1603		1.9	40.6	2.9
	PD–1604		1.9	40.6	2.9
	PD–1605		1.9	40.6	2.9
	PD–1620		1.3	27.0	1.9

Statutory and Executive Order Reviews

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

This proposed action is not a significant regulatory action and was, therefore, not submitted to the Office of Management and Budget (OMB) for review.

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

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

C. Paperwork Reduction Act

This proposed action does not impose an information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* Under the Paperwork Reduction Act, a ''collection of information'' is defined as a requirement for ''answers to * * * identical reporting or recordkeeping requirements imposed on ten or more persons * * *.'' 44 U.S.C. 3502(3)(A). The proposed action does not impose any new obligations or new enforcement duties on any state, local or tribal government or the private sector.

D. Regulatory Flexibility Act

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. In making this determination, the impact of concern is any significant adverse economic impact on small entities. An agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, has no net burden or otherwise has a positive economic effect on the small entities subject to the rule. This proposed action merely adds the erroneously omitted table to the CFR, it does not change any determination included in the FIP. We have, therefore, concluded that this action will have no net regulatory burden for all directly regulated small entities.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandates, as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal government or the private sector.

F. Executive Order 13132: Federalism

The proposed action does not have federalism implications. It would not have substantial direct effects on the

states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

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

This proposed action does not have tribal implications, as specified in Executive Order 13175. It will not have substantial direct effects on tribal governments. Thus, Executive Order 13175 does not apply to this rule.

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

This proposed action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866, and because the EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children.

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

This action is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not a significant regulatory action under Executive Order 12866.

J. National Technology Transfer and Advancement Act (NTTAA)

This proposed action does not involve technical standards.

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

The EPA believes this proposed action does not have potential disproportionately high and adverse human health or environmental effects on minority, low-income or indigenous populations. Through this action, the EPA is adding the erroneously omitted table to the CFR; it does not change any determination included in the FIP. This action does not remove any of the prior rule's environmental or procedural protections.

L. Congress Review Act (CRA)

This proposed rule is exempt from the CRA because it is a rule of particular applicability.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides.

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

Dated: February 10, 2021.

Walter Mugdan,

Acting Regional Administrator, Region 2.

Part 52, chapter I, title 40 of the Code of Federal Regulations is proposed to be 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 CCC—Virgin Islands

■ 2. In § 52.2781, paragraph (d)(5) is added to read as follows:

§ 52.2781 Visibility protection.

* * * * *

(d) * * *

(5) Emissions limitations, the owners/operators subject to this section shall not emit or cause to be emitted SO_2, NO_X, and PM in excess of the following limitations:

TABLE 1 TO PARAGRAPH (d)(5)

Facility	BART unit	BART controls/limits			
		Control	SO_2 (tons/year)	NO_2 (tons/year)	PM (tons/year)
HOVENSA	Boilers:				
	1 (B–1151)		330.1	450.6	40.6
	3 (B–1153)		330.1	450.6	40.6
	4 (B–1154)		322.5	443.5	39.7
	5 (B–1155)		484.9	676.9	60.7
	6 (B–3301)		330.8	435.3	40.6
	7 (B–3302)		330.8	435.3	40.6
	8 (B–3303)		640.1	559.8	78.6
	9 (B–3304)		640.1	559.8	78.6
	Turbines:				
	GT1 (G–1101E)		135.5	805.7	12.2
	GT2 (G–1101F)		135.5	805.7	12.2
	GT3 (G–1101G)		135.5	805.7	12.2
	GT4 (G–3404)		161.0	809.5	12.9
	GT5 (G–3405)		161.0	766.5	12.9
	GT6 (G–3406)		161.0	766.5	12.9
	GT7 (G–3407)		161.0	766.5	12.9
	GT8 (G–3408)		167.6	1002.1	15.1
	GT9 (G–3409)	Steam Injection for NO_X Control	52.2	150.2	14.0
	Process Heaters:				
	H–101		155.5	232.5	19.3
	H–104		115.5	172.8	17.2
	H–200		8.1	16.0	1.2
	H–201		8.2	16.1	1.2
	H–202		26.6	146.5	4.0
	H–401A		197.6	279.1	24.4

TABLE 1 TO PARAGRAPH (d)(5)—Continued

Facility	BART unit	BART controls/limits			
		Control	SO_2 (tons/year)	NO_2 (tons/year)	PM (tons/year)
	H–401B		197.6	279.1	24.4
	H–401C		197.6	279.1	24.4
	H–1401A		163.1	388.7	21.1
	H–1401B		155.4	370.2	20.1
	H–1500		13.0	25.5	2.0
	H–1501		13.7	26.8	2.0
	H–160		29.6	163.0	4.4
	H–600		11.5	22.5	1.7
	H–601		7.8	15.2	1.2
	H–602		62.6	344.4	9.4
	H–603		17.2	33.7	2.6
	H–604		8.1	15.9	1.2
	H–605		3.4	6.6	0.5
	H–606		11.8	23.1	1.8
	H–800A		9.4	18.4	1.4
	H–800B		9.4	18.4	1.4
	H–801		22.0	121.1	3.3
	H–2101		116.4	283.2	15.1
	H–2102		112.7	274.1	14.6
	H–2201A		13.4	26.3	2.0
	H–2201B		13.4	26.3	2.0
	H–2202		26.1	143.7	3.9
	H–2400		7.2	14.2	1.1
	H–2401		24.1	132.5	3.6
	H–2501		44.5	244.5	6.7
	H–4502		32.5	178.9	4.9
	H–4503		30.8	169.6	4.6
	H–4504		27.6	151.9	4.1
	H–4505		23.9	131.3	3.6
	H–3101A		356.7	507.1	48.1
	H–3101B		356.7	507.1	48.1
	H–4101A		356.7	507.1	48.1
	H–4101B		356.7	507.1	48.1
	H–4401		29.4	161.5	4.4
	H–4402		28.0	153.8	4.2
	H–4451		83.4	458.7	12.5
	H–4452		54.3	298.6	8.1
	H–4453		54.3	298.6	8.1
	H–4454		16.9	33.1	2.5
	H–4455		30.3	166.6	4.5
	H–4201		367.7	448.1	44.9
	H–4202		355.7	433.6	43.4
	H–5401		29.4	161.5	4.4
	H–5402		28	153.8	4.2
	H–5451		83.4	458.7	12.5
	H–5452		54.3	298.6	8.1
	H–5453		54.3	298.6	8.1
	H–5454		16.9	33.1	2.5
	H–5455		30.3	166.6	4.5
	H–4601A		13.4	26.3	2
	H–4601B		13.4	26.3	2
	H–4602		26.1	143.7	3.9
	H–4301A		14.6	28.7	2.2
	H–4301B		14.6	28.7	2.2
	H–4302		26.7	147.1	4
	H–5301A		14.6	28.7	2.2
	H–5301B		14.6	28.7	2.2
	H–5302		26.7	147.1	4
	TGT unit No. 2 Beavo:				
	H–4761 & T–4761		2.0	4.0	1.0
	TGI units:				
	H–1032		1.6	3.1	0.2
	H–1042		3.3	6.5	0.5
	H–4745		900.0	28.0	3.0

TABLE 1 TO PARAGRAPH (d)(5)—Continued

Facility	BART unit	BART controls/limits			
		Control	SO_2 (tons/year)	NO_2 (tons/year)	PM (tons/year)
	Compressors:				
	C–200A	Catalytic Converters for NO_X and CO control	0.0	33.1	0.2
	C–200B	Catalytic Converters for NO_X and CO control	0.0	33.1	0.2
	C–200C	Catalytic Converters for NO_X and CO control	0.0	33.1	0.2
	C–1500A		0.0	40.0	0.1
	C–1500B		0.0	40.0	0.1
	C–1500C		0.0	40.0	0.1
	C–2400A	Catalytic Converters for NO_X and CO control	0.0	19.4	0.3
	C–2400B	Catalytic Converters for NO_X and CO control	0.0	19.4	0.3
	C–4601A		0.0	380.6	0.9
	C–4601B		0.0	380.6	0.9
	C–4601C		0.0	380.6	0.9
	Flares:				
	#2 Flare (H–1105)		150.0	237.0	negligible
	#3 Flare (H–1104)		150.0	237.0	negligible
	#5 Flare (H–3351)		150.0	237.0	negligible
	#6 Flare (H–3352)		150.0	237.0	negligible
	#7 Flare (H–3301)		150.0	237.0	negligible
	Water Pumps:				
	PD–1602		1.9	40.6	2.9
	PD–1603		1.9	40.6	2.9
	PD–1604		1.9	40.6	2.9
	PD–1605		1.9	40.6	2.9
	PD–1620		1.3	27.0	1.9

[FR Doc. 2021–03057 Filed 2–18–21; 8:45 am]

BILLING CODE 6560–50–P

Notices

Federal Register

Vol. 86, No. 32

Friday, February 19, 2021

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

Notice of Request for Approval of an Information Collection

AGENCY: Office of Property and Environmental Management, Property Management Division, Department of Agriculture.

ACTION: Notice and request for public comments regarding an extension to an existing OMB clearance.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Office of Property and Environmental Management's intention to request an extension of a currently approved information Technical Equipment Pursuant to the 2008 Farm Bill.

DATES: Comments on this notice must be received by 60 days after publication in the **Federal Register** to be assured of consideration.

ADDRESSES: Office of Property and Environmental Management invites interested persons to submit comments on this notice. Comments may be submitted by one of the following methods:

☐ *Federal eRulemaking Portal:* This website provides the ability to type short comments directly into the comment field on this web page or attach a file for lengthier comments. Go to *http://www.regulations.gov.* Follow the on-line instructions at that site for submitting comments.

☐ *Mail:* U.S. Department of Agriculture, Property Management Division, Office of Property and Environmental Management, Attn: Pernell Ridley, 1400 Independence Ave. SW, Mailstop 9304, Suite 1069, Washington, DC 20250–9304.

☐ *Hand- or Courier-Delivered Submittals*: Deliver to U.S. Department of Agriculture, Office of Property and Environmental Management, 1400 Independence Ave. SW, Mailstop 9304, Suite 1069, Washington, DC 20250–9304.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number U.S. Department of Agriculture, Office of Property and Environmental Management, Docket Clerk, 1400 Independence Ave. SW, Mailstop 9304, Suite 1069, Washington, DC 20250–9304. 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.*

FOR FURTHER INFORMATION CONTACT: Contact Pernell Ridley Office of Property and Environmental Management, U.S. Department of Agriculture, 1400 Independence Ave. SW, Washington, DC 20250, Phone 202–309–1125 or by Email at *pernell.ridley@usda.gov.*

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), this notice announces the intention of Office of Property and Environmental Management to request approval for an existing collection in use without an OMB control number.

Title: Guidelines for the Transfer of Excess Computers or Other Technical Equipment Pursuant to Section 14220 of the 2008 Farm Bill.

OMB Number: 0505–0023.

Expiration Date of Approval: April 30, 2021.

Type of Request: Extension and revision of a currently approved information collection.

Abstract: USDA requires information in order to verify eligibility of requestors, determine availability of excess property, and have contact information for the requestor available to ensure an organization is designated to receive property on behalf of an eligible recipient. Information will be used to coordinate the transfer of excess property to eligible recipients. Respondents will be authorized representatives of a city, town, or local government entity located in a rural area as defined in 7 U.S.C. 1991 (a)(13)(A).

Estimate of Burden: Public reporting burden for this collection of information is estimated to average .167 hours per response.

Respondents: City, town, or local government entities located in a rural area.

Estimated Number of Respondents: 10.

Estimated Number of Responses per Respondent: 1.

Estimated Total Annual Burden on Respondents: 2 hours.

Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. Comments may be sent to Pernell Ridley at U.S. Department of Agriculture, Office of Property and Environmental Management, Docket Clerk, 1400 Independence Ave. SW, Mailstop 9304, Suite 1069, Washington, DC 20250–9304. All comments received will be available for public inspection during regular business hours at the same address.

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

Willie Scott Davis,

Director.

[FR Doc. 2021–03392 Filed 2–18–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

February 16, 2021.

The Department of Agriculture will submit the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13 on or after the date of publication of this notice. Comments are requested regarding: (1) Whether the

collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding these information collections are best assured of having their full effect if received by March 22, 2021. Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

National Agricultural Statistics Service (NASS)

Title: National Conservation Practice Adoption Motivations Pilot Survey.

OMB Control Number: 0535–0264.

Summary of Collection: The primary objectives of the National Agricultural Statistics Service (NASS) are to prepare and issue official State and national estimates of crop and livestock production, disposition and prices, economic statistics, and environmental statistics related to agriculture and to conduct the Census of Agriculture and its follow-on surveys. NASS will conduct a survey of select agricultural operations in four States: Nebraska, Oklahoma, Oregon, and Pennsylvania. Each selected farmer or rancher will be asked to provide data on practice, technical assistance, financial assistance, as well as obtain likert question data about motivations for each of the topic areas: (1) Cover crops, (2) nutrient management, (3) pest management, (4) tillage practices, (5) drainage water management, (6) runoff management practices, (7) edge of field improvements, (8) wetland conservation practices, and (9) irrigation management and system improvements, General authority for these data collection activities is granted under U.S.C. Title 7, Section 2204.

Need and Use of the Information: The purpose of the survey is to target operations who own or operate cropland, grazing land, concentrated livestock feeding operations, and forestry. NASS will collect information about these types of operations to understand conservation practices within the United States in terms of the following: (1) How often are specific conservation practices adopted without assistance, with technical assistance and/or financial assistance. (2) How does adoption evolve over time? What proportion of producers who ''try'' a given practice continue or expand use over time? How many discontinue the practice? (3) What motivates farmers to initially try a practice and then continue, expand, or discontinue use? The questions reflect a range of factors including conservation need, experience of neighbors, financial benefits or costs, producer time and effort, availability of technical and financial assistance, regulation or conservation compliance, and concern about the environmental quality. The United States Department of Agriculture's Natural Resources Conservation Service has entered into an interagency agreement with NASS to conduct this pilot survey. If this pilot is successful, NASS will submit a separate request to conduct the national survey.

Description of Respondents: A sample of all active operations who own or operate cropland, grazing land, concentrated livestock feeding operations, and/or forestry in Nebraska, Oklahoma, Oregon, and Pennsylvania.

Number of Respondents: 1,400.

Frequency of Responses: Reporting: Once.

Total Burden Hours: 974.

Levi S. Harrell,

Departmental Information Collection Clearance Officer.

[FR Doc. 2021–03371 Filed 2–18–21; 8:45 am]

BILLING CODE 3410–20–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

February 16, 2021.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are required regarding; whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by March 22, 2021 will be considered. Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Farm Service Agency

Title: Volunteer Programs.

OMB Control Number: 0560–0232.

Summary of Collection: Section 1526 of the Food and Agriculture Act of 1981 (7 U.S.C. 2272) permits the Secretary of Agriculture to establish a program to use volunteers to perform a wide range of activities to carry out the programs of or supported by the Department of Agriculture (USDA). Each USDA agency is granted the authority to establish programs designed to provide educationally related work assignments for students in non-pay status. USDA, Departmental Regulation 4230–1 requires documentation of service performed without compensation by persons who do not receive Federal appointment. For this requirement, the information collection request is necessary to continue implementation of the programs, which allows the Farm Service Agency (FSA) and Risk

Management Agency (RMA) to use volunteers to perform a wide range of activities to carry out the programs of or supported by the Agency.

Need and Use of the Information: Applicants who are accepted in the program will complete the ''Service Agreement and Attendance Record.'' FSA and RMA will use the reported information to respond to request for information on volunteers from the USDA Office of Human Resources Management. FSA Human Resource is responsible for determining how to document volunteer appointments. If the information were not collected for each volunteer, FSA and RMA would be unable to document service performed without compensation by persons in the program if this information were not collected for each volunteer.

Description of Respondents: Individuals or households.

Number of Respondents: 20.

Frequency of Responses: Reporting: Annually.

Total Burden Hours: 20.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2021–03373 Filed 2–18–21; 8:45 am]

BILLING CODE 3410–05–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

February 16, 2021.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding; whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by March 22, 2021 will be considered. Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Food and Nutrition Service

Title: Report of Supplemental Nutrition Assistance Program Issuance and Report of Commodity Distribution for Disaster Relief Recordkeeping Only.

OMB Control Number: 0584–0037.

Summary of Collection: Disaster assistance through the Supplemental Nutrition Assistance Program (SNAP) is authorized by sections 402 and 502 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121 *et seq.*) and the temporary emergency provisions contained in Section 5 of the Food and Nutrition Act of 2008, and in 7 CFR part 280 of the SNAP regulations. This program is initiated in a SNAP project area by FNS when all or part of the area has been affected by a disaster. Food distribution in a disaster situation is authorized under Section 32 of the Act of August 24, 1935. Surplus foods are made available by State distributing agencies for relief purposes to victims of natural disaster such as hurricanes, floods, tornadoes, etc. Distribution to these recipients is made primarily through such organizations as the American Red Cross or the Salvation Army. These organizations use surplus foods for both central feeding operations and for distribution to families in homes cut off from normal sources of food supply.

Need and Use of the Information: FNS will collect information through the use of form FNS–292–A and FNS 292–B, which is used to monitor program activity, assess coverage provided to recipients, and assure the validity of requested commodity reimbursement and to prepare budget requests. If the information were not collected, FNS would be unable to monitor the issuance of SNAP benefits and the distribution of surplus foods during disaster situations.

Description of Respondents: State, Local, or Tribal Government.

Number of Respondents: 108.

Frequency of Responses: Recordkeeping; On occasion.

Total Burden Hours: 14.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2021–03380 Filed 2–18–21; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF AGRICULTURE

Rural Business—Cooperative Service

Notice of Request for Comments on Extension of a Currently Approved Information Collection

AGENCY: Rural Business-Cooperative Service, USDA.

ACTION: Notice; comments requested.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Rural Business-Cooperative Service (RBCS) invites comments on this information collection for which approval from the Office of Management and Budget (OMB) will be requested. The intention is to request an extension of a currently approved information collection in support of the Guidelines for Designating Biobased Products for Federal Procurement.

DATES: Comments on this notice must be received by April 20, 2021 to be assured of consideration.

FOR FURTHER INFORMATION CONTACT: Vernell Thompson, Procurement Analyst, USDA Rural Development, 1400 Independence Avenue SW, Washington, DC 20250–1522. Telephone: (202) 720–4145, Email: *vernell.thompson@usda.gov.*

SUPPLEMENTARY INFORMATION: The Office of Management and Budget's (OMB) regulation (5 CFR 1320) implementing provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13) requires that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities (see 5 CFR 1320.8(d)). This notice identifies an information collection that RBCS is submitting to OMB for extension.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (c)

ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments may be sent by the following method:

• *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Follow the instructions for submitting comments.

Title: Guidelines for Designating Biobased Products for Federal Procurement.

OMB Control Number: 0570–0073.

Expiration Date of Approval: April 30, 2021.

Type of Request: Extension of a currently approved information collection.

Abstract: The USDA BioPreferred Program provides that qualifying biobased products that fall under product categories (generic groups of biobased products) that have been designated for preferred procurement by rule making are required to be purchased by Federal agencies in lieu of their fossil energy-based counterparts, with certain limited exceptions. Further, USDA is required by section 9002 of the Farm Security and Rural Investment Act of 2002, as amended by the Food, Conservation, and Energy Act of 2008 and the Agricultural Act of 2014, and the Agricultural Improvement Act of 2018, to provide certain information on qualified biobased products to Federal agencies. To meet these statutory requirements, USDA will gather that information from manufacturers and vendors of biobased products. The information sought by USDA can be transmitted electronically using the website *http://www.biopreferred.gov.* If for any reason the requested information cannot be electronically transmitted, USDA will provide technical assistance to support the transmission of information to USDA. The information collected will enable USDA to meet statutory information requirements that will then permit USDA to designate product categories for preferred procurement under the BioPreferred Program. Once product categories are designated, manufacturers and vendors of qualifying biobased products that fall under these designated product categories will benefit from preferred procurement by Federal agencies. This collection was previously approved under 0503–0011, and on February 4, 2021, was transferred to Rural Development and assigned OMB Control No. 0570–0073.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 40 hours per response.

Respondents: Manufacturers and vendors of biobased products. Participation is entirely voluntary.

Estimated Annual Number of Respondents: 220.

Estimated Number of Responses per Respondent: One per manufacturer or vendor.

Estimated Total Annual Burden on Respondents: 8,800 hours, one time only. Manufacturers and vendors are only asked to respond once for each stand-alone product or product family. Therefore, there is no ongoing annual paperwork burden on respondents unless they wish to add additional stand-alone products or product families. Furthermore, their participation in the BioPreferred Program is entirely voluntary.

Copies of this information collection can be obtained from Kimble Brown, Innovation Center—Regulations Management Division, at (202) 720–6780, Email: *kimble.brown@wdc.usda.gov.*

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

Mark Brodziski,

Acting Administrator, Rural Business-Cooperative Service.

[FR Doc. 2021–03349 Filed 2–18–21; 8:45 am]

BILLING CODE 3410–XY–P

CIVIL RIGHTS COMMISSION

Notice of Public Meetings of the Minnesota Advisory Committee

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the Minnesota Advisory Committee (Committee) will hold a meeting via the online platform WebEx on Tuesday, March 2, 2021 at 12:00 p.m. Central Time. The purpose of the meeting is to discuss civil rights concerns in the state.

DATES: The meeting will be held on:

• Tuesday, March 2, 2021, at 12:00 p.m. Central Time

Web link: *https://civilrights.webex.com/civilrights/j.php?MTID=m420abb3fcbead88ea6b941423d45b858*

Join by phone: 800–360–9505 USA Toll Free

Access Code: 199 498 4717

FOR FURTHER INFORMATION CONTACT: David Barreras, Designated Federal Officer, at *dbarreras@usccr.gov* or (202) 499–4066.

SUPPLEMENTARY INFORMATION: Members of the public may listen to this discussion through the above call-in number. An open comment period will be provided to allow members of the public to make a statement as time allows. Callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. An individual who is deaf, deafblind, and hard of hearing may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the conference call number and conference ID number.

Members of the public are entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be emailed to David Barreras at *dbarreras@usccr.gov.*

Records generated from this meeting may be inspected and reproduced at the Regional Programs Unit Office, as they become available, both before and after the meeting. Records of the meeting will be available via *www.facadatabase.gov* under the Commission on Civil Rights, Minnesota Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's website, *http://www.usccr.gov,* or may contact the Regional Programs Unit at the above email address.

Agenda

I. Welcome & Roll Call
II. Chair's Comments
III. Committee Discussion
IV. Public Comment
VI. Adjournment

Dated: February 12, 2021.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2021–03347 Filed 2–18–21; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meetings of the Illinois Advisory Committee

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the Illinois Advisory Committee (Committee) will hold a meeting via the online platform WebEx on Tuesday, March 9, 2021 at 12:00 p.m. Central Time. The purpose of the meeting is for the Committee to start preparing for their upcoming WebEx briefing on Education and Civil Rights concerns in the state.

DATES: The meeting will be held on:

- Tuesday, March 9, 2021, at 12:00 p.m. Central Time. Web link: *https://civilrights.webex.com/civilrights/j.php?MTID=md4d564c28cf610f9e94e7291a3d9bf0d.* Join by phone: 800–360–9505 USA Toll Free. Access code: 199 496 5009.

FOR FURTHER INFORMATION CONTACT: David Barreras, Designated Federal Officer, at *dbarreras@usccr.gov* or (202) 499–4066.

SUPPLEMENTARY INFORMATION: Members of the public may listen to this discussion through the above call-in number. An open comment period will be provided to allow members of the public to make a statement as time allows. Callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Individual who is deaf, deafblind and hard of hearing may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the conference call number and conference ID number.

Members of the public are entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be emailed to David Barreras at *dbarreras@usccr.gov.*

Records generated from this meeting may be inspected and reproduced at the Regional Programs Unit Office, as they become available, both before and after the meeting. Records of the meeting will be available via *https://www.facadatabase.gov/FACA/FACAPublicViewCommitteeDetails?id=a10t0000001gzlZAAQ* under the Commission on Civil Rights, Illinois Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's website, *http://www.usccr.gov,* or may contact the Regional Programs Unit at the above email or street address.

Agenda

I. Welcome & Roll Call
II. Chair's comments
III. Discussion: Education Project
IV. Next Steps
V. Public Comment
VI. Adjournment

Dated: February 12, 2021.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2021–03346 Filed 2–18–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Bureau of the Census

[Docket Number 210212–0021]

Urban Areas for the 2020 Census—Proposed Criteria

AGENCY: Bureau of the Census, Department of Commerce.

ACTION: Notice of proposed program and request for comments.

SUMMARY: This notice provides the Bureau of the Census' (hereafter, Census Bureau's) proposed criteria for defining urban areas based on the results of the 2020 Decennial Census. It also provides a description of the changes from the final criteria used for the 2010 Census. The Census Bureau is requesting public comment on these proposed criteria. The Census Bureau delineates urban areas after each decennial census by applying specified criteria to decennial census and other data. Since the 1950 Census, the Census Bureau has reviewed and revised these criteria, as necessary, for each decennial census in order to improve the classification of urban areas by taking advantage of newly available data and advancements in geographic information processing technology.

DATES: Written comments must be submitted on or before May 20, 2021.

ADDRESSES: Please direct all written comments on this proposed program via email at *geo.urban@census.gov* to Vincent Osier, Geographic Standards, Criteria, and Quality Branch, Geography Division, U.S. Census Bureau. Please note that paper comments cannot be reviewed due to limited building access caused by the COVID–19 pandemic. Phone: 301–763–1128.

FOR FURTHER INFORMATION CONTACT: Requests for additional information on this proposed program should be directed to Vincent Osier, Geographic Standards, Criteria, and Quality Branch, Geography Division, U.S. Census Bureau, via email at *geo.urban@census.gov.* Phone: 301–763–1128.

SUPPLEMENTARY INFORMATION: The Census Bureau's urban area classification is fundamentally a delineation of geographical areas, identifying individual urban areas as well as the rural portion of the nation. The Census Bureau's urban areas represent densely developed territory, and encompass residential, commercial, and other non-residential urban land uses. The boundaries of the urban areas have been defined primarily by using measures based on population counts and residential population density, and also by using measures based on criteria that account for non-residential urban land uses, such as commercial, industrial, transportation, and open space that are part of the urban landscape. Since the 1950 Census, when the Census Bureau first defined densely settled urbanized areas of 50,000 or more people, the urban area delineation process has addressed non-residential urban land uses through criteria designed to account for commercial enclaves, special land uses such as airports, and densely developed noncontiguous territory.

In delineating urban areas, the Census Bureau does not take into account or attempt to meet the requirements of any nonstatistical uses of these areas or their associated data. Nonetheless, the Census Bureau recognizes that some federal and state agencies use the Census Bureau's urban area classification for nonstatistical uses such as allocating program funds, setting program standards, and implementing aspects of their programs. The agencies that use the classification and data for such nonstatistical uses should be aware that the changes to the urban area criteria also might affect the implementation of their programs. In addition, the Census Bureau is not responsible for the use of its urban area classification in nonstatistical programs. If a federal, tribal, state, or local agency uses the urban area classification for nonstatistical purposes, it is that agency's responsibility to ensure that the classification is appropriate for such use.

(1) History

Over the course of a century defining urban areas, the Census Bureau has introduced conceptual and methodological changes to ensure that the urban area classification keeps pace with changes in settlement patterns and with changes in theoretical and practical approaches to interpreting and understanding the definition of urban areas. Prior to the 1950 Census, the Census Bureau primarily defined ''urban'' as any population, housing,

and territory located within incorporated places with a population of 2,500 or more. That definition was easy and straightforward to implement, requiring no need to calculate population density; to understand and account for actual settlement patterns on the ground in relation to boundaries of administrative units; or to consider densely settled populations existing outside incorporated municipalities. For much of the first half of the twentieth century, that definition was adequate for defining ''urban'' and ''rural'' in the United States, but by 1950 it became clear that it was incomplete.

Increasing suburbanization, particularly outside the boundaries of large incorporated places led the Census Bureau to adopt the urbanized area concept for the 1950 Census. At that time, the Census Bureau formally recognized that densely settled communities outside the boundaries of large incorporated municipalities were just as ''urban'' as the densely settled population inside those boundaries. Outside of urbanized areas of 50,000 or more people, the Census Bureau continued to recognize urban places with at least 2,500 and less than 50,000 persons. This basic conceptual approach to identifying urban areas remained in effect through the 1990 Census, albeit with some changes to criteria and delineation methods.

The Census Bureau adopted six substantial changes to its urban area criteria for the 2000 Census:

- Defining urban clusters using the same criteria as urbanized areas.
- Disregarding incorporated place and census designated place (CDP) boundaries when defining urbanized areas and urban clusters.
- Adoption of 500 persons per square mile (ppsm) as the minimum density criterion for recognizing some types of urban territory.
- An increase in the maximum jump distance for linking densely developed territory separated from the main body of the urban area by intervening low density territory from 1.5 to 2.5 miles. This recognized the prospect that larger clusters of non-residential urban uses might offset contiguity of densely settled territory.
- Introduction of the hop concept to provide an objective basis for recognizing that nonresidential urban uses, such as small commercial areas or parks, create small gaps between densely settled residential territories, but are part of the pattern of urbanization.
- Adoption of a zero-based approach to defining urban areas.

For the 2010 Census, the Census Bureau adopted moderate changes and enhancements to the criteria to improve upon the classification of urban and rural areas while continuing to meet the objective of a uniform application of criteria nationwide. These changes were:

- Use of census tracts as analysis units in the initial phase of delineation.
- Use of land use/land cover data from the National Land Cover Database (NLCD) to identify qualifying areas of non-residential urban land uses.
- Qualification of airports for inclusion in urban areas.
- Elimination of the designation of central places within urban areas.[1]
- Requirement for minimum population residing outside institutional group quarters.
- Splitting large urban agglomerations.

The conceptual and criteria changes adopted for both the 2000 and 2010 Censuses, as well as the history of the Census Bureau's urban area classification, are discussed in more detail in the document ''A Century of Delineating a Changing Landscape: The Census Bureau's Urban and Rural Classification, 1910 to 2010,'' available at *https://www2.census.gov/geo/pdfs/reference/ua/Century_of_Defining_Urban.pdf.*

(2) Proposed Changes for the 2020 Urban Areas

Adoption of a Housing Unit Density Threshold for Qualification of Census Blocks

The Census Bureau proposes adopting a housing unit density threshold of 385 housing units per square mile as the primary criterion for determining whether a census block qualifies for inclusion in an urban area, replacing the use of population density. The 385 housing units (occupied or vacant) per square mile density threshold utilized in the delineation of urban areas is consistent with the 1,000 persons per square mile density used in the past, based on the 2019 American Community Survey (ACS) 1-year data average of an estimated 2.6 persons per household for the United States. Housing unit density provides a more direct measure of the densely developed landscape than population density. The use of housing unit density will allow the Census Bureau to more accurately account for areas with substantial concentrations of housing that are considered part of the urban landscape, but have smaller than average persons per housing unit or seasonal populations or both. This change also will provide the ability to update the extent of urban areas between censuses, based on housing unit information in the Census Bureau's Master Address File. Intercensal updates of urban areas have not been possible to date, due to the lack of population counts at the census block-level between decennial censuses. As a result, although the Census Bureau presented estimated populations for urban areas based on the ACS, these data were produced using boundaries defined based on data from the previous decennial census and did not keep pace with changes to the extent of urbanization. In addition, the Census Bureau's decision to adopt differential privacy methodology as a means for protecting the privacy of individual responses to the decennial census has been accompanied by the decision that published census block-level populations should be variant—that is, the published population count for any given census block will vary from the enumerated population count in order to protect individuals from reidentification. This will affect the calculation of population density at the census block-level. Housing unit counts, however, are invariant and will reflect the number of housing units enumerated in each block, and thus are a more consistent measure.

Qualify Urban Areas Based on a Minimum Threshold of 4,000 Housing Units or 10,000 Persons Instead of a Minimum Threshold of 2,500 Persons

The Census Bureau proposes that an area will qualify as urban if it contains at least 4,000 housing units or has a population of at least 10,000. The proposed increase in the minimum population responds to calls for the Census Bureau to increase its minimum threshold for defining urban areas from the 2,500-person minimum established in 1910. The proposed 10,000-person minimum threshold aligns with thresholds used by other federal agencies to distinguish between urban and rural areas as well as with the Office of Management and Budget's minimum threshold for urban areas that form the cores of micropolitan statistical areas. The proposal to adopt a housing unit threshold is consistent with our proposed shift to housing unit density and is proposed for the same reasons: It provides a more direct measure of settlement and the built environment

[1] The central place concept was not necessary for urban area delineation and the resulting list of qualified central places largely duplicated the list of principal cities identified by the Metropolitan and Micropolitan Statistical Area standards. There was no conceptual reason to continue identifying two slightly different lists of cities and other places that were central to their respective regions.

and bases qualification on a measure that is not subject to variance resulting from the Census Bureau's disclosure avoidance methodology. The proposed 4,000-housing unit threshold approximates the 10,000-person threshold based on the national average of 2.6 persons per household. We are proposing use of either threshold for qualification of an area as urban, based on the recognition that some areas have average persons per household sizes larger than the national average of 2.6, or may contain a substantial number of persons living in group quarters (or both), and, as a result, may have populations of 10,000 or more, but less than 4,000 housing units.

Cease Distinguishing Different Types of Urban Areas

The Census Bureau proposes to cease distinguishing different types of urban areas. In adopting this proposal, the Census Bureau would identify urban areas of 4,000 or more housing units or 10,000 or more persons without distinguishing types of urban areas. The 50,000-person threshold that has been used to distinguish between urbanized areas and smaller urban areas (whether urban places outside urbanized areas or urban clusters) no longer has the same meaning as when it was adopted in 1950 and, therefore, should no longer be used to distinguish types of urban areas. Further, the threshold is, to some extent, arbitrary; that is, as far as the Census Bureau has been able to determine from scholarship, there is no reason to assume that an urban area of just over 50,000 persons is fundamentally different in terms of economic and social functions and services than an area with just under 50,000 persons. Lastly, federal agencies apply a range of thresholds to various urban-rural classifications. These thresholds can be applied to the published data by the individual agencies to meet their own objectives.

Maximum Distances of Jumps

Jumps (and the shorter distance hops) recognize that urban development is not always a continuous and contiguous process across the landscape, and facilitate inclusion of noncontiguous densely developed territory that is considered part of the nearby urban area. (For more information about the history and evolution of the jump and hop concepts, see ''A Century of Delineating a Changing Landscape: The Census Bureau's Urban and Rural Classification, 1910 to 2010,'' available at *https://www2.census.gov/geo/pdfs/reference/ua/Century_of_Defining_Urban.pdf.*) The Census Bureau proposes reducing the maximum jump distance to 1.5 miles, returning to the maximum distance employed in urban area delineation from the 1950 Census through the 1990 Census. Data users, analysts, and some urban geographers expressed concern that the 2.5 mile maximum jump distance adopted for the 2000 Census was too generous in some situations and resulted in overextension of urban area territory. The Census Bureau proposed reverting to 1.5 miles in the proposed criteria for the 2010 Census, but responses from commenters were inconclusive and, as a result, no change was made. We continue to be concerned about the possible overextension of urban area territory in some situations as a result of the 2.5 mile maximum jump distance. The impervious surface criteria adopted in 2010 accounted for non-residential urban land uses, many of which also were in mind when we extended the jump distance for the 2000 Census. Thus, the two criteria serve largely the same purpose, but are applied separately, and when taken together, they can result in overextension of urban territory.

No Longer Include the Low Density Hop or Jump ''Corridor'' in the Urban Area

The Census Bureau proposes to no longer include within an urban area the low density territory intervening between the main body of the urban area and the outlying qualifying territory that is the destination of a hop or a jump or exempted territory that has been separated from the urban area core by water or wetlands. This will result in noncontiguous urban areas. Review of 2010 Census urban areas indicates that, due to their often irregular and relatively large geographic extent, including the corridor blocks sometimes resulted in the inclusion of population, housing, and territory that is otherwise of a rural nature and contains land uses that are not consistent with those found in the densely developed blocks on either end of the hop or jump corridor. We note that the 1950 Census criteria for defining urbanized areas, while permitting jumps of up to 1.5 miles across low density intervening territory, did not call for inclusion of the low density jump corridor in the urban area. This change in criteria will result in a more accurate depiction of the patterns of urban development.

No Longer Include Low-Density Territory Located Within Indentations Formed During the Urban Area Delineation Process

Consistent with concerns about overbounding of urban areas and with the decision to no longer include the low-density hop and jump corridors within urban areas, we propose to cease including low-density territory within indentations that are formed during the delineation process when densely developed, qualifying territory surrounds low-density territory on three sides. Previous urban area criteria provided for the inclusion of indentations, when specified conditions were met, to (1) account for potential non-residential urban land uses that may be located within the indentation, (2) account for the potential for higher density development in the near future, and (3) produce smoother, less complicated boundaries for mapping purposes. Review of land uses within indentations formed during the 2010 urban area delineation has indicated that much of the territory remains less developed and less urban in character. Given that the impervious surface criteria are sufficient for identifying non-residential urban land uses and that modern computerized mapping and visualization methods provide the ability for users to view boundaries are various scales or ''zoom levels,'' thus reducing the need for smoother boundaries, we no longer see a need to close off indentations when delineating urban areas.

Splitting of Large Agglomerations of Densely Settled Territory

The automated process utilized by the Census Bureau results in the delineation of large agglomerations of continuously developed territory. While there is value in the identification of large agglomerations, some are too large and extensive to be of use for most analyses involving urban areas. Examples of large agglomerations of continuously developed territory exist throughout the United States and Puerto Rico, some encompassing only a pair of urban areas; others encompassing three or more urban areas extending across multiple states.

The question of when and how to merge adjacent urban areas or split large agglomerations has existed since the delineation of urban areas for the 1960 Census. Past criteria relied upon metropolitan statistical area or primary metropolitan statistical area definitions to determine whether to merge adjacent urban areas or, as was the case in the 2010 Census criteria, split agglomerations based on the previous decade's urbanized areas. Neither of these approaches relied upon objective measures consistent with the same time frame as the measures used in the delineation process. In other words, agglomerations were delineated based

on data either from or contemporary with the decennial census, but were split based on the results of the previous decade's data and delineation.

For the 2020 Census, the Census Bureau proposes using worker flow data (*i.e.,* commuting flows) from the Longitudinal Employer-Household Dynamics (LEHD) Program to identify whether the agglomeration represents a single functionally integrated region or whether commuting patterns indicate the presence of distinct urban areas within the larger agglomeration. The LEHD worker flow data would be used in two stages. The first stage is an analysis of adjacent 2010 Census urban areas, based on aggregate commuter flows into and out of each urban area. Adjacent 2010 Census urban areas will be merged if 50 percent or more of the workers in the smaller urban area are working in the larger urban area and 50 percent or more of the jobs in the smaller urban area are filled by workers residing in the larger urban area. If not merged, urban areas are selected for further analysis and split boundary adjustment. The second stage is identification of where to split large agglomerations, based on patterns observed by performing ''community'' detection on the LEHD worker flow data. ''Community'' boundaries resulting from application of the Leiden Algorithm [2] to the worker flow data will be used to adjust 2010 Census urban area split boundaries for the final 2020 Census urban areas. Application of this criterion could shift territory from one 2010 urban area to a different 2020 urban area. The resulting splits will reflect contemporaneous commuting patterns, which in turn, serve as proxy measures for other kinds of economic and social interactions within urban areas.

(3) Proposed Urban Area Criteria for the 2020 Census

The proposed criteria outlined herein apply to the United States,[3] Puerto Rico, and the Island Areas of American Samoa, the Commonwealth of the Northern Mariana Islands, Guam, and the U.S. Virgin Islands. The Census Bureau proposes the following criteria and characteristics for use in identifying the areas that will qualify for designation as urban areas for use in tabulating data from the 2020 Census, the American Community Survey (ACS), the Puerto Rico Community Survey, and potentially other Census Bureau censuses and surveys.

A. 2020 Census Urban Area Definitions

For the 2020 Census, an urban area will comprise a densely developed core of census blocks [4] that meet minimum housing unit density requirements, along with adjacent territory containing non-residential urban land uses as well as other lower density territory included to link outlying densely settled territory with the densely settled core. To qualify as an urban area, the territory identified according to the proposed criteria must encompass at least 4,000 housing units or at least 10,000 persons. The term ''rural'' encompasses all population, housing, and territory not included within an urban area.

As a result of the urban area delineation process, an incorporated place or census designated place (CDP) may be partly inside and partly outside an urban area. Any census geographic areas, with the exception of census blocks, may be partly within and partly outside an urban area.

All proposed criteria based on land area, housing unit density, and population, reflect the information contained in the Census Bureau's Master Address File/Topologically Integrated Geographic Encoding and Referencing (MAF/TIGER) Database (MTDB) at the time of the initial delineation. All calculations of housing unit density include only land; the areas of water contained within census blocks are not used in density calculations. Housing unit, population, and worker flow data used in the urban area delineation process will be those published by the Census Bureau for all public and official uses.

B. Proposed Urban Area Delineation Criteria

The Census Bureau proposes to define urban areas primarily on the basis of housing unit density measured at the census block level of geography. The 385 housing units per square mile density threshold utilized in the delineation of urban areas is consistent with the 1,000 persons per square mile density used in the past, based on the 2019 ACS 1-year data average of an estimated 2.6 persons per household for the United States.

1. Identification of Initial Urban Area Cores

The Census Bureau proposes to begin the delineation process by identifying and aggregating contiguous census blocks each having a housing unit density of at least 385 housing units per square mile. This aggregation of continuous census blocks would be known as the ''initial urban area core.'' The initial urban area core must encompass at least 385 housing units (consistent with the requirement for at least 1,000 people in the 2010 criteria).

After the initial urban area core is identified, additional census blocks would be included if it is adjacent to other qualifying territory and if it meets any of the following criteria:

a. It has a housing unit density of at least 385 housing units per square mile.

b. At least one-third of the census block consists of territory with a level of imperviousness of at least twenty percent,[5] and is compact in nature as defined by a shape index. A census block is considered compact when the shape index is at least 0.185 using the following formula: $I = 4\pi A/P^2$ where I is the shape index, A is the area of the entity, and P is the perimeter of the entity.

c. At least one-third of the census block consists of territory with a level of imperviousness of at least twenty percent, and at least forty percent of its boundary is contiguous with qualifying territory.

The Census Bureau would apply proposed criteria 1.a, 1.b, and 1.c above until there are no blocks to add to the urban area. Any ''holes'' or remaining nonqualifying territory completely contained within an initial urban area core that is less than five square miles in area will qualify as urban via the criteria for inclusion of enclaves, as set forth below in the III. B. 5., subheading entitled, ''5. Inclusion of Enclaves.''

2. Inclusion of Group Quarters

Census blocks containing institutional and non-institutional group quarters that are adjacent to census blocks qualifying based on the criteria outlined in step 1 above (''1. Identification of Initial Urban Area Cores'') will be included in the urban area. This criterion accounts for the fact that group quarters, such as college dormitories, are not considered housing units by the

[2] Thomas, I., A. Adam, and A. Verhetsel. Migration and commuting interactions fields: A new geography with community detection algorithm? 2017. *Belgeo.* [Online], 4. *http://journals.openedition.org/belgeo/20507.* Traag V.A, L. Waltman and N.J. van Eck. From Louvain to Leiden: Guaranteeing well-connected communities. 2019. *Scientific Reports.* 9:5233.

[3] For Census Bureau purposes, the United States includes the 50 States and the District of Columbia.

[4] A census block is the smallest geographic area for which the Census Bureau tabulates data and is an area normally bounded by visible features, such as streets, rivers or streams, shorelines, and railroads, and by nonvisible features, such as the boundary of an incorporated place, minor civil division, county, or other 2020 Census tabulation entity.

[5] The Census Bureau has found in testing the NLCD that territory with an impervious percent less than twenty percent results in the inclusion of road and structure edges, and not the actual roads or buildings themselves.

Census Bureau, but generally are part of the urban landscape.

3. Inclusion of Noncontiguous Territory via Hops and Jumps

Noncontiguous territory that meets the proposed housing density criteria specified in section B.1.a and b above, but is separated from an initial urban area core of 385 housing units or more, may be added via a hop along a road connection of no more than 0.5 miles. Multiple hops may be made along a single road connection, thus accounting for the nature of contemporary urban development, which often encompasses alternating patterns of residential and non-residential uses.

After adding territory to an initial urban area core via hop connections, the Census Bureau will identify all urban area cores that have a housing unit count of 577 or more (consistent with the requirement for at least 1,500 people in the 2010 criteria) and add other qualifying territory via a jump connection.[6] Jumps are used to connect densely settled noncontiguous territory separated from the urban area core by territory with low housing unit density measuring greater than 0.5 and no more than 1.5 road miles across. This process recognizes the existence of larger areas of non-residential uses or other territory with low housing unit density that do not provide a substantial barrier to interaction between outlying territory with high housing unit density and the urban area core. Because it is possible that any given densely developed area could qualify for inclusion in multiple cores via a jump connection, the identification of jumps in an automated process starts with the initial urban area core that has the largest total population and continues in descending order based on the total population of each initial urban area core. Only one jump is permitted along any given road connection. This limitation, which has been in place since the inception of the urban area delineation process for the 1950 Census, prevents the artificial extension of urban areas over large distances that result in the inclusion of communities that are not commonly perceived as connected to the particular initial urban area core. Exempted territory is not taken into account when measuring road distances across hop and jump corridors. In the case of both hops and jumps, the intervening, low density block or blocks are not included in the urban area.

4. Inclusion of Noncontiguous Territory Separated by Exempted Territory

The Census Bureau proposes to identify and exempt territory in which residential development is substantially constrained or not possible due to either topographical or land use conditions.[7] Such exempted territory offsets urban development due to particular land use, land cover, or topographic conditions. For the 2020 Census, the Census Bureau proposes the following to be exempted territory:

- Bodies of water; and
- Wetlands (belonging to one of eight wetlands class definitions [8])

Noncontiguous qualifying territory would be added to a core via a hop or jump when separated by exempted territory, provided that it meets the following criteria:

a. The road connection across the exempted territory (located on both sides of the road) is no greater than five miles, and

b. The total length of the road connection between the initial urban area core and the noncontiguous territory, including the exempt distance and non-exempt hop or jump distances, is also no greater than five miles.

The intervening, low density block or blocks of water or wetlands are not included in the urban area.

5. Inclusion of Enclaves

The Census Bureau will add enclaves (that is, nonqualifying area completely surrounded by area already qualified for inclusion as urban) within the urban area, provided that they are surrounded only by land area that qualified for inclusion in the urban area based on housing unit density criteria, and at least one of the following conditions is met:

a. The area of the enclave must be less than five square miles.

b. All area of the enclave is surrounded by territory that qualified for inclusion in the initial urban area core and is more than a straight-line distance of 1.5 miles from a land block that is not part of the urban area.

Additional enclaves will be identified and included within the urban area if:

a. The area of the enclave is less than five square miles,

b. The enclave is surrounded by both land that qualified for inclusion in the urban area and water, and

c. The length of the line of adjacency with the water is less than the length of the line of adjacency with the land.

6. Inclusion of Airports

After all territory has been added to the urban area core via hop and jump connections, and enclaves, the Census Bureau will then add whole census blocks that approximate the territory of airports, provided at least one of the blocks that represent the airport is within a distance of 0.5 miles of the edge of qualifying urban territory. An airport qualifies for inclusion if it is currently functional and one of the following criteria (per the Federal Aviation Administration's (FAA) Air Carrier Activity Information System [9]) applies:

a. It is a qualified cargo airport.

b. It has an annual passenger enplanement of at least 2,500 in any year between 2011 and 2019.

7. Additional Nonresidential Urban Territory

The Census Bureau will identify additional nonresidential urban-related territory that is noncontiguous, yet near the urban area. The Census Bureau recognizes the existence of large commercial and/or industrial land uses that are separated from an urban area by a relatively thin ''green buffer,'' small amount of undeveloped territory, and/or a narrow census block required for tabulation (such as a water feature, offset boundary, road median, or area between a road and rail feature). The Census Bureau will review all groups of census blocks whose members qualify as urban via the impervious surface criteria set forth in Section 1.b, have a total area of at least 0.15 square miles,[10] and are within 0.25 miles of an urban area. A final review of these census blocks and surrounding territory [11] will

[6] All initial urban area cores with less than 4,000 housing units or 10,000 persons are not selected to continue the delineation as separate urban areas; however, these cores still are eligible for inclusion in an urban area using subsequent proposed criteria and procedures.

[7] The land cover and land use types used to define exempted territory are limited to only those that are included in or can be derived from the Census Bureau's MTDB or the MRLC's most recent version of the NLCD nationally, consistently, and with some reasonable level of accuracy.

[8] For the MRLC's 2016 NLCD, wetlands are identified as belonging to one of eight wetlands class definitions including woody, palustrine forested, palustrine scrub/shrub, estuarine forested, estuarine scrub/shrub, emergent herbaceous, palustrine emergent (persistent), or estuarine emergent.

[9] The annual passenger boarding data only includes primary, non-primary commercial service, and general aviation enplanements as defined and reported by the FAA Air Carrier Activity Information System.

[10] The Census Bureau found in testing that individual (or groups of) census blocks with a high degree of impervious surface land cover with an area less than 0.15 square miles tend to be more associated with road infrastructure features such as cloverleaf overpasses and multilane highways.

[11] Additional census blocks within eighty feet of the initial groups also qualifying as impervious, but failing the shape index, are also identified for review.

determine whether to include this territory in an urban area.

8. Splitting Large Agglomerations and Merging Individual Urban Areas

Population growth and redistribution coupled with the automated urban area delineation methodology that will be used for the 2020 Census may result in large agglomerations of continuously developed territory that may encompass territory defined as separate urban areas for the 2010 Census. If such results occur, the Census Bureau will apply split and merge criteria.

For the 2020 Census, the Census Bureau proposes using worker flow data (*i.e.,* commuting flows) from the Longitudinal Employer-Household Dynamics (LEHD) Program to identify whether the agglomeration represents a single functionally integrated region or whether commuting patterns indicate the presence of distinct urban areas within the larger agglomeration. An agglomeration that encompasses two or more 2010 Census urban areas will be a candidate for splitting into smaller urban areas. This condition will trigger application of the following splitting criteria:

a. Each pair of 2010 Census urban areas will be analyzed to determine whether to split or to remain merged. The 2010 urban area with the smaller population will be analyzed in relation to the 2010 urban area with the larger population.

b. The 2010 Census urban area with the smaller population will remain in the agglomeration if at least 50 percent of its resident workers are employed within the larger 2010 Census urban area and at least 50 percent of the jobs in the smaller urban area are filled by workers residing within the larger 2010 Census urban area. If either of these conditions are not met, the smaller urban area will be split from the agglomeration and categorized based on the worker flow data.

c. The 2010 Census urban areas are organized into four categories:

1. Worker flows are 50 percent or more to or from another 2010 Census urban area, but not in both directions;

2. Worker flows are less than 50 percent internal, but also less than 50 percent with any other single 2010 Census urban area;

3. Adjacent 2010 Census urban areas that are in categories 1 or 2;

4. Worker flows are 50 percent or more internal to the 2010 Census urban area.

d. Community detection is performed on the LEHD worker flow data using the Leiden Algorithm to identify commuter-based communities. The resulting communities are used to adjust the 2010 Census urban area split boundaries based on thresholds set to each of the four categories. However, for all categories, at least 50 percent of the worker flow must be internal to all resulting urban areas. The boundary between two urban areas may also be modified to avoid splitting an incorporated place, CDP, or minor civil division (MCD) between two urban areas at the time of delineation.

e. Upon running the community detection algorithm, the resulting communities are used to adjust the 2010 Census urban area split boundaries, and to identify the potential boundary between the resulting 2020 urban areas, starting with urban areas in the first category (below) and progressing to the fourth category (below).

- Category 1. For the smaller of each urban area pair, adjacent communities (identified by the Leiden Algorithm) are added from the larger urban area until the internal worker flow of the smaller urban area is greater than 50 percent. Communities can only be added to the smaller urban area until the total housing unit count increases by less than 50 percent.
- Category 2. For the smaller of each urban area pair, adjacent communities (identified by the Leiden Algorithm) are added from the larger urban area until the internal worker flow is greater than 50 percent.
- Category 3. If there is greater than 10 percent worker flow between adjacent urban areas in categories 1 and 2, then they will be combined as one urban area and the criteria of the lowest category will be applied.
- Category 4. Split boundaries will be adjusted to their nearest community boundary.

9. Assigning Urban Area Titles

A clear, unambiguous title based on commonly recognized place names helps provide context for data users and ensures that the general location and setting of the urban area can be clearly identified and understood. The title of an urban area identifies the place(s) that is (are) the most populated within the urban area. All population requirements for places and MCDs apply to the portion of the entity's population that is within the specific urban area being named. The Census Bureau proposes the following criteria to determine the title of an urban area:

a. The most populous incorporated place within the urban area that has a population of 10,000 or more will be listed first in the urban area title.

b. If there is no incorporated place with a population of 10,000 or more, the urban area title will include the name of the most populous incorporated place or CDP within the urban area that has at least 2,500 people.

c. Up to two additional places, in descending order of population size, may be included in the title of an urban area, provided that the place meets one of the following criteria:

a. The place has 250,000 or more people.

b. The place has at least 2,500 people, and that population is at least two-thirds of the urban area population of the most populous place in the urban area.

If the urban area does not contain a place of at least 2,500 people, the Census Bureau will consider the name of the incorporated place, CDP, or MCD with the largest total population in the urban area, or a local name recognized for the area by the United States Geological Survey's (USGS) Geographic Names Information System (GNIS), with preference given to names also recognized by the United States Postal Service (USPS). The urban area title will include the USPS abbreviation of the name of each state or statistically equivalent entity in which the urban area is located or extends. The order of the state abbreviations is the same as the order of the related place names in the urban area title.[12]

If a single place or MCD qualifies as the title of more than one urban area, the largest urban area will use the name of the place or MCD. The smaller urban area will have a title consisting of the place or MCD name and the direction (North, South, East, or West) of the smaller urban area as it relates geographically to the larger urban area with the same place or MCD name.

If any title of an urban area duplicates the title of another urban area within the same state, or uses the name of an incorporated place, CDP, or MCD that is duplicated within a state, the name of the county that has most of the population of the largest place or MCD is appended, in parentheses, after the duplicate place or MCD name for each urban area. If there is no incorporated place, CDP, or MCD name in the urban area title, the name of the county having the largest total population residing in the urban area will be appended to the title.

[12] In situations where an urban area is only associated with one place name but is located in more than one state, the order of the state abbreviations will begin with the state within which the place is located and continue in descending order of population of each state's share of the population of the urban area.

C. Definitions of Key Terms

Census Block: A geographic area bounded by visible and/or invisible features shown on a map prepared by the Census Bureau. A census block is the smallest geographic entity for which the Census Bureau tabulates decennial census data.

Census Designated Place (CDP): A statistical geographic entity encompassing a concentration of population, housing, and commercial structures that is clearly identifiable by a single name, but is not within an incorporated place. CDPs are the statistical counterparts of incorporated places for distinct unincorporated communities.

Census Tract: A small, relatively permanent statistical geographic subdivision of a county or county equivalent defined for the tabulation and publication of Census Bureau data. The primary goal of the census tract program is to provide a set of nationally consistent small, statistical geographic units, with stable boundaries that facilitate analysis of data across time.

Contiguous: Refers to two or more areas sharing common boundaries.

Core Based Statistical Area (CBSA): A statistical geographic entity defined by the U.S. Office of Management and Budget, consisting of the county or counties or equivalent entities associated with at least one core of at least 10,000 population, plus adjacent counties having a high degree of social and economic integration with the core as measured through commuting ties with the counties containing the core. Metropolitan and micropolitan statistical areas are the two types of core based statistical areas.

Enclave: An area with population or housing unit density lower than the minimum for qualification that is completely surrounded by area already qualified for inclusion as urban.

Exempted Territory: Pre-existing land cover that offsets the pattern of urban development.

Group Quarters (GQs): A place where people live or stay, in a group living arrangement that is owned or managed by an entity or organization providing housing and/or services for the residents. These services may include custodial or medical care, as well as other types of assistance, and residency is commonly restricted to those receiving these services. This is not a typical household-type living arrangement. People living in GQs are usually not related to each other. GQs include such facilities as college residence halls, residential treatment centers, skilled nursing facilities, group homes, military barracks, correctional facilities, and workers' dormitories.

Impervious Surface: Paved, man-made surfaces, such as roads, parking lots, and rooftops.

Indentation: Areas that are partially enveloped by, and likely to be affected by and integrated with, an already qualified urban territory.

Incorporated Place: A type of governmental unit, incorporated under state law as a city, town (except in New England, New York, and Wisconsin), borough (except in Alaska and New York), or village, generally to provide specific governmental services for a concentration of people within legally prescribed boundaries.

Metropolitan Statistical Area: A core based statistical area associated with at least one urban area that has a population of at least 50,000. The metropolitan statistical area comprises the central county or counties or equivalent entities containing the core, plus adjacent outlying counties having a high degree of social and economic integration with the central county or counties as measured through commuting.

Micropolitan Statistical Area: A core based statistical area associated with at least one urban area that has a population of at least 10,000, but less than 50,000. The micropolitan statistical area comprises the central county or counties or equivalent entities containing the core, plus adjacent outlying counties having a high degree of social and economic integration with the central county or counties as measured through commuting.

Minor Civil Division (MCD): The primary governmental or administrative division of a county or equivalent entity in 29 states and the Island Areas having legal boundaries, names, and descriptions. MCDs represent many different types of legal entities with a wide variety of characteristics, powers, and functions depending on the state and type of MCD. In some states, some or all of the incorporated places also constitute MCDs.

New England City and Town Area (NECTA): A statistical geographic entity that is delineated by the U.S. Office of Management and Budget based on county subdivisions—usually cities and towns. NECTAs are defined using the same criteria as county-based CBSAs, and, similar to CBSAs, NECTAs are categorized as metropolitan or micropolitan.

Noncontiguous: Two or more areas that do not share common boundaries, such that the areas are separated by intervening territory.

Rural: Territory not defined as urban.

Topologically Integrated Geographic Encoding and Referencing (TIGER): Database developed by the Census Bureau to support its mapping needs for the decennial census and other Census Bureau programs. The topological structure of the TIGER database defines the location and relationship of boundaries, streets, rivers, railroads, and other features to each other and to the numerous geographic areas for which the Census Bureau tabulates data from its censuses and surveys.

Urban: Generally, densely developed territory, encompassing residential, commercial, and other non-residential urban land uses within which social and economic interactions occur.

Urban Area Core: Continuous area qualified as urban prior to the application of the hop and jump criteria.

Urban Cluster: A statistical geographic entity consisting of a densely settled core created from census tracts or blocks and contiguous qualifying territory that together have at least 2,500 persons but fewer than 50,000 persons.

Urbanized Area: A statistical geographic entity consisting of a densely settled core created from census tracts or blocks and adjacent densely settled territory that together have a minimum population of 50,000 people.

Ron S. Jarmin, Acting Director, Bureau of the Census, approved the publication of this Notice in the **Federal Register**.

Authority: Title 13, U.S.C., Chapter V.

Dated: February 16, 2021.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2021–03412 Filed 2–18–21; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–62–2020]

Foreign-Trade Zone (FTZ) 266—Dane County, Wisconsin; Authorization of Production Activity; Coating Place, Inc. (Pharmaceuticals); Verona, Wisconsin

On October 16, 2020, Coating Place, Inc. submitted a notification of proposed production activity to the FTZ Board for its facility within FTZ 266, in Verona, Wisconsin.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the **Federal Register** inviting public comment (85 FR 67709, October 26, 2020). On February 16, 2021, the

applicant was notified of the FTZ Board's decision that no further review of the activity is warranted at this time. The production activity described in the notification was authorized, subject to the FTZ Act and the FTZ Board's regulations, including Section 400.14.

Dated: February 16, 2021.

Elizabeth Whiteman,

Acting Executive Secretary.

[FR Doc. 2021–03399 Filed 2–18–21; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–116, C–428–848, C–533–894, C–475–841]

Forged Steel Fluid End Blocks From the People's Republic of China, the Federal Republic of Germany, India, and Italy: Correction to Countervailing Duty Orders

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

SUMMARY: The Department of Commerce (Commerce) is correcting the orders for the countervailing duty (CVD) investigations on forged steel fluid end blocks (FEBs) from the People's Republic of China (China), the Federal Republic of Germany (Germany), India, and Italy.

DATES: Applicable February 19, 2021.

FOR FURTHER INFORMATION CONTACT: Jaron Moore at (202) 482–3640 or Janae Martin at (202) 482–0238 (China); Joseph Dowling at (202) 482–1646 or Robert Palmer at (202) 482–9068 (Germany); William Langley at (202) 482–3861 or Nicholas Czajkowski at (202) 482–1395 (India); and Konrad Ptaszynski at (202) 482–6187 or Nicholas Czajkowski at (202) 482–1395 (Italy); AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230.

SUPPLEMENTARY INFORMATION: On January 29, 2021, Commerce published orders for the CVD investigations on FEBs from China, Germany, India, and Italy and an amended final determination for the CVD investigation on FEBs from China.[1] Commerce is correcting the *Orders* to include the names of the cross-owned affiliates of certain companies which were inadvertently omitted from the *Orders.*

Correction to the Orders

We are correcting the *Orders* to reflect that the net countervailable subsidy rates in the *Orders* are also applicable to the cross-owned companies of certain companies as reflected in the charts below.

Suspension of Liquidation and Cash Deposits

In accordance with section 706 of the Act, Commerce will instruct U.S. Customs and Border Protection (CBP) to reinstitute the suspension of liquidation of FEBs from China, Germany, India, and Italy, as described in the appendix to this notice, effective on the date of publication of the International Trade Commission's (ITC's) notice of final determination in the **Federal Register**, and to assess, upon further instruction by Commerce, pursuant to section 706(a)(1) of the Tariff Act of 1930, as amended (the Act), countervailing duties for each entry of the subject merchandise in an amount based on the net countervailable subsidy rates for the subject merchandise as stated in the charts below. On or after the date of publication of the ITC's final injury determination in the **Federal Register**, CBP must require, at the same time as importers would normally deposit estimated duties on this merchandise, a cash deposit equal to the rates stated in the charts below. The all-others rate applies to all producers or exporters not specifically listed below.

Exporter/producer	Subsidy rate (percent)
China:	
Nanjing Develop Advanced Manufacturing Co., Ltd[2]	16.80
Shanghai Qinghe Machinery Co., Ltd[3]	19.88
China Machinery Industrial Products Co., Ltd	337.07
Anhui Tianyu Petroleum Equipment Manufacturing Co., Ltd.	
CNCCC Sichuan Imp & Exp Co., Ltd.	

[1] *See Forged Steel Fluid End Blocks From the People's Republic of China, the Federal Republic of Germany, India, and Italy: Countervailing Duty Orders, and Amended Final Affirmative Countervailing Duty Determination for the People's Republic of China,* 85 FR 7535 (January 29, 2021) (*Orders*).

[2] Commerce has found the following company to be cross-owned with Nanjing Develop Advanced Manufacturing Co., Ltd.: Nanjing Develop Industrial and Commercial Co., Ltd. *See Forged Steel Fluid End Blocks from the People's Republic of China: Final Affirmative Countervailing Duty Determination,* 85 FR 80020, 80021 (December 11, 2020) (*China Final Determination*).

[3] Commerce has found the following companies to be cross-owned with Shanghai Qinghe Machinery Co., Ltd.: Haimo Technologies Group Corp.; and Lanzhou Chenglin Oil Drilling Equipment Co., Ltd. *See China Final Determination,* 85 FR at 80021.

[4] Commerce found the following companies to be cross-owned with BGH Edelstahl Siegen GmbH: Boschgotthardshütte O. Breyer GmbH; BGH Edelstahlwerke GmbH, Rohstoff-, Press- und Schneidbetrieb Siegen GmbH; and SRG Schrott und Recycling GmbH. *See Forged Steel Fluid End Blocks from the Federal Republic of Germany: Final Affirmative Countervailing Duty Determination,* 85 FR 80011, 80012 (December 11, 2020) (*Germany Final Determination*).

[5] Commerce found the following companies to be cross-owned with Schmiedewerke Gröditz GmbH: GMH Schmiedetechnik GmbH; Georgsmarienhütte Holding GmbH; and GHM Recycling GmbH. *See Germany Final Determination,* 85 FR at 80012.

[6] Commerce found the following company to be cross-owned with Bharat Forge Limited: Saarloha Advanced Materials Private Limited. The name of this company was also inadvertently omitted from the final determination notice. *See Forged Steel Fluid End Blocks from India: Final Affirmative Countervailing Duty Determination,* 85 FR 79999 (December 11, 2020) (*India Final Determination*), and accompanying Issues and Decision Memorandum (IDM). It was listed in the preliminary determination notice, and there were no changes which impacted this cross-ownership determination for the final determination. *See Forged Steel Fluid End Blocks from India: Preliminary Affirmative Countervailing Duty Determination, and Alignment of Final Determination With Final Antidumping Duty Determination,* 85 FR 31452, 31453 (May 26, 2020); *see also India Final Determination* IDM at 3.

[7] Commerce has found the following companies to be cross-owned with Lucchini Mame Forge S.p.A.: Lucchini RS S.p.A.; Lucchini Industries; Bicomet S.p.A.; and Setrans SrL. The names of these companies were also inadvertently omitted from the final determination notice. *See Forged Steel Fluid End Blocks from Italy: Final Affirmative Countervailing Duty Determination,* 85 FR 80022 (December 11, 2020) (*Italy Final Determination*), and accompanying IDM. They were listed in the preliminary determination notice, and there were no changes which impacted this cross-ownership determination for the final determination. *See Forged Steel Fluid End Blocks from Italy: Preliminary Affirmative Countervailing Duty Determination, and Alignment of Final Determination With Final Antidumping Duty Determination,* 85 FR 31460, 31461 (May 26, 2020) (*Italy Prelim Determination*); *see also Italy Final Determination* IDM at 3.

[8] Commerce has found the following companies to be cross-owned with Metalcam S.p.A.: Adamello Meccanica S.r.l.; and B.S. S.r.l. The names of these companies were also inadvertently omitted from the final determination notice. *See Italy Final Determination* IDM. They were listed in the preliminary determination notice, and there were no changes which impacted this cross-ownership determination for the final determination. *See Italy Prelim Determination,* 85 FR at 31461; *see also Italy Final Determination* IDM at 3.

Exporter/producer	Subsidy rate (percent)
GE Petroleum Equipment (Beijing) Co., Ltd.	
Jiaxing Shenghe Petroleum Machinery Co., Ltd.	
Ningbo Minmetals & Machinery Imp & Exp Co., Ltd.	
Qingdao RT G&M Co., Ltd.	
Shandong Fenghuang Foundry Co., Ltd.	
Shandongshengjin Ruite Energy Equipment Co., Ltd. (part of Shengli Oilfield R&T Group).	
Shanghai Baisheng Precision Machine.	
Shanghai Boss Petroleum Equipment.	
Shanghai CP Petrochemical and General Machinery Co., Ltd.	
Suzhou Douson Drilling & Production Equipment Co., Ltd.	
Zhangjiagang Haiguo New Energy Equipment Manufacturing Co., Ltd.	
Anhui Yingliu Electromechanical Co., Ltd.	
Daye Special Steel Co., Ltd., (Citic Specific Steel Group).	
Suzhou Fujie Machinery Co., Ltd., (Fujie Group).	
All Others	19.52
Germany:	
BGH Edelstahl Siegen GmbH [4]	5.86
Schmiedewerke Gröditz GmbH [5]	6.71
voestalpine Bohler Group	14.81
All Others	6.29
India:	
Bharat Forge Limited [6]	5.20
All Others	5.20
Italy:	
Lucchini Mame Forge S.p.A [7]	4.76
Metalcam S.p.A [8]	3.12
All Others	3.52
Companies Subject to AFA (non-respondent companies): Forge Mochieri S.p.A.; Imer International S.p.A.; Galperti Group, Mimest S.p.A.; P. Technologies S.r.L	44.86

Dated: February 12, 2021.

Christian Marsh,

Acting Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2021–03395 Filed 2–18–21; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–552–801; A–549–820; A–570–832]

Certain Frozen Fish Fillets From the Socialist Republic of Vietnam: Final Results of the Expedited Third Sunset Review of the Antidumping Duty Order; Prestressed Concrete Steel Wire Strand From Thailand: Preliminary Results of Antidumping Duty Administrative Review; and Pure Magnesium From the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review; 2018–2019; Correction

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

SUMMARY: On February 4, 2021, the Department of Commerce (Commerce) inadvertently published three **Federal Register** notices that had previously been published, and were not intended for republication. This notice serves as a notification of, and correction to, their inadvertent publication.

DATES: Applicable February 19, 2021.

FOR FURTHER INFORMATION CONTACT: Kathryn Wallace, AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–6251.

SUPPLEMENTARY INFORMATION:

Background

On February 4, 2021, the Department of Commerce (Commerce) inadvertently republished the final results of the third sunset review of the antidumping duty order on certain frozen fish fillets from the Socialist Republic of Vietnam; [1] the preliminary results of the antidumping duty administrative review of prestressed concrete steel wire strand from Thailand; [2] and the preliminary results of the antidumping duty administrative review of pure magnesium from the People's Republic of China.[3] The inadvertent republication of these notices does not constitute redetermination of the respective proceedings. This notice serves as a notification of, and correction to, their inadvertent publication.

Dated: February 12, 2021.

Christian Marsh,

Acting Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2021–03396 Filed 2–18–21; 8:45 am]

BILLING CODE 3510–DS–P

[1] *See Certain Frozen Fish Fillets from the Socialist Republic of Vietnam: Final Results of the Expedited Third Sunset Review of the Antidumping Duty Order,* 86 FR 8176 (February 4, 2021); initially published at 85 FR 6500 (February 5, 2020).

[2] *See Prestressed Concrete Steel Wire Strand from Thailand: Preliminary Results of Antidumping Duty Administrative Review; 2018,* 86 FR 8177 (February 4, 2021), initially published at 85 FR 6501 (February 5, 2020).

[3] *See Pure Magnesium from the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review; 2018–2019,* 86 FR 8179 (February 4, 2021), initially published at 85 FR 6509 (February 5, 2020).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–090, C–570–091]

Certain Steel Wheels 12 to 16.5 Inches in Diameter From the People's Republic of China: Notice of Covered Merchandise Referral

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

SUMMARY: Pursuant to the Enforce and Protect Act of 2015 (EAPA), the Department of Commerce (Commerce) received a covered merchandise referral from U.S. Customs and Border Protection (CBP) in connection with a CBP EAPA investigation concerning the antidumping duty (AD) and

countervailing duty (CVD) orders on certain steel wheels 12 to 16.5 inches in diameter (certain steel wheels) from the People's Republic of China (China). In accordance with EAPA, Commerce intends to determine whether the merchandise subject to the referral is covered by the scope of the orders and promptly transmit its determination to CBP. Commerce is providing notice of the referral and inviting participation from interested parties.

DATES: Applicable February 19, 2021.

FOR FURTHER INFORMATION CONTACT: Brendan Quinn or Charles Doss, AD/CVD Operations Office III, Enforcement & Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–5848 or (202) 482–4474, respectively.

SUPPLEMENTARY INFORMATION:

Background

On February 24, 2016, the Trade Facilitation and Trade Enforcement Act of 2015 was signed into law, which contains Title IV-Prevention of Evasion of Antidumping and Countervailing Duty Orders, commonly referred to as the Enforce and Protect Act of 2015 or EAPA.[1] Effective August 22, 2016, section 421 of EAPA added section 517 to the Tariff Act of 1930, as amended (the Act), which establishes a formal process for CBP to investigate allegations of the evasion of AD and CVD orders. Section 517(b)(4)(A) of the Act provides a procedure whereby if, during the course of an EAPA investigation, CBP is unable to determine whether the merchandise at issue is covered merchandise within the meaning of section 517(a)(3) of the Act, it shall refer the matter to Commerce to make such a determination. Section 517(a)(3) of the Act defines covered merchandise as merchandise that is subject to an AD order issued under section 736 of the Act or a CVD order issued under section 706 of the Act. Section 517(b)(4)(B) of the Act states that Commerce, after receiving a covered merchandise referral from CBP, shall determine whether the merchandise is covered merchandise and promptly transmit its determination to CBP. The Act does not establish a deadline within which Commerce must issue its determination.

On December 17, 2020, Commerce received a covered merchandise referral from CBP regarding CBP EAPA Investigation No. 7459,[2] which concerns the AD and CVD orders on certain steel wheels from China.[3] Specifically, CBP has requested that Commerce issue a determination as to whether certain types of steel trailer wheels produced in Thailand from inputs sourced from China (*i.e.,* either the rim or disc component is sourced from China and the corresponding rim or disc component is produced in Thailand, which may or may not involve using inputs sourced from China), as identified in a scope ruling request previously submitted to Commerce by Asia Wheel Co., Ltd.,[4] and currently under consideration in ongoing segments of the AD and CVD proceedings, are subject to the *Orders.*

Notification to Interested Parties

Commerce is hereby notifying interested parties that it has received the covered merchandise referral referenced above. As the covered merchandise referral requests a determination on merchandise identified in a request for a scope ruling previously submitted to Commerce and currently under consideration, we will address the covered merchandise referral and Asia Wheel Co., Ltd.'s scope ruling request in the ongoing scope segments of the AD and CVD proceedings. Based on our determinations in the ongoing scope segments of the AD and CVD proceedings, we intend to notify CBP as to whether the merchandise subject to the referral is covered merchandise within the meaning of section 517(a)(3) of the Act.

Commerce intends to provide interested parties with the opportunity to participate in these segments of the proceedings, including through the submission of comments, and, if appropriate, new factual information and verification. Specifically, Commerce will notify parties on the segment-specific service list for these segments of the proceedings of a schedule for comments. In addition, Commerce may request factual information from any person to assist in making its determination and may verify submissions of factual information, if Commerce determines that such verification is appropriate. The current deadline for Commerce to issue final scope rulings under 19 CFR 351.225(d) or initiate scope inquiries under 19 CFR 351.225(e) in the ongoing scope segments of the AD and CVD proceedings is March 22, 2021.

Parties are also hereby notified that this is the only notice that Commerce intends to publish in the **Federal Register** concerning this covered merchandise referral. Interested parties that wish to participate in these segments of the proceedings, and receive notice of the final determinations, must submit their letters of appearance as discussed below. Further, any party desiring access to business proprietary information in these segments of the proceedings must file an application for access to business proprietary information under administrative protective order (APO), as discussed below.

Finally, we note that covered merchandise referrals constitute a new type of segment of a proceeding at Commerce and, therefore, Commerce intends to develop its practice and procedures in this area as it gains more experience.

Scope of the Orders

The products covered by the *Orders* are certain on-the-road steel wheels, discs, and rims for tubeless tires with a nominal wheel diameter of 12 inches to 16.5 inches, regardless of width. Certain on-the-road steel wheels with a nominal wheel diameter of 12 inches to 16.5 inches within the scope are generally for road and highway trailers and other towable equipment, including, inter alia, utility trailers, cargo trailers, horse trailers, boat trailers, recreational trailers, and towable mobile homes. The standard widths of certain on-the-road steel wheels are 4 inches, 4.5 inches, 5 inches, 5.5 inches, 6 inches, and 6.5 inches, but all certain on-the-road steel wheels, regardless of width, are covered by the scope.

The scope includes rims and discs for certain on-the-road steel wheels, whether imported as an assembly, unassembled, or separately. The scope includes certain on-the-road steel wheels regardless of steel composition, whether cladded or not cladded, whether finished or not finished, and

[1] Title IV—Prevention of Evasion of Antidumping and Countervailing Duty Orders, Public Law 114–125, 130 Stat. 122, 155 (February 24, 2016).

[2] *See* CBP's Letter, ''Scope Referral Request for Merchandise under EAPA Cons. Investigation 7459, Imported by Lionshead Specialty Tire and Wheel LLC; Tex Trail LLC; and Trailstar LLC., and concerning the Investigation of Evasion of the Antidumping and Countervailing Duty Orders (A–570–090 and C–570–091) on Steel Trailer Wheels from the People's Republic of China,'' dated December 17, 2020. Commerce intends to make available this document and any supporting documents on Enforcement and Compliance's Antidumping Duty and Countervailing Duty Centralized Electronic Service System (ACCESS) within five days of publication of this notice.

[3] *See Certain Steel Trailer Wheels 12 to 16.5 Inches from the People's Republic of China: Antidumping Duty and Countervailing Duty Orders,* 84 FR 45952 (September 3, 2019) (*Orders*).

[4] *See* Asia Wheel Co., Ltd.'s Letters, ''Certain Steel Wheels (12 to 16.5 Inches in Diameter) from the People's Republic of China: Request for Scope Ruling for Asia Wheel's Steel Trailer Wheels,'' dated November 10, 2020.

whether coated or uncoated. The scope also includes certain on-the-road steel wheels with discs in either a ''hub-piloted'' or ''stud-piloted'' mounting configuration, though the stud-piloted configuration is most common in the size range covered.

All on-the-road wheels sold in the United States must meet Standard 110 or 120 of the National Highway Traffic Safety Administration's (NHTSA) Federal Motor Vehicle Safety Standards, which requires a rim marking, such as the ''DOT'' symbol, indicating compliance with applicable motor vehicle standards. See 49 CFR 571.110 and 571.120. The scope includes certain on-the-road steel wheels imported with or without NHTSA's required markings.

Certain on-the-road steel wheels imported as an assembly with a tire mounted on the wheel and/or with a valve stem or rims imported as an assembly with a tire mounted on the rim and/or with a valve stem are included in the scope of these orders. However, if the steel wheels or rims are imported as an assembly with a tire mounted on the wheel or rim and/or with a valve stem attached, the tire and/or valve stem is not covered by the scope.

The scope includes rims, discs, and wheels that have been further processed in a third country, including, but not limited to, the painting of wheels from China and the welding and painting of rims and discs from China to form a steel wheel, or any other processing that would not otherwise remove the merchandise from the scope of the *Orders* if performed in China.

Excluded from this scope are the following:

(1) Steel wheels for use with tube-type tires; such tires use multi piece rims, which are two-piece and three-piece assemblies and require the use of an inner tube;

(2) aluminum wheels;

(3) certain on-the-road steel wheels that are coated entirely in chrome. This exclusion is limited to chrome wheels coated entirely in chrome and produced through a chromium electroplating process, and does not extend to wheels that have been finished with other processes, including, but not limited to, Physical Vapor Deposition (PVD);

(4) steel wheels that do not meet Standard 110 or 120 of the NHTSA's requirements other than the rim marking requirements found in 49 CFR 571.110S4.4.2 and 571.120S5.2;

(5) steel wheels that meet the following specifications: Steel wheels with a nominal wheel diameter ranging from 15 inches to 16.5 inches, with a rim width of 8 inches or greater, and a wheel backspacing ranging from 3.75 inches to 5.5 inches; and

(6) steel wheels with wire spokes.

Certain on-the-road steel wheels subject to these *Orders* are properly classifiable under the following category of the Harmonized Tariff Schedule of the United States (HTSUS): 8716.90.5035 which covers the exact product covered by the scope whether entered as an assembled wheel or in components. Certain on-the-road steel wheels entered with a tire mounted on them may be entered under HTSUS 8716.90.5059 (Trailers and semi-trailers; other vehicles, not mechanically propelled, parts, wheels, other, wheels with other tires) (a category that will be broader than what is covered by the scope). While the HTSUS subheadings are provided for convenience and customs purposes, the written description of the subject merchandise is dispositive.

Filing Requirements

All submissions to Commerce must be filed electronically using ACCESS.[5] An electronically filed document must be received successfully in its entirety by the time and date it is due. Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information.[6]

Letters of Appearance and Administrative Protective Order

Interested parties that wish to participate in the AD and CVD segments of these proceedings and be added to the public service list for AD and CVD segments of these proceedings must file a letter of appearance in accordance with 19 CFR 351.103(d)(1), with one exception: The parties publicly identified by CBP in the covered merchandise referral (referenced above) are not required to submit a letter of appearance, and will be added to the public service list for these segments of the proceedings by Commerce.

Commerce placed an APO on the existing AD and CVD records on November 24, 2020,[7] and established the APO service lists for use in these segments. Commerce intends to place the covered merchandise referral letter on the records of these proceedings in ACCESS within five days of publication of this notice.

Interested parties must submit applications for disclosure under the APO in accordance with the procedures outlined in Commerce's regulations at 19 CFR 351.305. Those procedures apply to these segments of the proceeding, with one exception: APO applicants representing the parties that have been identified by CBP as an importer in the covered merchandise referral (referenced above) are exempt from the additional filing requirements for importers pursuant to 19 CFR 351.305(d).

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2021–03398 Filed 2–18–21; 8:45 am]

BILLING CODE 3510–DS–P

[5] *See Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011), as amended in *Enforcement and Compliance; Change of Electronic Filing System Name,* 79 FR 69046 (November 20, 2014) for details of Commerce's electronic filing requirements, effective August 5, 2011. Information on help using ACCESS can be found at *https://access.trade.gov/help.aspx* and a handbook can be found at *https://access.trade.gov/help/Handbook%20on%20Electronic%20Filing%20Procedures.pdf.*

[6] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19,* 85 FR 17006 (March 26, 2020); *see also Temporary Rule Modifying AD/CVD Service Requirements Due to COVID19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

[7] *See* the Administrative Protective Orders, dated November 24, 2020.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–016, C–570–017]

Certain Passenger Vehicle and Light Truck Tires From the People's Republic of China: Continuation of Antidumping Duty and Countervailing Duty Orders

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

SUMMARY: As a result of the determinations by the Department of Commerce (Commerce) and the International Trade Commission (ITC) that revocation of the antidumping duty (AD) and countervailing duty (CVD) orders on certain passenger vehicle and light truck tires (passenger tires) from the People's Republic of China (China) would likely lead to continuation or recurrence of dumping or countervailable subsidies, and material injury to an industry in the United States, Commerce is publishing a notice of continuation of these AD and CVD orders.

DATES: Applicable February 19, 2021.

FOR FURTHER INFORMATION CONTACT: Jacqueline Arrowsmith, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade

Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–5255.

SUPPLEMENTARY INFORMATION:

Background

On August 10, 2015, Commerce published the amended final affirmative determinations in the AD and CVD investigations of passenger tires from China as well as the AD and CVD orders for passenger tires in the **Federal Register**.[1] On July 1, 2020, the ITC instituted,[2] and Commerce initiated,[3] the five-year (sunset) reviews of the AD and CVD orders on passenger tires from China, pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act). As a result of its reviews, Commerce determined that revocation of the *Orders* on passenger tires from China would be likely to lead to continuation or recurrence of dumping and countervailable subsidies and, therefore, notified the ITC of the magnitude of the margins and net subsidy rates likely to prevail should the *Orders* be revoked.[4] On February 11, 2021, the ITC published its determinations, pursuant to sections 751(c) and 752(a) of the Act, that revocation of the *Orders* would likely lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.[5]

Scope of the Orders

The scope of the *Orders* is passenger vehicle and light truck tires. Passenger vehicle and light truck tires are new pneumatic tires, of rubber, with a passenger vehicle or light truck size designation. Tires covered by these *Orders* may be tube-type, tubeless, radial, or non-radial, and they may be intended for sale to original equipment manufacturers or the replacement market.

Subject tires have, at the time of importation, the symbol ''DOT'' on the sidewall, certifying that the tire conforms to applicable motor vehicle safety standards. Subject tires may also have the following prefixes or suffix in their tire size designation, which also appears on the sidewall of the tire:

Prefix designations:

P—Identifies a tire intended primarily for service on passenger cars

LT—Identifies a tire intended primarily for service on light trucks

Suffix letter designations:

LT—Identifies light truck tires for service on trucks, buses, trailers, and multipurpose passenger vehicles used in nominal highway service.

All tires with a ''P'' or ''LT'' prefix, and all tires with an ''LT'' suffix in their sidewall markings are covered by this investigation regardless of their intended use.

In addition, all tires that lack a ''P'' or ''LT'' prefix or suffix in their sidewall markings, as well as all tires that include any other prefix or suffix in their sidewall markings, are included in the scope, regardless of their intended use, as long as the tire is of a size that is among the numerical size designations listed in the passenger car section or light truck section of the *Tire and Rim Association Yearbook,* as updated annually, unless the tire falls within one of the specific exclusions set out below.

Passenger vehicle and light truck tires, whether or not attached to wheels or rims, are included in the scope. However, if a subject tire is imported attached to a wheel or rim, only the tire is covered by the scope.

Specifically excluded from the scope of the *Orders* are the following types of tires: Racing car tires; such tires do not bear the symbol ''DOT'' on the sidewall and may be marked with ''ZR'' in size designation;

(1) New pneumatic tires, of rubber, of a size that is not listed in the passenger car section or light truck section of the *Tire and Rim Association Yearbook;*

(2) pneumatic tires, of rubber, that are not new, including recycled and retreaded tires;

(3) non-pneumatic tires, such as solid rubber tires;

(5) tires designed and marketed exclusively as temporary use spare tires for passenger vehicles which, in addition, exhibit each of the following physical characteristics:

(a) The size designation and load index combination molded on the tire's sidewall are listed in Table PCT–1B (''T'' Type Spare Tires for Temporary Use on Passenger Vehicles) of the *Tire and Rim Association Yearbook,*

(b) the designation ''T'' is molded into the tire's sidewall as part of the size designation, and,

(c) the tire's speed rating is molded on the sidewall, indicating the rated speed in MPH or a letter rating as listed by *Tire and Rim Association Yearbook,* and the rated speed is 81 MPH or a ''M'' rating;

(6) tires designed and marketed exclusively for specialty tire (ST) use which, in addition, exhibit each of the following conditions:

(a) The size designation molded on the tire's sidewall is listed in the ST sections of the *Tire and Rim Association Yearbook,*

(b) the designation ''ST'' is molded into the tire's sidewall as part of the size designation,

(c) the tire incorporates a warning, prominently molded on the sidewall, that the tire is ''For Trailer Service Only'' or ''For Trailer Use Only'',

(d) the load index molded on the tire's sidewall meets or exceeds those load indexes listed in the *Tire and Rim Association Yearbook* for the relevant ST tire size, and

(e) either

(i) The tire's speed rating is molded on the sidewall, indicating the rated speed in MPH or a letter rating as listed by *Tire and Rim Association Yearbook,* and the rated speed does not exceed 81 MPH or an ''M'' rating; or

(ii) the tire's speed rating molded on the sidewall is 87 MPH or an ''N'' rating, and in either case the tire's maximum pressure and maximum load limit are molded on the sidewall and either

(1) Both exceed the maximum pressure and maximum load limit for any tire of the same size designation in either the passenger car or light truck section of the *Tire and Rim Association Yearbook;* or

(2) if the maximum cold inflation pressure molded on the tire is less than any cold inflation pressure listed for that size designation in either the passenger car or light truck section of the *Tire and Rim Association Yearbook,* the maximum load limit molded on the tire is higher than the maximum load limit listed at that cold inflation pressure for that size designation in either the passenger car or light truck section of the *Tire and Rim Association Yearbook;*

(7) tires designed and marketed exclusively for off-road use and which, in addition, exhibit each of the following physical characteristics:

(a) The size designation and load index combination molded on the tire's

[1] *See Certain Passenger Vehicle and Light Truck Tires from the People's Republic of China: Amended Final Affirmative Antidumping Duty Determination and Antidumping Duty Order; and Amended Final Affirmative Countervailing Duty Determination and Countervailing Duty Order,* 80 FR 47902 (August 10, 2015) (*Orders*).

[2] *See Passenger Vehicle and Light Truck Tires from China; Institution of Five-Year Reviews,* 85 FR 39581 (July 1, 2020).

[3] *See Initiation of Five-Year (Sunset) Reviews,* 85 FR 39526 (July 1, 2020).

[4] *See Certain Passenger Vehicle and Light Truck Tires from People's Republic of China: Final Results of the First Expedited Sunset Review of the Antidumping Duty Order,* 85 FR 70128 (November 4, 2020); *see also Certain Passenger Vehicle and Light Truck Tires from the People's Republic of China: Final Results of the Expedited First Sunset Review of the Countervailing Duty Order,* 85 FR 71313 (November 9, 2020).

[5] *See Passenger Vehicle and Light Truck Tires from China (Inv. No 701–TA–522 and 731–TA–1258 (Review)),* 86 FR 9084 (February 11, 2021); *see also Passenger Vehicle and Light Truck Tires from China (Inv. Nos. 701–TA–522 and 731–TA–1258 (Review).*

sidewall are listed in the off-the-road, agricultural, industrial or ATV section of the *Tire and Rim Association Yearbook,*

(b) in addition to any size designation markings, the tire incorporates a warning, prominently molded on the sidewall, that the tire is ''Not for Highway Service'' or ''Not for Highway Use'',

(c) the tire's speed rating is molded on the sidewall, indicating the rated speed in MPH or a letter rating as listed by the *Tire and Rim Association Yearbook,* and the rated speed does not exceed 55 MPH or a ''G'' rating, and

(d) the tire features a recognizable off-road tread design.

The products covered by the *Orders* are currently classified under the following Harmonized Tariff Schedule of the United States (HTSUS) subheadings: 4011.10.10.10, 4011.10.10.20, 4011.10.10.30, 4011.10.10.40, 4011.10.10.50, 4011.10.10.60, 4011.10.10.70, 4011.10.50.00, 4011.20.10.05, and 4011.20.50.10. Tires meeting the scope description may also enter under the following HTSUS subheadings: 4011.99.45.10, 4011.99.45.50, 4011.99.85.10, 4011.99.85.50, 8708.70.45.45, 8708.70.45.60, 8708.70.60.30, 8708.70.60.45, and 8708.70.60.60. While HTSUS subheadings are provided for convenience and for customs purposes, the written description of the subject merchandise is dispositive.

Continuation of the Orders

As a result of the determinations by Commerce and the ITC that revocation of these *Orders* would likely lead to a continuation or a recurrence of dumping and net countervailable subsidies and of material injury to an industry in the United States, pursuant to section 751(d)(2) of the Act and 19 CFR 351.218(a), Commerce hereby orders the continuation of these *Orders.* U.S. Customs and Border Protection will continue to collect AD and CVD cash deposits at the rates in effect at the time of entry for all imports of subject merchandise.

The effective date of the continuation of these *Orders* will be the date of publication in the **Federal Register** of this notice of continuation. Pursuant to section 751(c)(2) of the Act and 19 CFR 351.218(c)(2), Commerce intends to initiate the next five-year review of these *Orders* not later than 30 days prior to the fifth anniversary of the effective date of continuation.

Administrative Protective Order

This notice also serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return/destruction or conversion to judicial protective order of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Failure to comply is a violation of the APO which may be subject to sanctions.

Notification to Interested Parties

These five-year (sunset) reviews and this notice are in accordance with sections 751(c) of the Act and published in accordance with section 777(i) of the Act, and 19 CFR 351.218(f)(4).

Dated: February 12, 2021.

Christian Marsh,

Acting Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2021–03397 Filed 2–18–21; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; National Marine Sanctuary Permits

AGENCY: National Oceanic & Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of Information Collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act of 1995 (PRA), invites the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. The purpose of this notice is to allow for 60 days of public comment preceding submission of the collection to OMB.

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before April 20, 2021.

ADDRESSES: Interested persons are invited to submit written comments to Adrienne Thomas, NOAA PRA Officer, at *Adrienne.thomas@noaa.gov.* Please reference OMB Control Number 0648–0141 in the subject line of your comments. Do not submit Confidential Business Information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or specific questions related to collection activities should be directed to Vicki Wedell, National Resource Protection and Permit Coordinator, National Oceanic and Atmospheric Administration, 1305 East-West Highway, Silver Spring, MD, 240–676–3805, and *Vicki.Wedell@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

This request is for revision and extension of a currently approved information collection by the Office of National Marine Sanctuaries (ONMS). ONMS manages national marine sanctuaries pursuant to the purposes and policies of the National Marine Sanctuaries Act (NMSA, 16 U.S.C. 1431 *et seq.*).

National marine sanctuary regulations at 15 CFR part 922 list specific activities that are prohibited in national marine sanctuaries. These regulations also state that otherwise prohibited activities are permissible if a permit is issued by ONMS. Persons desiring a permit must submit an application, and anyone obtaining a permit is generally required to submit one or more reports on the activity allowed under the permit. The recordkeeping and reporting requirements at 15 CFR part 922 form the basis for this collection of information.

This information is required by ONMS to protect and manage sanctuary resources. The permit application collects information about the proposed activities, the methods proposed to be used, the potential effects to sanctuary resources, and information on the regulatory review criteria at 15 CFR part 922. ONMS uses this information to evaluate whether the proposed activities are consistent with the goals and objectives of the sanctuary and the intent of the NMSA.

Changes to this information collection include revisions to the permit application and instructions to improve clarity. The estimated number of permits issued per year also changed from 555 to 419. This is based on an estimated five additional permits from the designation of the Mallows Bay—Potomac River National Marine Sanctuary (84 FR 5073; Sept. 29, 2019) and a reduction of 141 permits per year because the Florida Keys National Marine Sanctuary is no longer issuing lionfish removal permits.

II. Method of Collection

Depending on the permit being requested, an application, reports, and telephone calls may be required from applicants. Applications and reports can be submitted via email, fax, or traditional mail. Applicants are encouraged to use electronic means to apply for permits and submit reports whenever possible.

III. Data

OMB Control Number: 0648–0141.

Form Number(s): None.

Type of Review: Regular submission (revision and extension of a currently approved information collection).

Affected Public: Business or other for-profit organizations; individuals or households; not-for-profit institutions; Federal government; state, local, or tribal government.

Estimated Number of Respondents: 419.

Estimated Time per Response: General permits, 1 hour and 30 minutes; special use permits, 8 hours; historical resources permits, 13 hours; baitfish permits, 5 minutes; permit amendments and certifications, 30 minutes; voluntary registrations, 15 minutes; appeals, 24 hours; Tortugas access permits, 6 minutes.

Estimated Total Annual Burden Hours: 2,047.

Estimated Total Annual Cost to Public: $1,095.00 in recordkeeping/reporting costs.

Respondent's Obligation: Required to obtain or retain benefits.

Legal Authority: 16 U.S.C. 1431 *et seq.*

IV. Request for Comments

We are soliciting public comments to permit the Department/Bureau to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used; (c) Evaluate ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. 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 may 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.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2021–03364 Filed 2–18–21; 8:45 am]

BILLING CODE 3510–NK–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Southeast Region Vessel and Gear Identification Requirements

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

ACTION: Notice of Information Collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act of 1995 (PRA), invites the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. The purpose of this notice is to allow for 60 days of public comment preceding submission of the collection to the Office of Management and Budget (OMB).

DATES: To ensure consideration, comments regarding this proposed information collection must be received by April 20, 2021.

ADDRESSES: Submit all written comments to Adrienne Thomas, NOAA PRA Officer, at *adrienne.thomas@noaa.gov.* Please reference OMB Control Number 0648–0358 in the subject line of your comments. All comments received are part of the public record and will generally be posted on *www.regulations.gov* without change. Do not submit confidential business information, or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or specific questions related to collection activities should be directed to Adam Bailey, NMFS, Southeast Regional Office, Sustainable Fisheries Division, 263 13th Ave. South, St. Petersburg, FL 33701, telephone: 727–824–5305, email: *adam.bailey@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

The NMFS Southeast Region manages the U.S. fisheries in the exclusive economic zone of the Caribbean, Gulf of Mexico, and South Atlantic regions under multiple fishery management plans (FMPs). The regional fishery management councils prepare the FMPs pursuant to the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). NMFS implements the regulations for the FMPs, which are located at 50 CFR part 622.

The recordkeeping and reporting regulations located at 50 CFR part 622 form the basis for the information collection requirements that are currently approved under OMB Control Number 0648–0358. NMFS proposes to extend the information collections under 0648–0358 without change. Regulations at 50 CFR part 622 require that all federally permitted fishing vessels must be marked with the official identification number or some other form of identification. A vessel's official number, under most regulations, must be displayed on the port and starboard sides of the deckhouse or hull, and on the weather deck. In addition, regulations for certain fisheries also require the display of the assigned color code for the vessel. The official number and color code identify each vessel and should be visible at distance from the sea and in the air. These markings provide law enforcement personnel with a means to monitor fishing, at-sea processing, and other related activities, as well as to ascertain whether the vessel's observed activities are in accordance with those authorized for that vessel. The identifying official number is used by NMFS, the United States Coast Guard, and other marine agencies in issuing violations, prosecutions, and other enforcement actions. Vessels that are authorized for particular fisheries are readily identified, gear violations are more readily prosecuted, and this allows for more cost-effective enforcement.

In addition to vessel marking, requirements that fishing gear be marked are essential to facilitate enforcement. The ability to link fishing gear to the vessel owner is crucial to enforcement of regulations issued under the authority of the Magnuson-Stevens

Act. The marking of fishing gear is also valuable in actions concerning damage, loss, and civil proceedings. The requirements imposed in the U.S. southeast region are for aquacultured live rock; golden crab traps; spiny lobster traps; black sea bass pots; Spanish mackerel gillnets; and buoy gear.

II. Method of Collection

Markings, such as numbers, are placed directly on fishing vessels and gear.

III. Data

OMB Control Number: 0648–0358.

Form Number(s): None.

Type of Review: Regular submission (extension of a current information collection).

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 7,825.

Estimated Time per Response: Vessel marking: 75 minutes. Gear marking: Aquacultured live rocks, 10 seconds each; golden crab traps, 2 minutes each; spiny lobster traps, 7 minutes each; sea bass pots, 16 minutes each; and Spanish mackerel gillnets, 20 minutes each; and buoy gear, 10 minutes each.

Estimated Total Annual Burden Hours: 51,070.

Estimated Total Annual Cost to Public: $673,277 in recordkeeping and reporting costs.

Respondent's Obligation: Mandatory.

Legal Authority: Magnuson-Stevens Act, 16 U.S.C. 1801 *et seq.*

IV. Request for Comments

We are soliciting public comments to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used; (c) Evaluate ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this information collection request. 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 may 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.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2021–03366 Filed 2–18–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No.: PTO–P–2021–0009]

Grant of Interim Extension of the Term of U.S. Patent No. 7,534,790; Vernakalant Hydrochloride

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Notice of interim patent term extension.

SUMMARY: The United States Patent and Trademark Office has issued an order granting interim extension for a one-year interim extension of the term of U.S. Patent No. 7,534,790.

FOR FURTHER INFORMATION CONTACT: Raul Tamayo by telephone at 571–272–7728; by mail marked to his attention and addressed to the Commissioner for Patents, Mail Stop Hatch-Waxman PTE, P.O. Box 1450, Alexandria, VA 22313–1450; by fax marked to his attention at 571–273–7728; or by email to *raul.tamayo@uspto.gov.*

SUPPLEMENTARY INFORMATION: Section 156 of Title 35, United States Code, generally provides that the term of a patent may be extended for a period of up to five years if the patent claims a product, or a method of making or using a product, that has been subject to certain defined regulatory review, and that the patent may be extended for interim periods of up to one year if the regulatory review is anticipated to extend beyond the expiration date of the patent. On February 9, 2021, Correvio International Sàrl, the patent owner of record, timely filed an application under 35 U.S.C. 156(d)(5) for a third interim extension of the term of U.S. Patent No. 7,534,790. The patent claims the human drug product vernakalant hydrochloride. The application for patent term extension indicates that New Drug Application (NDA) 22–034 was submitted to the Food and Drug Administration (FDA) on December 19, 2006.

Review of the patent term extension application indicates that, except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. 156, and that the patent should be extended for one year as required by 35 U.S.C. 156(d)(5)(B). Because the regulatory review period will continue beyond the twice-extended expiration date of the patent, March 31, 2021, interim extension of the patent term under 35 U.S.C. 156(d)(5) is appropriate.

An interim extension under 35 U.S.C. 156(d)(5) of the term of U.S. Patent No. 7,534,790 is granted for a period of one year from the extended expiration date of the patent.

Robert Bahr,

Deputy Commissioner for Patent Examination Policy, United States Patent and Trademark Office.

[FR Doc. 2021–03427 Filed 2–18–21; 8:45 am]

BILLING CODE 3510–16–P

COMMODITY FUTURES TRADING COMMISSION

Global Markets Advisory Committee

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice of meeting.

SUMMARY: The Commodity Futures Trading Commission (CFTC) announces that on March 11, 2021, from 9:00 a.m. to 1:00 p.m. (Eastern Standard Time), the Global Markets Advisory Committee (GMAC) will hold a public meeting via teleconference. At this meeting, the GMAC will continue discussions on the impact of market volatility related to the coronavirus pandemic and recent effects on international central counterparties and the global clearing ecosystem; and hear presentations and provide dialogue on matters related to retail participation in the derivatives markets.

DATES: The meeting will be held on March 11, 2021, from 9:00 a.m. to 1:00 p.m. (Eastern Standard Time). Members of the public who wish to submit written statements in connection with the meeting should submit them by March 18, 2021.

ADDRESSES: The meeting will take place via teleconference. You may submit public comments, identified by ''Global Markets Advisory Committee,'' via the CFTC's website, *http://comments.cftc.gov.* If you are unable to submit comments via the CFTC's website, contact Andrée Goldsmith,

Designated Federal Officer, via the contact information listed below to discuss alternate means of submitting your comments. Any statements submitted in connection with the committee meeting will be made available to the public, including publication on the CFTC's website, *http://www.cftc.gov.*

FOR FURTHER INFORMATION CONTACT: Andrée Goldsmith, GMAC Designated Federal Officer, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581; (202) 418–6624; *agoldsmith@cftc.gov.*

SUPPLEMENTARY INFORMATION: Members of the public may listen to the meeting by telephone by calling a domestic toll-free telephone or international toll or toll-free number to connect to a live, listen-only audio feed. Call-in participants should be prepared to provide their first name, last name, and affiliation.

Domestic Toll Free: 1–877–951–7311.

International Toll and Toll Free: Will be posted on the CFTC's website, *http://www.cftc.gov,* on the page for the meeting, under Related Links.

Pass Code/Pin Code: 9530502.

The meeting time and agenda may change to accommodate other GMAC priorities. For time and agenda updates, please visit the GMAC committee's website at: *https://www.cftc.gov/About/CFTCCommittees/GlobalMarketsAdvisory/gmac_meetings.html.*

After the meeting, a transcript of the meeting will be published through a link on the CFTC's website at: *http://www.cftc.gov.* All written submissions provided to the CFTC in any form will also be published on the CFTC's website. Persons requiring special accommodations to attend the meeting because of a disability should notify the contact person above.

Authority: 5 U.S.C. App. 2.

Dated: February 16, 2021.

Robert Sidman,

Deputy Secretary of the Commission.

[FR Doc. 2021–03405 Filed 2–18–21; 8:45 am]

BILLING CODE 6351–01–P

COUNCIL ON ENVIRONMENTAL QUALITY

National Environmental Policy Act Guidance on Consideration of Greenhouse Gas Emissions

AGENCY: Council on Environmental Quality (CEQ).

ACTION: Notice of rescission of draft guidance.

SUMMARY: The Council on Environmental Quality (CEQ) is rescinding its ''Draft National Environmental Policy Act Guidance on Consideration of Greenhouse Gas Emissions'' consistent with Executive Order (E.O.) 13990, ''Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis.''

FOR FURTHER INFORMATION CONTACT: Jomar Maldonado, Associate Director for the National Environmental Policy Act, 730 Jackson Place NW, Washington, DC 20503, *jomar.maldonadovazquez@ceq.eop.gov* or (202) 395–5750.

SUPPLEMENTARY INFORMATION: The National Environmental Policy Act of 1969 (NEPA), 42 U.S.C. 4321 *et seq.,* sets forth a national environmental policy to harmonize environmental, economic, and social goals, and is a cornerstone of the Nation's efforts to protect the environment. *See* 42 U.S.C. 4321, 4331. NEPA also created the Council on Environmental Quality (CEQ), 42 U.S.C. 4342, which oversees its implementation. NEPA requires Federal agencies to consider the environmental effects of its proposed actions and involve the public in its decision-making processes. CEQ's NEPA implementing regulations at 40 CFR parts 1500 through 1508 set forth the procedures for agencies to comply with NEPA. Additionally, CEQ issues guidance to agencies on how to fulfil NEPA's mandates. *See* 40 CFR 1506.7.

Many projects and programs proposed, funded, or approved by Federal agencies have the potential to emit or sequester greenhouse gases (GHGs), and may be affected by climate change. Federal courts consistently have held that NEPA requires agencies to disclose and consider climate impacts in their reviews. *See, e.g., Ctr. for Biological Diversity* v. *Nat'l Highway Traffic Safety Admin.,* 538 F.3d 1172 (9th Cir. 2008). On March 31, 2016, CEQ issued ''Final Guidance for Federal Departments and Agencies on Consideration of Greenhouse Gas Emissions and the Effects of Climate Change in National Environmental Policy Act Reviews'' (2016 GHG Guidance) to help agencies with this requirement. 81 FR 51866 (Aug. 5, 2016).

E.O. 13873, ''Promoting Energy Independence and Economic Growth,'' directed CEQ to withdraw this guidance. E.O. 13783, 82 FR 16093 (Mar. 31, 2017). CEQ withdrew the guidance on April 5, 2017. 82 FR 16576. CEQ then proposed for public comment, but never finalized, ''Draft National Environmental Policy Act Guidance on Consideration of Greenhouse Gas Emissions'' (2019 Draft GHG Guidance). 84 FR 30097 (June 26, 2019), RIN 0331–ZA03.

On January 20, 2021, President Biden issued E.O. 13990, ''Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis,'' to establish a national policy ''to empower our workers and communities; promote and protect our public health and the environment; and conserve our national treasures and monuments, places that secure our national memory.'' 86 FR 7037 (Jan. 25, 2021). Section 7(e) directs CEQ to rescind the 2019 Draft GHG Guidance and review, revise, and update its 2016 GHG Guidance. In accordance with this E.O., CEQ is rescinding the 2019 Draft GHG Guidance. The withdrawal of this guidance does not change any law, regulation, or other legally binding requirement. CEQ will address in a separate notice its review of and any appropriate revisions and updates to the 2016 GHG Guidance. In the interim, agencies should consider all available tools and resources in assessing GHG emissions and climate change effects of their proposed actions, including, as appropriate and relevant, the 2016 GHG Guidance. For more information on NEPA and Federal agency compliance with NEPA, please see *nepa.gov.*

Jomar Maldonado,

Associate Director for the National Environmental Policy Act.

[FR Doc. 2021–03355 Filed 2–18–21; 8:45 am]

BILLING CODE 3225–F1–P

DEPARTMENT OF EDUCATION

Applications for New Awards: Disability Innovation Fund—Career Advancement Initiative Model Demonstration Project

AGENCY: Office of Special Education and Rehabilitative Services, Department of Education.

ACTION: Notice; corrections.

SUMMARY: On January 7, 2021, the U.S. Department of Education (the Department) published in the **Federal Register** a notice inviting applications for new awards for fiscal year (FY) 2021 for the Disability Innovation Fund—Career Advancement Initiative Model Demonstration Project, Assistance Listing Number 84.421C (NIA). We are correcting the date that applications were made available to January 8, 2021, the deadline for transmittal of

applications to April 8, 2021, and the deadline for intergovernmental review to June 7, 2021. All other information in the NIA remains the same.

DATES: These corrections are applicable February 19, 2021.

FOR FURTHER INFORMATION CONTACT: Cassandra P. Shoffler, U.S. Department of Education, 400 Maryland Avenue SW, Room 5065A, Potomac Center Plaza, Washington, DC 20202–2800. Telephone: (202) 245–7827. Email: *84.421C@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: On January 7, 2021, the Department published the NIA in the **Federal Register** (86 FR 1092). The NIA provided that applications would be available on January 7, 2021, and that the deadline for transmittal of applications would be 90 days later, on April 7, 2021. However, applications were not available on *Grants.gov* until January 8, 2021. Therefore, this notice corrects the Applications Available date to January 8, 2021, and adjusts the Deadline for Transmittal of Applications by one day to April 8, 2021, to allow 90 days for applicants to submit applications. We also correct the deadline for intergovernmental review to June 7, 2021. All other requirements and conditions in the NIA remain the same.

Corrections:

In FR Doc. 2021–00149 appearing on page 1092 in the **Federal Register** of January 7, 2021, the following corrections are made:

1. On page 1092, in the second column, under **DATES**, and after ''Applications Available:'', we remove the date ''January 7, 2021'' and add, in its place, the date ''January 8, 2021''.

2. On page 1092, in the second column, under **DATES**, and after ''Deadline for Transmittal of Applications:'', we remove the date ''April 7, 2021'' and add, in its place, the date ''April 8, 2021''.

3. On page 1092, in the third column, under **DATES**, and after ''Deadline for Intergovernmental Review:'', we remove the date ''May 7, 2021'' and add, in its place, the date ''June 7, 2021''.

Program Authority: Further Consolidated Appropriations Act, 2020 (Pub. L. 116–94), 133 Stat. 2590–91.

Accessible Format: On request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document and a copy of the application package in an accessible format. The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF) or text format (txt), a thumb drive, an MP3 file, braille, large print, audiotape, or compact disc, or other accessible format.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at *www.govinfo.gov.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register,** in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

David Cantrell,

Deputy Director, Office of Special Education Programs. Delegated the authority to perform the functions and duties of the Assistant Secretary for the Office of Special Education and Rehabilitative Services.

[FR Doc. 2021–03430 Filed 2–18–21; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Applications for New Awards; Training and Information for Parents of Children With Disabilities—Community Parent Resource Centers

AGENCY: Office of Special Education and Rehabilitative Services, Department of Education.

ACTION: Notice.

SUMMARY: The Department of Education (Department) is issuing a notice inviting applications for new awards for fiscal year (FY) 2021 for Training and Information for Parents of Children with Disabilities—Community Parent Resource Centers, Assistance Listing Number 84.328C. These centers will provide objective information, resources, and impartial training that support parents and youth in working in partnership with professionals to establish and meet high expectations for children and youth with disabilities. This notice relates to the approved information collection under OMB control number 1820–0028.

DATES:

Applications Available: February 19, 2021.

Deadline for Transmittal of Applications: April 20, 2021.

Date of Pre-Application Meeting: The Office of Special Education Programs (OSEP) will conduct a pre-application meeting specific to this competition via webinar on March 24, 2021, at 3:00 p.m., Eastern Time. In addition, no later than February 24, 2021, OSEP will post a pre-recorded informational webinar designed to provide technical assistance to interested applicants. Information about the teleconference and the pre-recorded webinar may be found at *www2.ed.gov/fund/grant/apply/osep/new-osep-grants.html.*

Deadline for Intergovernmental Review: June 21, 2021.

ADDRESSES: For the addresses for obtaining and submitting an application, please refer to our Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on February 13, 2019 (84 FR 3768) and available at *www.govinfo.gov/content/pkg/FR-2019-02-13/pdf/2019-02206.pdf.*

FOR FURTHER INFORMATION CONTACT: Carmen Sanchez, U.S. Department of Education, 400 Maryland Avenue SW, Room 5162, Potomac Center Plaza, Washington, DC 20212–5076. Telephone: (202) 245–6595. Email: *Carmen.Sanchez@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The purpose of the Training and Information for Parents of Children with Disabilities—Community Parent Resource Centers, Assistance Listing Number 84.328C, is to ensure that parents of children with disabilities receive impartial training and objective information to help improve outcomes and raise expectations for their children.

Priority: In accordance with 34 CFR 75.105(b)(2)(iv) and (v), this absolute priority is based on allowable activities specified in the statute, or otherwise authorized in the statute (see sections 672 and 681(d) of the Individuals with Disabilities Education Act (IDEA), 20 U.S.C. 1472 and 1481).

Absolute Priority: For FY 2021 and any subsequent year in which we make awards from the list of unfunded applications from this competition, this

priority is an absolute priority. Under 34 CFR 75.105(c)(3) we consider only applications that meet this priority.

This priority is:

Community Parent Resource Centers.

Background

The purpose of this priority is to fund 25 Community Parent Resource Centers (CPRCs) in geographically defined communities. The CPRCs are designed to meet the information and training needs of parents of infants, toddlers, children, and youth with disabilities, ages birth through 26 (collectively, ''children with disabilities''), and youth with disabilities who experience significant isolation from available sources of information and support. These parents can include, for example, low-income parents, parents with limited English proficiency, and parents with disabilities. Youth can include, for example, youth living in low-income households and youth with limited English proficiency.

These CPRCs, consistent with the statute, will provide individualized assistance, training, and resources to help parents work with schools, early childhood providers, and early childhood and educational systems to meet the unique needs of their children and set high expectations and challenging objectives for every child with a disability. CPRCs will also provide high-quality, accurate, and impartial information to families of children with disabilities on the range of educational options that may be available in their State and local community and will coordinate with Parent Training and Information Centers (PTIs) (Assistance Listing Number 84.328M) funded to serve their communities.

CPRCs (*www.parentcenterhub.org/find-your-center/*) promote the effective education of children with disabilities by ''strengthening the role and responsibility of parents and ensuring that families of such children have meaningful opportunities to participate in the education of their children at school and at home'' (section 601(c)(5)(B) of IDEA, 20 U.S.C. 1400(c)(5)(B)). CPRCs, consistent with section 672(b)(4) of IDEA (20 U.S.C. 1472(b)(4)), meet the specific needs of families who experience significant isolation from available sources of information and support, such as underserved families, families with limited English proficiency, and families in which a parent may also experience a disability, among others. CPRCs help parents: (a) Navigate systems providing early intervention, special education and related services, general education, and postsecondary options; (b) understand the educational and service options available to them and their children; (c) understand the nature of their children's disabilities; (d) learn about their rights and responsibilities under IDEA; (e) expand their knowledge of evidence-based [1] practices to help their children succeed; (f) strengthen their collaboration with professionals; (g) locate resources for themselves and their children; and (h) advocate for improved child outcomes and student achievement, increased graduation rates, and improved postsecondary outcomes for all children through participation in program and school reform activities.

By providing parents with impartial information and individualized assistance and training, CPRCs enable parents to—(a) make informed decisions when choosing educational and early learning options that best meet the needs of their children; (b) help their children meet developmental and academic goals; (c) help their children meet challenging expectations established for all children; and (d) prepare their children to achieve positive postsecondary outcomes that lead to lives that are as productive and independent as possible. In addition, CPRCs help youth with disabilities understand their rights and responsibilities and learn self-advocacy skills to prepare them to lead productive lives as independently as possible.

CPRCs are also valuable partners to State and local agencies, providing expertise on how to better support families and youth with disabilities so that they can effectively and efficiently access IDEA services.

Priority

The Department intends to fund 25 grants to establish and operate 25 CPRCs in geographically defined communities proposed by the applicants.

At a minimum, the CPRCs must—(a) increase parents' [2] capacity to help their children with disabilities [3] improve their early learning, school-aged, and postsecondary outcomes; (b) increase parents' knowledge of educational and early learning options; and (c) increase youth with disabilities' capacity to be effective self-advocates.

In addition to these programmatic requirements, to be considered for funding under this priority, applicants must meet the following application and administrative requirements in this priority:

(a) In the narrative section of the application under ''Significance,'' the applicant must—

(1) Present appropriate information on—

(i) The needs of parents in the geographically defined community proposed, including, but not limited to, underserved parents, low-income parents, parents with limited English proficiency, and parents with disabilities;

(ii) The needs of youth with disabilities in the geographically defined community proposed, such as incarcerated youth, youth in foster care, and youth with limited English proficiency, among others; and

(iii) The variety of educational options available within the State and local communities, and how parents and youth are made aware of these options; and

(2) Demonstrate how the proposed project will, within the geographically defined community proposed,—

(i) Address the needs of parents of children with disabilities for high-quality services that increase parents' capacity to help their children with disabilities improve their early learning, school-aged, and postsecondary outcomes. To meet this requirement the applicant must—

(A) Demonstrate knowledge of best practices on providing training and information to the variety of parents in the geographically defined community proposed;

(B) Demonstrate knowledge of best practices in outreach and family-centered services;

(C) Demonstrate knowledge of current education practices and policy initiatives to improve outcomes in early intervention and early childhood education, general and special education, transition services, and postsecondary options; and

(D) Demonstrate knowledge of how to identify and work with appropriate partners in the community and State, including local providers and lead agencies providing services under Part C of IDEA (Part C); State and local educational agencies; State child welfare agencies; disability-specific systems and entities serving families, such as the State's protection and advocacy system; vocational rehabilitation (VR) agencies; and other nonprofits serving families in order to improve outcomes; and

[1] The term ''evidence-based'' means, at a minimum, demonstrating a rationale (as defined in 34 CFR 77.1).

[2] The term ''parent'' includes natural, adoptive, and foster parents, guardians, and individuals acting in the role of ''parent'' as defined in section 602(23) of IDEA, 20 U.S.C. 1401(23).

[3] The term ''disabilities'' refers to the full range of disabilities described in section 602(3) of IDEA, 20 U.S.C. 1401(3).

(ii) Address the needs of youth with disabilities for high-quality services that increase their capacity to be effective self-advocates. To meet this requirement the applicant must—

(A) Demonstrate knowledge of best practices for providing training and information to the variety of youth with disabilities in the geographically defined community proposed;

(B) Demonstrate knowledge of current education practices and policy initiatives in self-advocacy; and

(C) Demonstrate knowledge of how to work with appropriate partners serving youth with disabilities, including State and local VR agencies, other nonprofits, and independent living centers that provide assistance such as postsecondary education options, employment training, and supports.

(b) Demonstrate, in the narrative section of the application under ''Quality of project design and services,'' how the proposed project will—

(1) Use a project logic model [4] to guide the development of project plans and activities within the geographically defined community proposed;

Note: The following websites provide more information on logic models and conceptual frameworks: *www.osepideasthatwork.org/logicModel* and *www.osepideasthatwork.org/resources-grantees/program-areas/ta-ta/tad-project-logic-model-and-conceptual-framework.*

(2) Develop and implement an outreach plan to inform parents of children with disabilities, who experience significant isolation from available sources of information and support, of how they can benefit from the services provided by the CPRC;

(3) Develop and implement an outreach plan to inform youth with disabilities how they can benefit from the services provided by the CPRC;

(4) Provide high-quality services that increase parents' capacity to help their children with disabilities improve their early learning, school-aged, and postsecondary outcomes. To meet this requirement the applicant must include information as to how the services will—

(i) Increase parents' knowledge of—

(A) The nature of their children's disabilities, including their children's strengths and academic, behavioral, and developmental challenges;

(B) The importance of having high expectations for their children and how to help them meet those expectations;

(C) The local, State, and Federal resources available to assist them and their children and local resources that strengthen their connection to their communities;

(D) IDEA and IDEA regulations, and State regulations, policies, and practices implementing IDEA, including—

(*1*) Their rights and responsibilities under IDEA, including procedural safeguards and dispute resolution;

(*2*) Their role on Individualized Family Service Plan (IFSP) and Individualized Education Program (IEP) Teams and how to effectively participate on IFSP and IEP Teams; and

(*3*) How services are provided under IDEA;

(E) Other relevant educational and health care legislation, including the Elementary and Secondary Education Act of 1965, as amended (ESEA); the Rehabilitation Act, especially section 504 of the Rehabilitation Act (Section 504) and the provisions established by the Workforce Innovation and Opportunity Act (WIOA); and the Americans with Disabilities Act (ADA);

(F) Transition services, at all levels, including Part C early intervention to Part B preschool, preschool to elementary school, elementary school to secondary school, secondary school to postsecondary education and workforce options, and re-entry of incarcerated youth to school and the community;

(G) The options available within the State and their community to educate and help their children meet educational and developmental outcomes;

(H) How their children can access and participate in the general education curriculum and inclusive early learning programs, including access to corresponding academic standards and assessments, extracurricular and enrichment opportunities, and other initiatives available to all children;

(I) Early intervention and education practices that improve outcomes and help children meet high expectations; and

(J) School reform efforts to improve student achievement and increase graduation rates; and

(ii) Increase parents' capacity to—

(A) Effectively support their children with disabilities and participate in their children's education;

(B) Make informed decisions when choosing educational and early learning options that best meet the needs of their children;

(C) Communicate effectively and work collaboratively in partnership with early intervention service providers, school-based personnel, related services personnel, and administrators;

(D) Resolve disputes effectively; and

(E) Participate in school reform activities to improve outcomes for all children;

(5) Provide high-quality services that increase youth with disabilities' capacity to be effective self-advocates. To meet this requirement the applicant must include information as to how the services will—

(i) Increase the knowledge of youth with disabilities about—

(A) The nature of their disabilities, including their strengths and their academic, behavioral, and developmental challenges;

(B) The importance of having high expectations for themselves and how to meet those expectations;

(C) The resources available to support their success in secondary and postsecondary education and employment and full participation in their communities;

(D) IDEA, Section 504, the Rehabilitation Act, WIOA, ADA, and other legislation, regulations, and policies that affect people with disabilities;

(E) Their rights and responsibilities while receiving services under IDEA, the Rehabilitation Act, and WIOA, and after transitioning to post-school programs, services, and employment;

(F) How they can participate on IEP Teams;

(G) The options available within the State and their community to help them meet their educational and post-transition outcomes; and

(H) Supported decision making necessary to transition to adult life; and

(ii) Increase the capacity of youth with disabilities to—

(A) Advocate for themselves, including communicating effectively and working collaboratively in partnership with providers; and

(B) Make informed decisions when choosing educational options that best meet their needs;

(6) Use various methods to deliver services, including in-person and remotely through the use of technology;

(7) Use best practices for providing training and information to adult learners and youth;

(8) Establish cooperative partnerships with the PTI funded in the State under section 671 of IDEA serving the CPRC's geographically defined community;

(9) Establish cooperative partnerships with the Parent Training and Information Centers funded under the Rehabilitation Act (Assistance Listing Number 84.235F), the Regional Parent

[4] Logic model (also referred to as a theory of action) means a framework that identifies key project components of the proposed project (*i.e.,* the active ''ingredients'' that are hypothesized to be critical to achieving the relevant outcomes) and describes the theoretical and operational relationships among the key project components and relevant outcomes. See 34 CFR 77.1.

Technical Assistance Centers (Regional PTACs) (Assistance Listing Number 84.328R) region to which they belong, and the Center for Parent Information and Resources (Assistance Listing Number 84.328R); and

(10) Network with local, State, and national organizations and agencies, such as protection and advocacy agencies and VR agencies that serve parents and families of children with disabilities, to better support families and children with disabilities to effectively and efficiently access IDEA and pre-employment transition services.

(c) In the narrative section of the application under ''Quality of the project evaluation,'' include an evaluation plan for the project as described in the following paragraphs. The evaluation plan must describe: Measures for evaluating the quality, accuracy, and impartiality of project services and products; measures of progress in implementation, including the criteria for determining the extent to which the project's products and services have met the goals for reaching its target population; measures of intended outcomes or results of the project's activities in order to evaluate those activities; and how well the goals or objectives of the proposed project, as described in its logic model, have been met.

(d) Demonstrate, in the narrative section of the application under ''Adequacy of resources and quality of project personnel,'' how—

(1) The applicant and any key partners have adequate resources to carry out the proposed activities;

(2) The proposed costs are reasonable in relation to the anticipated results and benefits;

(3) The proposed project will encourage applications for employment from persons who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability, as appropriate; and

(4) The proposed key project personnel, consultants, and subcontractors have the qualifications and experience to carry out the proposed activities and achieve the project's intended outcomes.

(e) Demonstrate, in the narrative section of the application under ''Quality of the management plan,'' how—

(1) The proposed management plan will ensure that the project's intended outcomes will be achieved on time and within budget. To address this requirement, the applicant must describe—

(i) Clearly defined responsibilities for key project personnel, consultants, and subcontractors, as applicable; and

(ii) Timelines and milestones for accomplishing the project tasks;

(2) Key project personnel and any consultants and subcontractors will be allocated and how these allocations are appropriate and adequate to achieve the project's intended outcomes;

(3) The proposed management plan will ensure that the products and services provided are of high quality, impartial, relevant, and useful to recipients;

(4) The board of directors will be used to provide appropriate oversight to the project;

(5) The proposed project will benefit from a diversity of perspectives, including those of families using a variety of education options, youth, educators, and State and local providers, among others, in its development and operation;

(6) The proposed project will ensure that the annual performance reports submitted to the Department will—

(i) Be accurate and timely;

(ii) Include information on the projects' outputs and outcomes; and

(iii) Include, at a minimum, the number and demographics of parents and youth to whom the CPRC provided information and training, the parents' and youth's unique needs, and the levels of service provided to them; and

(7) The project management and staff will—

(i) Make use of the technical assistance (TA) and products provided by the OSEP-funded Center on Parent Information and Resources, Regional PTACs, and other TA centers, as appropriate;

(ii) Participate in developing individualized TA plans with the Regional PTAC, as appropriate; and

(iii) Facilitate one site visit from the Regional PTAC during the grant cycle.

(f) Address the following application requirements. The applicant must—

(1) Include, in Appendix A, a logic model for the project;

(2) Include, in Appendix A, personnel-loading charts and timelines, as applicable, to illustrate the management plan described in the narrative;

(3) Include, in the budget, travel funds to support the project director's attendance annually at one meeting sponsored by OSEP or the Regional PTACs, at a minimum;

(4) Maintain a website that meets government or industry-recognized standards for accessibility and that includes, at a minimum, a current calendar of upcoming events, free informational publications for families, and links to webinars or other online multimedia resources; and

(5) Assure that the information provided to parents is accurate and impartial.

Waiver of Proposed Rulemaking: Under the Administrative Procedure Act (APA) (5 U.S.C. 553), the Department generally offers interested parties the opportunity to comment on proposed priorities and requirements. Section 681(d) of IDEA, however, makes the public comment requirements of the APA inapplicable to the priority in this notice.

Program Authority: 20 U.S.C. 1472 and 1481.

Note: Projects will be awarded and must be operated in a manner consistent with the nondiscrimination requirements contained in Federal civil rights laws.

Applicable Regulations: (a) The Education Department General Administrative Regulations in 34 CFR parts 75, 77, 79, 81, 82, 84, 86, 97, 98, and 99. (b) The Office of Management and Budget Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: Congress has appropriated $27,411,000 for the Training and Information for Parents of Children with Disabilities program for FY 2021, of which we intend to use an estimated $3,000,000 for this competition.

Contingent upon the availability of funds and the quality of applications, we may make additional awards in subsequent years from the list of unfunded applications from this competition.

Estimated Average Size of Awards: $120,000.

Maximum Award: We will not make an award exceeding $120,000 for a single budget period of 12 months.

Estimated Number of Awards: 25.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 60 months.

III. Eligibility Information

1. *Eligible Applicants:* Local parent organizations.

Note: A ''local parent organization'' is a private nonprofit organization (other

than an institution of higher education (IHE)). Section 672(a)(2) of IDEA requires that an eligible local parent organization—

(a) Has a board of directors the majority of whom are parents of children with disabilities ages birth through 26 from the community to be served; and

(b) Has as its mission serving parents of children with disabilities who—

(1) Are ages birth through 26; and

(2) Have the full range of disabilities described in section 602(3) of IDEA.

Note: If you are a nonprofit organization, under 34 CFR 75.51, you may demonstrate your nonprofit status by providing: (1) Proof that the Internal Revenue Service currently recognizes the applicant as an organization to which contributions are tax deductible under section 501(c)(3) of the Internal Revenue Code; (2) a statement from a State taxing body or the State attorney general certifying that the organization is a nonprofit organization operating within the State and that no part of its net earnings may lawfully benefit any private shareholder or individual; (3) a certified copy of the applicant's certificate of incorporation or similar document if it clearly establishes the nonprofit status of the applicant; or (4) any item described above if that item applies to a State or national parent organization, together with a statement by the State or parent organization that the applicant is a local nonprofit affiliate.

2. a. *Cost Sharing or Matching:* This program does not require cost sharing or matching.

b. *Indirect Cost Rate Information:* This program uses an unrestricted indirect cost rate. For more information regarding indirect costs, or to obtain a negotiated indirect cost rate, please see *www2.ed.gov/about/offices/list/ocfo/intro.html.*

c. *Administrative Cost Limitation:* This program does not include any program-specific limitation on administrative expenses. All administrative expenses must be reasonable and necessary and conform to Cost Principles described in 2 CFR part 200 subpart E of the Uniform Guidance.

3. *Subgrantees:* Under 34 CFR 75.708(b) and (c), a grantee under this competition may award subgrants—to directly carry out project activities described in its application—to the following types of entities: IHEs and private nonprofit organizations suitable to carry out the activities proposed in the application.

The grantee may award subgrants to entities it has identified in an approved application.

4. *Other General Requirements:* (a) Recipients of funding under this program must make positive efforts to employ and advance in employment qualified individuals with disabilities (see section 606 of IDEA).

(b) Each applicant for, and recipient of, funding under this program must involve individuals with disabilities, or parents of individuals with disabilities ages birth through 26, in planning, implementing, and evaluating the project (see section 682(a)(1)(A) of IDEA).

IV. Application and Submission Information

1. *Application Submission Instructions:* Applicants are required to follow the Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on February 13, 2019 (84 FR 3768) and available at *www.govinfo.gov/content/pkg/FR-2019-02-13/pdf/2019-02206.pdf,* which contain requirements and information on how to submit an application.

2. *Intergovernmental Review:* This competition is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this competition.

3. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

4. *Recommended Page Limit:* The application narrative is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. We recommend that you (1) limit the application narrative to no more than 50 pages, and (2) use the following standards:

- A ''page'' is 8.5″ x 11″, on one side only, with 1″ margins at the top, bottom, and both sides.
- Double space (no more than three lines per vertical inch) all text in the application narrative, including titles, headings, footnotes, quotations, reference citations, and captions, as well as all text in charts, tables, figures, graphs, and screen shots.
- Use a font that is 12 point or larger.
- Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial.

The recommended page limit does not apply to the cover sheet; the budget section, including the narrative budget justification; the assurances and certifications; or the abstract (follow the guidance provided in the application package for completing the abstract), the table of contents, the list of priority requirements, the resumes, the reference list, the letters of support, or the appendices. However, the recommended page limit does apply to all of the application narrative, including all text in charts, tables, figures, graphs, and screen shots.

V. Application Review Information

1. *Selection Criteria:* The selection criteria for this competition are from 34 CFR 75.210 and are as follows:

(a) *Significance.* (20 points)

(1) The Secretary considers the significance of the proposed project.

(2) In determining the significance of the proposed project, the Secretary considers the following factors:

(i) The extent to which specific gaps or weaknesses in services, infrastructure, or opportunities have been identified and will be addressed by the proposed project, including the nature and magnitude of those gaps or weaknesses; and

(ii) The importance or magnitude of the results or outcomes likely to be attained by the proposed project.

(b) *Quality of project design and services.* (30 points)

(1) The Secretary considers the quality of the services to be provided by the proposed project.

(2) In determining the quality of the services to be provided by the proposed project, the Secretary considers the quality and sufficiency of strategies for ensuring equal access and treatment for eligible project participants who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability.

(3) In addition, the Secretary considers the following factors:

(i) The extent to which the goals, objectives, and outcomes to be achieved by the proposed project are clearly specified and measurable;

(ii) The extent to which the services to be provided by the proposed project reflect up-to-date knowledge from research and effective practice;

(iii) The extent to which the services to be provided by the proposed project are appropriate to the needs of the intended recipients or beneficiaries of those services;

(iv) The extent to which the services to be provided by the proposed project involve the collaboration of appropriate partners for maximizing the effectiveness of project services; and

(v) The extent to which the TA services to be provided by the proposed

project involve the use of efficient strategies, including the use of technology, as appropriate, and the leveraging of non-project resources.

(c) *Quality of the project evaluation.* (15 points)

(1) The Secretary considers the quality of the evaluation to be conducted of the proposed project.

(2) In determining the quality of the evaluation, the Secretary considers the following factors:

(i) The extent to which the methods of evaluation are thorough, feasible, and appropriate to the goals, objectives, and outcomes of the proposed project;

(ii) The extent to which the methods of evaluation are appropriate to the context within which the project operates;

(iii) The extent to which the methods of evaluation will provide performance feedback and permit periodic assessment of progress toward achieving intended outcomes; and

(iv) The extent to which the methods of evaluation include the use of objective performance measures that are clearly related to the intended outcomes of the project and will produce quantitative and qualitative data to the extent possible.

(d) *Adequacy of resources and quality of project personnel.* (20 points)

(1) The Secretary considers the adequacy of resources and quality of project personnel for the proposed project.

(2) In determining the adequacy of resources and quality of project personnel for the proposed project, the Secretary considers the following factors:

(i) The adequacy of support, including facilities, equipment, supplies, and other resources, from the applicant organization or the lead applicant organization;

(ii) The extent to which the costs are reasonable in relation to the objectives, design, and potential significance of the proposed project;

(iii) The extent to which the applicant encourages applications for employment from persons who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability;

(iv) The qualifications, including relevant training and experience, of key project personnel;

(v) The relevance and demonstrated commitment of each partner in the proposed project to the implementation and success of the project.

(e) *Quality of the management plan.* (15 points)

(1) The Secretary considers the quality of the management plan for the proposed project.

(2) In determining the quality of the management plan for the proposed project, the Secretary considers the following factors:

(i) The adequacy of the management plan to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, timelines, and milestones for accomplishing project tasks;

(ii) The extent to which the time commitments of the project director and principal investigator and other key project personnel are appropriate and adequate to meet the objectives of the proposed project;

(iii) The adequacy of mechanisms for ensuring high-quality products and services from the proposed project; and

(iv) How the applicant will ensure that a diversity of perspectives are brought to bear in the operation of the proposed project, including those of parents, teachers, the business community, a variety of disciplinary and professional fields, recipients or beneficiaries of services, or others, as appropriate.

2. *Review and Selection Process:* We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary requires various assurances including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

3. *Additional Review and Selection Process Factors:*

In the past, the Department has had difficulty finding peer reviewers for certain competitions because so many individuals who are eligible to serve as peer reviewers have conflicts of interest. The standing panel requirements under section 682(b) of IDEA also have placed additional constraints on the availability of reviewers. Therefore, the Department has determined that, for some discretionary grant competitions, applications may be separated into two or more groups and ranked and selected for funding within specific groups. This procedure will make it easier for the Department to find peer reviewers by ensuring that greater numbers of individuals who are eligible to serve as reviewers for any particular group of applicants will not have conflicts of interest. It also will increase the quality, independence, and fairness of the review process, while permitting panel members to review applications under discretionary grant competitions for which they also have submitted applications.

4. *Risk Assessment and Specific Conditions:*

Consistent with 2 CFR 200.206, before awarding grants under this competition the Department conducts a review of the risks posed by applicants. Under 2 CFR 200.208, the Secretary may impose specific conditions and, under 2 CFR 3474.10, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

5. *Integrity and Performance System:* If you are selected under this competition to receive an award that over the course of the project period may exceed the simplified acquisition threshold (currently $250,000), under 2 CFR 200.206(a)(2) we must make a judgment about your integrity, business ethics, and record of performance under Federal awards—that is, the risk posed by you as an applicant—before we make an award. In doing so, we must consider any information about you that is in the integrity and performance system (currently referred to as the Federal Awardee Performance and Integrity Information System (FAPIIS)), accessible through the System for Award Management. You may review and comment on any information about yourself that a Federal agency previously entered and that is currently in FAPIIS.

Please note that, if the total value of your currently active grants, cooperative agreements, and procurement contracts from the Federal Government exceeds $10,000,000, the reporting requirements in 2 CFR part 200, Appendix XII, require you to report certain integrity information to FAPIIS semiannually. Please review the requirements in 2 CFR part 200, Appendix XII, if this grant plus all the other Federal funds you receive exceed $10,000,000.

6. *In General:* In accordance with the Office of Management and Budget's guidance located at 2 CFR part 200, all applicable Federal laws, and relevant Executive guidance, the Department will review and consider applications for funding pursuant to this notice inviting applications in accordance with—

(a) Selecting recipients most likely to be successful in delivering results based on the program objectives through an objective process of evaluating Federal award applications (2 CFR 200.205);

(b) Prohibiting the purchase of certain telecommunication and video surveillance services or equipment in alignment with section 889 of the National Defense Authorization Act of 2019 (Pub. L. 115–232) (2 CFR 200.216);

(c) Providing a preference, to the extent permitted by law, to maximize use of goods, products, and materials produced in the United States (2 CFR 200.322); and

(d) Terminating agreements in whole or in part to the greatest extent authorized by law if an award no longer effectuates the program goals or agency priorities (2 CFR 200.340).

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Open Licensing Requirements:* Unless an exception applies, if you are awarded a grant under this competition, you will be required to openly license to the public grant deliverables created in whole, or in part, with Department grant funds. When the deliverable consists of modifications to pre-existing works, the license extends only to those modifications that can be separately identified and only to the extent that open licensing is permitted under the terms of any licenses or other legal restrictions on the use of pre-existing works. Additionally, a grantee or subgrantee that is awarded competitive grant funds must have a plan to disseminate these public grant deliverables. This dissemination plan can be developed and submitted after your application has been reviewed and selected for funding. For additional information on the open licensing requirements, please refer to 2 CFR 3474.20.

4. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *www.ed.gov/fund/grant/apply/appforms/appforms.html.*

(c) Under 34 CFR 75.250(b), the Secretary may provide a grantee with additional funding for data collection analysis and reporting. In this case, the Secretary establishes a data collection period.

5. *Performance Measures:*

Under the Government Performance and Results Act of 1993 (GPRA) and for Department reporting requirements under 34 CFR 75.110, the Department has established a set of performance measures, including long-term measures, that are designed to yield information on the quality, relevance, and usefulness of the materials, products, and services of the Training and Information for Parents of Children with Disabilities program. These measures are:

- Program Performance Measure 1: The percentage of materials used by projects that are deemed to be of high quality;
- Program Performance Measure 2: The percentage of products and services deemed to be of high relevance to educational and early intervention policy and practice;
- Program Performance Measure 3: The percentage of all products and services deemed to be useful to improve educational or early intervention policy or practice; and
- Program Performance Measure 4: The percentage of individuals with disabilities and their families receiving PTI services who report enhanced knowledge and understanding of IDEA services.

Grantees will be required to report information on their project's performance in annual reports to the Department (34 CFR 75.590).

6. *Continuation Awards:* In making a continuation award under 34 CFR 75.253, the Secretary considers, among other things: Whether a grantee has made substantial progress in achieving the goals and objectives of the project; whether the grantee has expended funds in a manner that is consistent with its approved application and budget; and, if the Secretary has established performance measurement requirements, the performance targets in the grantee's approved application.

In making a continuation award, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Other Information

Accessible Format: On request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document and a copy of the application package in an accessible format. The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF) or text format (txt), a thumb drive, an MP3 file, braille, large print, audiotape, or compact disc, or other accessible format.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at *www.govinfo.gov.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at *www.federalregister.gov.* Specifically, through the advanced

search feature at this site, you can limit your search to documents published by the Department.

David Cantrell,

Deputy Director, Office of Special Education Programs. Delegated the authority to perform the functions and duties of the Assistant Secretary for the Office of Special Education and Rehabilitative Services.

[FR Doc. 2021–03418 Filed 2–18–21; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

[OE Docket No. EA–488]

Application To Export Electric Energy; Mercuria Commodities Canada Corporation

AGENCY: Office of Electricity, Department of Energy.

ACTION: Notice of application.

SUMMARY: Mercuria Commodities Canada Corporation (Applicant or MCCC) has applied for authorization to transmit electric energy from the United States to Canada pursuant to the Federal Power Act.

DATES: Comments, protests, or motions to intervene must be submitted on or before March 22, 2021.

ADDRESSES: Comments, protests, motions to intervene, or requests for more information should be addressed by electronic mail to *Electricity.Exports@hq.doe.gov,* or by facsimile to (202) 586–8008.

FOR FURTHER INFORMATION CONTACT: Matt Aronoff, 202–586–5863, *matthew.aronoff@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: The Department of Energy (DOE) regulates exports of electricity from the United States to a foreign country, pursuant to sections 301(b) and 402(f) of the Department of Energy Organization Act (42 U.S.C. 7151(b) and 42 U.S.C. 7172(f)). Such exports require authorization under section 202(e) of the Federal Power Act (16 U.S.C. 824a(e)).

On January 7, 2020, MCCC filed an application with DOE (Application or App.) to transmit electric energy from the United States to Canada for a term of five years. MCCC states that its principal place of business is in Houston, Texas and that it ''is a direct, wholly-owned subsidiary of Mercuria Energy Group Holding S.A. (MEGHSA), a Swiss holding company.'' App. at 1. MCCC represents that it does not ''own, operate or control electric transmission or distribution facilities in the United States over which the export of wholesale electricity could have a reliability, fuel use, or system stability impact,'' and that it is not ''affiliated with any entity that owns, operates, or controls electric transmission or distribution facilities in the United States over which the export of wholesale electricity could have a reliability, fuel use, or system stability impact.'' *Id.* at 3.

MCCC further states that it ''will buy and sell wholesale electricity in the wholesale electric markets within the United States, and will export electricity transmitted across international transmission facilities to be utilized by Presidential permits issued pursuant to Executive Order 10485, as amended.'' App. at 2. MCCC contends that its exports ''will not impair or tend to impede the sufficiency of electricity supplies in the United States or the regional coordination of electric utility planning or operations.'' *Id.* at 4.

MCCC states that its exports ''will be purchased from other suppliers (*i.e.* generators, electric utilities, and other power marketers) voluntarily, and therefore will be surplus to the needs of the selling entities.'' App. at 3–4.

The existing international transmission facilities to be utilized by the Applicant have previously been authorized by Presidential permits issued pursuant to Executive Order 10485, as amended, and are appropriate for open access transmission by third parties.

Procedural Matters: Any person desiring to be heard in this proceeding should file a comment or protest to the Application at the address provided above. Protests should be filed in accordance with Rule 211 of the Federal Energy Regulatory Commission's (FERC) Rules of Practice and Procedure (18 CFR 385.211). Any person desiring to become a party to this proceeding should file a motion to intervene at the above address in accordance with FERC Rule 214 (18 CFR 385.214).

Comments and other filings concerning MCCC's application to export electric energy to Canada should be clearly marked with OE Docket No. EA–488. Additional copies are to be provided directly to Chloe Cromarty, 20 E Greenway Plaza, Suite 650, Houston, Texas 77046, *ccromarty@mercuria.com;* and Greg Johnston, 326 11th Avenue SW, Suite 600, Calgary, Alberta T2R0C5, Canada, *gjohnston@mercuria.com.*

A final decision will be made on the Application after the environmental impacts have been evaluated pursuant to DOE's National Environmental Policy Act Implementing Procedures (10 CFR part 1021) and after DOE determines that the proposed action will not have an adverse impact on the sufficiency of supply or reliability of the U.S. electric power supply system.

Copies of the Application will be made available, upon request, by accessing the program website at *http://energy.gov/node/11845,* or by emailing Matt Aronoff at *matthew.aronoff@hq.doe.gov.*

Signed in Washington, DC, on February 1, 2021.

Christopher Lawrence,

Management and Program Analyst, Energy Resilience Division, Office of Electricity.

[FR Doc. 2021–03401 Filed 2–18–21; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

[OE Docket No. EA–290–D]

Application To Export Electric Energy; Ontario Power Generation Inc.

AGENCY: Office of Electricity, Department of Energy.

ACTION: Notice of application.

SUMMARY: Ontario Power Generation Inc. (Applicant or OPG) has applied for authorization to transmit electric energy from the United States to Canada pursuant to the Federal Power Act.

DATES: Comments, protests, or motions to intervene must be submitted on or before March 22, 2021.

ADDRESSES: Comments, protests, motions to intervene, or requests for more information should be addressed by electronic mail to *Electricity.Exports@hq.doe.gov,* or by facsimile to (202) 586–8008.

FOR FURTHER INFORMATION CONTACT: Matt Aronoff, 202–586–5863, *matthew.aronoff@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: The Department of Energy (DOE) regulates exports of electricity from the United States to a foreign country, pursuant to sections 301(b) and 402(f) of the Department of Energy Organization Act (42 U.S.C. 7151(b) and 42 U.S.C. 7172(f)). Such exports require authorization under section 202(e) of the Federal Power Act (16 U.S.C. 824a(e)).

On January 19, 2021, OPG filed an application with DOE (Application or App.) to transmit electric energy from the United States to Canada for a term of ten years. OPG states that it ''is an Ontario corporation having its principal place of business at Toronto, Ontario, Canada.'' App. at 1. OPG further represents that ''all of the outstanding shares of OPG are held in the name of the Provincial Government of Ontario.'' *Id.* OPG represents that it ''does not own

or control any transmission or distribution assets and does not have a franchised service area in the United States.'' *Id.* OPG clarifies that ''OPGET, a power marketing and trading entity owned by OPG makes power sales within the United States, and at the international border with Canada pursuant to its FERC market-based rate authorization[, but] does *not* export power from the United States to Canada.'' *Id.* at 2.

OPC further states that it ''will purchase the power to be exported from a variety of sources such as power marketers, independent power producers or U.S. electric utilities and Federal power marketing agencies as those terms are defined in section 3(22) and 3(19) of the FPA.'' App. at 4. OPG adds that ''by definition, such power is surplus to the system of the generator''. *Id.* OPG contends that ''the electric power that [it] will export to Canada from these markets, on either a firm or interruptible basis, will not impair the sufficiency of the electric power supply within the United States.'' *Id.*

The existing international transmission facilities to be utilized by the Applicant have previously been authorized by Presidential permits issued pursuant to Executive Order 10485, as amended, and are appropriate for open access transmission by third parties.

Procedural Matters: Any person desiring to be heard in this proceeding should file a comment or protest to the Application at the address provided above. Protests should be filed in accordance with Rule 211 of the Federal Energy Regulatory Commission's (FERC) Rules of Practice and Procedure (18 CFR 385.211). Any person desiring to become a party to this proceeding should file a motion to intervene at the above address in accordance with FERC Rule 214 (18 CFR 385.214).

Comments and other filings concerning OPG's application to export electric energy to Canada should be clearly marked with OE Docket No. EA–290–D. Additional copies are to be provided directly to Jerry L Pfeffer, 1440 New York Avenue NW, Washington, DC 20005, *jpfeffer@skadden.com;* and Karen Cooke, 700 University Avenue, Toronto, Ontario MSG IX6, Canada, *karen.cooke@opg.com.*

A final decision will be made on the Application after the environmental impacts have been evaluated pursuant to DOE's National Environmental Policy Act Implementing Procedures (10 CFR part 1021) and after DOE determines that the proposed action will not have an adverse impact on the sufficiency of supply or reliability of the U.S. electric power supply system.

Copies of the Application will be made available, upon request, by accessing the program website at *http://energy.gov/node/11845,* or by emailing Matt Aronoff at *matthew.aronoff@hq.doe.gov.*

Signed in Washington, DC, on February 1, 2021.

Christopher Lawrence,

Management and Program Analyst, Energy Resilience Division, Office of Electricity.

[FR Doc. 2021–03400 Filed 2–18–21; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2879–012]

Green Mountain Power Corporation; Notice of Intent To Prepare an Environmental Assessment

On January 30, 2020, Green Mountain Power Corporation filed an application for a new major license to continue operating the existing 7.5-megawatt Bolton Falls Hydroelectric Project No. 2879 (Bolton Falls Project or project). The project is located on the Winooski River in Washington County, Vermont. The project does not occupy federal land.

In accordance with the Commission's regulations, on December 1, 2020, Commission staff issued a notice that the project was ready for environmental analysis (REA notice). Based on the information in the record, including comments filed on the REA notice, staff does not anticipate that licensing the project would constitute a major federal action significantly affecting the quality of the human environment. Therefore, staff intends to prepare a draft and final Environmental Assessment (EA) on the application to license the Bolton Falls Project.

The EA will be issued and circulated for review by all interested parties. All comments filed on the EA will be analyzed by staff and considered in the Commission's final licensing decision.

The application will be processed according to the following schedule. Revisions to the schedule may be made as appropriate.

Milestone	Target date
Commission issues Draft EA	August 2021.
Comments on Draft EA	September 2021.
Commission issues Final EA	February 2022.[1]

[1] The Council on Environmental Quality's (CEQ) regulations under 40 CFR 1501.10(b)(1) require that EAs be completed within 1 year of the federal action agency's decision to prepare an EA. This notice establishes the Commission's intent to prepare an EA for the Bolton Falls Project. Therefore, in accordance with CEQ's regulations, the Final EA must be issued within 1 year of the issuance date of this notice.

Any questions regarding this notice may be directed to Michael Tust at (202) 502–6522 or *michael.tust@ferc.gov.*

Dated: February 12, 2021.

Kimberly D. Bose,

Secretary.

[FR Doc. 2021–03369 Filed 2–18–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP21–45–000]

Florida Gas Transmission Company, LLC; Notice of Application and Establishing Intervention and Protest Deadline

Take notice that on January 29, 2021, Florida Gas Transmission Company, LLC (Florida Gas), 1300 Main Street, Houston, Texas 77002, filed in the above referenced docket, an abbreviated application pursuant to section 7(c) of the Natural Gas Act (NGA) and Parts 157 and 284 of the Federal Energy Regulatory Commission's regulations, for authorization to (1) construct two segments of 36-inch-diameter mainline loop extensions totaling 3.2 miles and relocate two associated pig receiver stations in Calhoun and Jefferson Counties, Florida; and (3) uprate a total of 8,000 additional HP distributed among the existing compressor stations

CS 12, CS 14, CS 15, and CS 24 located in Santa Rosa, Gadsden, Taylor, and Gilchrist Counties, Florida (Big Bend Project). Florida Gas states that the project will generate 29,000 MMBtu/d of firm transportation service to the Tampa Electric Company's electric generation plant in Hillsborough County, Florida. Florida Gas estimates the total cost of the project to be $37,527,398 and proposes rolled-in rate treatment, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

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://ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Any questions regarding this application should be directed to Blair Lichtenwalter, Senior Director of Certificates, Florida Gas Transmission Company, LLC, 1300 Main Street, Houston, Texas 77002, or call (713) 989–2605, or fax (713) 989–1205, or by email *blair.lichtenwalter@energytransfer.com.*

Pursuant to section 157.9 of the Commission's Rules of Practice and Procedure,[1] within 90 days of this Notice the Commission staff will either: Complete its environmental review and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or environmental assessment (EA) for this proposal. The filing of an EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

Water Quality Certification

Applicant stated that a water quality certificate under section 401 of the Clean Water Act is required for the project from Florida Department of Environmental Protection (FDEP), Northwest District. The request for certification must be submitted to the certifying agency and to the Commission concurrently. Proof of the certifying agency's receipt date must be filed no later than five (5) days after the request is submitted to the certifying agency.

Public Participation

There are three ways to become involved in the Commission's review of this project: You can file a protest to the project, you can file a motion to intervene in the proceeding, and you can file comments on the project. There is no fee or cost for filing protests, motions to intervene, or comments. The deadline for filing protests, motions to intervene, and comments is 5:00 p.m. Eastern Time on March 5, 2021. How to file protests, motions to intervene, and comments is explained below.

Protests

Pursuant to section 157.205 of the Commission's regulations under the NGA,[2] any person [3] or the Commission's staff may file a protest to the request. If no protest is filed within the time allowed or if a protest is filed and then withdrawn within 30 days after the allowed time for filing a protest, the proposed activity shall be deemed to be authorized effective the day after the time allowed for protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request for authorization will be considered by the Commission.

Protests must comply with the requirements specified in section 157.205(e) of the Commission's regulations,[4] and must be submitted by the protest deadline, which is March 5, 2021. A protest may also serve as a motion to intervene so long as the protestor states it also seeks to be an intervenor.

Interventions

Any person has the option to file a motion to intervene in this proceeding. Only intervenors have the right to request rehearing of Commission orders issued in this proceeding and to subsequently challenge the Commission's orders in the U.S. Circuit Courts of Appeal.

To intervene, you must submit a motion to intervene to the Commission in accordance with Rule 214 of the Commission's Rules of Practice and Procedure [5] and the regulations under the NGA [6] by the intervention deadline for the project, which is March 5, 2021. As described further in Rule 214, your motion to intervene must state, to the extent known, your position regarding the proceeding, as well as your interest in the proceeding. For an individual, this could include your status as a landowner, ratepayer, resident of an impacted community, or recreationist. You do not need to have property directly impacted by the project in order to intervene. For more information about motions to intervene, refer to the FERC website at *https://www.ferc.gov/resources/guides/how-to/intervene.asp.*

All timely, unopposed [7] motions to intervene are automatically granted by operation of Rule 214(c)(1).[8] Motions to intervene that are filed after the intervention deadline are untimely and may be denied. Any late-filed motion to intervene must show good cause for being late and must explain why the time limitation should be waived and provide justification by reference to factors set forth in Rule 214(d) of the Commission's Rules and Regulations.[9] A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies (paper or electronic) of all documents filed by the applicant and by all other parties.

Comments

Any person wishing to comment on the project may do so. The Commission considers all comments received about the project in determining the appropriate action to be taken. To ensure that your comments are timely and properly recorded, please submit your comments on or before March 5, 2021. The filing of a comment alone will not serve to make the filer a party to the

[1] 18 CFR (Code of Federal Regulations) § 157.9.

[2] 18 CFR 157.205.

[3] Persons include individuals, organizations, businesses, municipalities, and other entities. 18 CFR 385.102(d).

[4] 18 CFR 157.205(e).

[5] 18 CFR 385.214.

[6] 18 CFR 157.10.

[7] The applicant has 15 days from the submittal of a motion to intervene to file a written objection to the intervention.

[8] 18 CFR 385.214(c)(1).

[9] 18 CFR 385.214(b)(3) and (d).

proceeding. To become a party, you must intervene in the proceeding.

How To File Protests, Interventions, and Comments

There are two ways to submit protests, motions to intervene, and comments. In both instances, please reference the Project docket number CP21–45–000 in your submission.

(1) You may file your protest, motion to intervene, and comments by using the Commission's *eFiling* feature, which is located on the Commission's website (*www.ferc.gov)* under the link to *Documents and Filings*. New eFiling users must first create an account by clicking on ''*eRegister*.'' You will be asked to select the type of filing you are making; first select General'' and then select ''Protest'', ''Intervention'', or ''Comment on a Filing''.

The Commission's eFiling staff are available to assist you at (202) 502–8258 or *FercOnlineSupport@ferc.gov*.

(2) You can file a paper copy of your submission. Your submission must reference the Project docket number CP21–45–000.

To mail via USPS, use the following address: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

To mail via any other courier, use the following address: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

Protests and motions to intervene must be served on the applicant either by mail at: 1300 Main Street, Houston, Texas 77002 or email (with a link to the document) at: *blair.lichtenwalter@energytransfer.com*. Any subsequent submissions by an intervenor must be served on the applicant and all other parties to the proceeding. Contact information for parties can be downloaded from the service list at the eService link on FERC Online.

Tracking The Proceeding

Throughout the proceeding, additional information about the project will be available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC website at *www.ferc.gov* using the ''eLibrary'' link as described above. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. For more information and to register, go to *www.ferc.gov/docs-filing/esubscription.asp*.

Intervention Deadline: 5:00 p.m. Eastern Time on March 5, 2021.

Dated: February 12, 2021.

Kimberly D. Bose,

Secretary.

[FR Doc. 2021–03370 Filed 2–18–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL21–47–000]

Green Development, LLC v. New England Power Company, Narragansett Electric Company; Notice of Complaint

Take notice that on February 10, 2021, pursuant to sections 206 and 306, of the Federal Power Act, 16 U.S.C. 824e and 825e and Rule 206 and 212 of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR 385.206 and 385.212, Green Development, LLC (Complainant or Green Development) filed a formal complaint against New England Power Company (NEP) and Narragansett Electric Company (NEC) (collectively, Respondents) alleging that: (1) That NEP has assessed, and continues to assess, unauthorized FERC-jurisdictional Direct Assignment Facility Charges (DAF Charges) in connection with four 9.6 MW (AC) solar photovoltaic projects that are interconnected to NEC's distribution system, which charges are not authorized under the Transmission, Markets, and Services Tariff of ISO New England (ISO–NE Tariff); (2) that NEC and NEP have violated and continue to violate the filed-rate (*i.e.,* the ISO–NE Tariff) and FERC precedent through their attempt to pass through the unauthorized DAF Charges to Green Development, and (3) that NEP and NEC have violated and continue to violate the FPA, by seeking to originate and recover unauthorized FERC-jurisdictional DAF Charges via a state jurisdictional tariff. Green Development requests that the Commission find that NEP and NEC's actions are unjust and unreasonable, order the Respondents to cease the unauthorized charges, and to pay refunds as necessary, all as more fully explained in the complaint.

The Complainant certifies that copies of the complaint were served on the contacts listed for Respondents in the Commission's list of Corporate Officials.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. The Respondents' answer and all interventions, or protests must be filed on or before the comment date. The Respondents' answer, motions to intervene, and protests must be served on the Complainant.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

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://ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov,* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on March 2, 2021.

Dated: February 12, 2021.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2021–03379 Filed 2–18–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC21–51–000.
Applicants: AL Sandersville, LLC.
Description: Application for Authorization Under Section 203 of the Federal Power Act of AL Sandersville, LLC.
Filed Date: 2/12/21.
Accession Number: 20210212–5207.
Comments Due: 5 p.m. ET 3/5/21.

Docket Numbers: EC21–52–000.
Applicants: WV Wind Holdco LLC, NedPower Mount Storm LLC.
Description: Joint Application for Authorization Under Section 203 of the Federal Power Act of WV Wind Holdco LLC, et al.
Filed Date: 2/12/21.
Accession Number: 20210212–5230.
Comments Due: 5 p.m. ET 3/5/21.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER12–637–007.
Applicants: Calhoun Power Company, LLC.
Description: Triennial Market Power Analysis for Southeast Region of Calhoun Power Company, LLC for Study Period 2017–2018.
Filed Date: 12/31/20.
Accession Number: 20201231–5088.
Comments Due: 5 p.m. ET 3/1/21.

Docket Numbers: ER21–502–001.
Applicants: New York Independent System Operator, Inc.
Description: Tariff Amendment: Deficiency Response: NYISO Demand Curve Reset 2021–2025 to be effective 3/15/2021.
Filed Date: 2/12/21.
Accession Number: 20210212–5124.
Comments Due: 5 p.m. ET 3/5/21.

Docket Numbers: ER21–700–001.
Applicants: Midcontinent Independent System Operator, Inc.
Description: Tariff Amendment: 2021–02–12_Amendment to Emergency Pricing Filing to be effective 6/1/2021.
Filed Date: 2/12/21.
Accession Number: 20210212–5192.
Comments Due: 5 p.m. ET 3/5/21.

Docket Numbers: ER21–708–001.
Applicants: PJM Interconnection, L.L.C.
Description: Tariff Amendment: Request to Defer Action: ISA, SA No. 5621; Queue No. AF1–195 to be effective 12/31/9998.
Filed Date: 2/12/21.
Accession Number: 20210212–5049.
Comments Due: 5 p.m. ET 3/5/21.

Docket Numbers: ER21–716–001.
Applicants: PJM Interconnection, L.L.C.
Description: Tariff Amendment: Request to Defer Action: ISA, SA No. 5692; Queue No. AF1–198 to be effective 12/31/9998.
Filed Date: 2/12/21.
Accession Number: 20210212–5050.
Comments Due: 5 p.m. ET 3/5/21.

Docket Numbers: ER21–1112–000.
Applicants: Dominion Energy South Carolina, Inc.
Description: § 205(d) Rate Filing: Southeast Energy Exchange Mkt Agr Concurrence to be effective 5/13/2021.
Filed Date: 2/12/21.
Accession Number: 20210212–5052.
Comments Due: 5 p.m. ET 3/14/21.

Docket Numbers: ER21–1136–000.
Applicants: Union Electric Company.
Description: § 205(d) Rate Filing: Co-Tenancy and Shared Facilities Agreement for Outlaw Wind Project to be effective 1/14/2021.
Filed Date: 2/12/21.
Accession Number: 20210212–5173.
Comments Due: 5 p.m. ET 3/5/21.

Docket Numbers: ER21–1137–000.
Applicants: NorthWestern Corporation.
Description: Compliance filing: Compliance Filing re Authority to Transact at MBR in the EIM, Docket No. 11–1858 to be effective 2/8/2021.
Filed Date: 2/12/21.
Accession Number: 20210212–5212.
Comments Due: 5 p.m. ET 3/5/21.

Docket Numbers: ER21–1138–000.
Applicants: ITC Midwest LLC.
Description: Tariff Cancellation: Notice of Cancellation of Rate Schedule No. 138 to be effective 10/5/2020.
Filed Date: 2/12/21.
Accession Number: 20210212–5219.
Comments Due: 5 p.m. ET 3/5/21.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: February 12, 2021.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2021–03382 Filed 2–18–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG21–88–000.
Applicants: Coso Battery Storage, LLC.
Description: Self-Certification of EG or FC of Coso Battery Storage, LLC.
Filed Date: 2/12/21.
Accession Number: 20210212–5103.
Comments Due: 5 p.m. ET 3/5/21.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER20–687–002.
Applicants: Tri-State Generation and Transmission As.
Description: Compliance filing: Compliance Filing to be effective 2/25/2020.
Filed Date: 2/12/21.
Accession Number: 20210212–5126.
Comments Due: 5 p.m. ET 3/5/21.

Docket Numbers: ER21–136–001.
Applicants: Flat Ridge 3 Wind Energy, LLC.
Description: Compliance filing: Flat Ridge 3 Compliance Filing to be effective 12/1/2020.
Filed Date: 2/11/21.
Accession Number: 20210211–5178.
Comments Due: 5 p.m. ET 3/4/21.

Docket Numbers: ER21–1107–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Original WMPA, Service Agreement No. 5978; Queue No. AB2–049 to be effective 8/10/2020.
Filed Date: 2/11/21.
Accession Number: 20210211–5182.
Comments Due: 5 p.m. ET 3/4/21.

Docket Numbers: ER21–1108–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Amendment to PJM SA No. 2824 (Davis-Besse) (amend) to be effective 6/1/2011.
Filed Date: 2/12/21.

Accession Number: 20210212–5019.
Comments Due: 5 p.m. ET 3/5/21.

Docket Numbers: ER21–1109–000.
Applicants: ISO New England Inc.
Description: ISO New England Inc. submits Fourth Quarter Capital Budget Report for 2020.
Filed Date: 2/11/21.
Accession Number: 20210211–5210.
Comments Due: 5 p.m. ET 3/4/21.

Docket Numbers: ER21–1110–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Amendment to Service Agreement No. 3563; Queue Position W4–004B_AT11 (amend) to be effective 4/26/2013.
Filed Date: 2/12/21.
Accession Number: 20210212–5030.
Comments Due: 5 p.m. ET 3/5/21.

Docket Numbers: ER21–1111–000.
Applicants: Alabama Power Company.
Description: § 205(d) Rate Filing: Southeast EEM Agreement Filing to be effective 5/13/2021.
Filed Date: 2/12/21.
Accession Number: 20210212–5033.
Comments Due: 5 p.m. ET 3/5/21.

Docket Numbers: ER21–1113–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Amendment to SA No. 2863; Queue No. U3–029 & U3–030 (amend) to be effective 4/6/2011.
Filed Date: 2/12/21.
Accession Number: 20210212–5054.
Comments Due: 5 p.m. ET 3/5/21.

Docket Numbers: ER21–1114–000.
Applicants: Louisville Gas and Electric Company.
Description: § 205(d) Rate Filing: LGE Concurrence to Southeast Energy Exchange Market Agreement to be effective 5/13/2021.
Filed Date: 2/12/21.
Accession Number: 20210212–5055.
Comments Due: 5 p.m. ET 3/5/21.

Docket Numbers: ER21–1115–000.
Applicants: Duke Energy Progress, LLC, Duke Energy Carolinas, LLC.
Description: § 205(d) Rate Filing: Revisions to Joint OATT to Implement NFEETS to be effective 12/31/9998.
Filed Date: 2/12/21.
Accession Number: 20210212–5056.
Comments Due: 5 p.m. ET 3/5/21.

Docket Numbers: ER21–1116–000.
Applicants: Duke Energy Carolinas, LLC.
Description: § 205(d) Rate Filing: DEC—Southeast Energy Exchange Market Agreement Concurrence to be effective 5/13/2021.
Filed Date: 2/12/21.
Accession Number: 20210212–5061.
Comments Due: 5 p.m. ET 3/5/21.

Docket Numbers: ER21–1117–000.
Applicants: Duke Energy Progress, LLC.
Description: § 205(d) Rate Filing: DEP—Southeast Energy Exchange Market Agreement Concurrence to be effective 5/13/2021.
Filed Date: 2/12/21.
Accession Number: 20210212–5067.
Comments Due: 5 p.m. ET 3/5/21.

Docket Numbers: ER21–1118–000.
Applicants: Louisville Gas and Electric Company.
Description: § 205(d) Rate Filing: Revisions to LG&E/KU Joint OATT Transmission Tariff to be effective 12/31/9998.
Filed Date: 2/12/21.
Accession Number: 20210212–5072.
Comments Due: 5 p.m. ET 3/5/21.

Docket Numbers: ER21–1119–000.
Applicants: Georgia Power Company.
Description: § 205(d) Rate Filing: Southeast EEM Agreement Filing to be effective 5/13/2021.
Filed Date: 2/12/21.
Accession Number: 20210212–5078.
Comments Due: 5 p.m. ET 3/5/21.

Docket Numbers: ER21–1120–000.
Applicants: Kentucky Utilities Company.
Description: § 205(d) Rate Filing: KU Concurrence to Southeast Energy Exchange Market Agreement to be effective 5/13/2021.
Filed Date: 2/12/21.
Accession Number: 20210212–5080.
Comments Due: 5 p.m. ET 3/5/21.

Docket Numbers: ER21–1121–000.
Applicants: Mississippi Power Company.
Description: § 205(d) Rate Filing: Southeast EEM Agreement Filing to be effective 5/13/2021.
Filed Date: 2/12/21.
Accession Number: 20210212–5081.
Comments Due: 5 p.m. ET 3/5/21.

Docket Numbers: ER21–1122–000.
Applicants: Louisville Gas and Electric Company.
Description: § 205(d) Rate Filing: EKPC Third Amended Interconnection Agreement to be effective 2/8/2021.
Filed Date: 2/12/21.
Accession Number: 20210212–5090.
Comments Due: 5 p.m. ET 3/5/21.

Docket Numbers: ER21–1123–000.
Applicants: Arizona Public Service Company.
Description: § 205(d) Rate Filing: Service Agreement No. 380, Amendment No. 1 to be effective 1/20/2021.
Filed Date: 2/12/21.
Accession Number: 20210212–5093.
Comments Due: 5 p.m. ET 3/5/21.

Docket Numbers: ER21–1124–000.
Applicants: Arizona Public Service Company.
Description: § 205(d) Rate Filing: Service Agreement No. 386—AES E&P Agreement to be effective 1/27/2021.
Filed Date: 2/12/21.
Accession Number: 20210212–5095.
Comments Due: 5 p.m. ET 3/5/21.

Docket Numbers: ER21–1125–000.
Applicants: Alabama Power Company.
Description: § 205(d) Rate Filing: OATT Amendments relating to Southeast EEM Agreement to be effective 12/31/9998.
Filed Date: 2/12/21.
Accession Number: 20210212–5096.
Comments Due: 5 p.m. ET 3/5/21.

Docket Numbers: ER21–1126–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Original WMPA, Service Agreement No. 5977; Queue Number AF2–161 to be effective 1/13/2021.
Filed Date: 2/12/21.
Accession Number: 20210212–5104.
Comments Due: 5 p.m. ET 3/5/21.

Docket Numbers: ER21–1127–000.
Applicants: Nevada Power Company.
Description: § 205(d) Rate Filing: Rate Schedule No. 139 Joint Dispatch Agreement Amendment to be effective 4/14/2021.
Filed Date: 2/12/21.
Accession Number: 20210212–5105.
Comments Due: 5 p.m. ET 3/5/21.
Docket Numbers: ER21–1128–000.
Applicants: Dominion Energy South Carolina, Inc.
Description: § 205(d) Rate Filing: Attachment P and P–1—Non-Firm Energy Exchange Transmission Service to be effective 12/31/9998.
Filed Date: 2/12/21.
Accession Number: 20210212–5106.
Comments Due: 5 p.m. ET 3/5/21.

Docket Numbers: ER21–1129–000.
Applicants: Polaris Power Services LLC.
Description: Baseline eTariff Filing: Polaris Power Services LLC Market-Based Rate Tariff to be effective 2/13/2021.
Filed Date: 2/12/21.
Accession Number: 20210212–5110.
Comments Due: 5 p.m. ET 3/5/21.

Docket Numbers: ER21–1130–000.
Applicants: ISO New England Inc., Central Maine Power Company, The United Illuminating Company, Maine Electric Power Company, Inc., Versant Power, Eversource Energy Service Company (as agent), The Connecticut Light and Power Company, NSTAR Electric Company, Public Service Company of New Hampshire, Green

Mountain Power Corporation, New England Power Company, New Hampshire Transmission, LLC, Unitil Energy Systems, Inc., Fitchburg Gas and Electric Light Company

Description: Compliance filing: New England Transmission Owners; Supplemental Order 864 Comp. Filing ER20–2572 to be effective 1/1/2020.

Filed Date: 2/12/21.

Accession Number: 20210212–5123.

Comments Due: 5 p.m. ET 3/5/21.

Docket Numbers: ER21–1131–000.

Applicants: Antelope Expansion 3A, LLC.

Description: § 205(d) Rate Filing: Antelope Expansion 3A, LLC MISA Certificate of Concurrence to be effective 3/1/2021.

Filed Date: 2/12/21.

Accession Number: 20210212–5127.

Comments Due: 5 p.m. ET 3/5/21.

Docket Numbers: ER21–1132–000.

Applicants: Antelope Expansion 3B, LLC.

Description: § 205(d) Rate Filing: Antelope Expansion 3B, LLC MISA Certificate of Concurrence to be effective 3/1/2021.

Filed Date: 2/12/21.

Accession Number: 20210212–5131.

Comments Due: 5 p.m. ET 3/5/21.

Docket Numbers: ER21–1133–000.

Applicants: Hummel Station, LLC.

Description: § 205(d) Rate Filing: Notice of Succession and Revisions to MBR Tariff and Request for Waiver to be effective 2/13/2021.

Filed Date: 2/12/21.

Accession Number: 20210212–5149.

Comments Due: 5 p.m. ET 3/5/21.

Docket Numbers: ER21–1134–000.

Applicants: Hummel Station, LLC.

Description: § 205(d) Rate Filing: Notice of Succession & Revisions to Reactive Service Tariff & Request fo to be effective 1/13/2021.

Filed Date: 2/12/21.

Accession Number: 20210212–5150.

Comments Due: 5 p.m. ET 3/5/21.

Docket Numbers: ER21–1135–000.

Applicants: Pacific Gas and Electric Company.

Description: § 205(d) Rate Filing: WPA For CDWR Delta Pumping Plant TO SA 275 to be effective 2/15/2021.

Filed Date: 2/12/21.

Accession Number: 20210212–5158.

Comments Due: 5 p.m. ET 3/5/21.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: February 12, 2021.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2021–03378 Filed 2–18–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 1508–000]

BOST2 Hydroelectric LLC; Notice of Preliminary Permit Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Competing Applications

On December 1, 2020, BOST2 Hydroelectric LLC filed an application for a preliminary permit, pursuant to section 4(f) of the Federal Power Act (FPA), proposing to study the feasibility of the Shawno County Pump Storage Project to be located near the Embarrass River and the Village of Tigerton, in Shawano County, Wisconsin. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land-disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

The proposed project would consist of the following: (1) A upper circular reservoir with a surface area of 120 acres at a maximum normal pool elevation of 967 feet to 1,017 feet mean sea level (msl); (2) a lower 115,000-foot-long reservoir consisting of eight concentric circular tunnels with varying diameters of approximately 5,400 feet to 4,200 feet at a maximum normal water surface elevation of 1,091 feet msl; (3) a 2,800-foot-long, 16-foot-diameter steel-lined penstock; (4) a 200-foot-long by 70-foot-wide by 130-foot-high powerhouse containing two 333-megawatt (MW) pump/turbines for a total project capacity of 666 MW; (5) a 240-foot-long by 50-foot-wide by 40-foot-high transformer gallery; (6) a 200-foot-long by 200-foot-wide substation; (7) a 200 to 500-foot-long 345-kilovolt transmission line; and (7) appurtenant facilities. The estimated annual generation of the Shawno Pump Storage Project would be 1,450 gigawatt-hours.

Applicant Contact: Mr. Douglas Spalding, c/o Nelson Energy, 8441 Wayzata Boulevard, Suite101, Golden Valley, MN 55426; phone: (952) 544–8133.

FERC Contact: Tyrone Williams; phone: (202) 502–6331.

Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications: 60 days from the issuance of this notice. Competing applications and notices of intent must meet the requirements of 18 CFR 4.36.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, notices of intent, and competing applications using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. The first page of any filing should include docket number P–15058–000.

More information about this project, including a copy of the application, can be viewed or printed on the ''eLibrary'' link of Commission's website at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the docket number (P–15058) in the docket number field to access the document. For assistance, contact FERC Online Support.

Dated: February 12, 2021.

Kimberly D. Bose,

Secretary.

[FR Doc. 2021–03368 Filed 2–18–21; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2020–0351; FRL–10020–42–OAR]

Ozone Transport Commission Recommendation That EPA Require Daily Limits for Emissions of Nitrogen Oxides From Certain Sources in Pennsylvania: Extension of Comment Period

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; extension of comment period.

SUMMARY: On January 15, 2021, EPA issued a **Federal Register** notice of public hearing and supplemental information regarding a recommendation submitted by the Ozone Transport Commission (OTC) to address ongoing ozone pollution in the northeastern United States. The OTC has recommended that EPA require Pennsylvania to revise its state implementation plan (SIP) to include additional control measures that would establish daily limits on emissions of nitrogen oxides (NO_X) from coal-fired electricity generating units (EGUs) with already-installed selective catalytic reduction (SCR) or selective noncatalytic reduction (SNCR) controls. This document extends the comment period for 30 days, from March 8, 2021 to April 7, 2021.

DATES: Comments identified by docket identification (ID) number EPA–HQ–OAR–2020–0351 must be received on or before April 7, 2021.

ADDRESSES: Follow the detailed instructions provided under **ADDRESSES** in the **Federal Register** document of January 15, 2021 (86 FR 4049).

FOR FURTHER INFORMATION CONTACT: Beth Murray, Clean Air Markets Division, Office of Atmospheric Programs, Office of Air and Radiation, Environmental Protection Agency, 202–343–9115, *murray.beth@epa.gov.*

SUPPLEMENTARY INFORMATION: This document extends the public comment period established in the **Federal Register** document of January 15, 2021 (86 FR 4049), which opened a public comment period for supplemental information concerning a recommendation submitted by the OTC to EPA under CAA section 184(c). In the January 15, 2021 notice, EPA discussed the relevant statutory provisions, described the steps EPA is following to facilitate public participation in the Agency's process for reaching a decision on the recommendation, discussed the OTC recommendation—including the Delaware, Maryland, and New Jersey rules that OTC believes should become the standards for EPA's approval of a responsive SIP revision from Pennsylvania, identified the potentially affected Pennsylvania EGUs, and summarized the supporting information provided by the OTC. EPA further provided information on the potentially affected EGUs' historical emissions and on regulatory context that may be relevant to EPA's decision on the recommendation.

EPA is hereby extending the public comment period, which was set to end on March 8, 2021, to April 7, 2021. After considering a request to extend the comment period received from a stakeholder, EPA is extending the comment period for the following reasons: (1) The legal and technical complexity of the analysis of the recommendation; (2) the need for stakeholders to consider the interaction of this decision with other actions the Agency is concurrently considering; (3) the stakeholders' need for additional time to review and develop constructive comments and related analyses on the recommendation. To submit comments, or access the docket, please follow the detailed instructions provided under **ADDRESSES** in the **Federal Register** document of January 15, 2021. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

Hans Christopher Grundler,

Director, Office of Atmospheric Programs.

[FR Doc. 2021–03367 Filed 2–18–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPPT–2020–0738; FRL–10019–82]

Chemical Category for Octahydro-Tetramethyl-Naphthalenyl-Ethanone (OTNE); Manufacturer Request for Risk Evaluation Under the Toxic Substances Control Act (TSCA); Notice of Availability and Request for Comments

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is announcing the availability of and soliciting public comment on a manufacturer request for a risk evaluation under the Toxic Substances Control Act (TSCA) of ethanone, 1-(1,2,3,4,5,6,7,8-octahydro-2,3,5,5-tetramethyl-2-naphthalenyl), ethanone, 1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8-tetramethyl-2-naphthalenyl), ethanone, 1-(1,2,3,4,6,7,8,8a-octahydro-2,3,8,8-tetramethyl-2-naphthalenyl), and ethanone, 1-(1,2,3,5,6,7,8,8a-octahydro-2,3,8,8-tetramethyl-2-naphthalenyl) (collectively, ''OTNE''). The request was made by International Flavors and Fragrances, Inc. (IFF), Privi Organics USA Corporation (Privi), and DRT America, Inc. (DRT) through the OTNE Consortium. EPA conducts risk evaluations to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment without consideration of costs or other non-risk factors, including an unreasonable risk to potentially exposed or susceptible subpopulations, under the conditions of use. In the docket associated with this request is the manufacturer request for an EPA-conducted risk evaluation and possible additional conditions of use EPA has identified for inclusion within the scope of a risk evaluation of OTNE. EPA specifically invites public comment on the inclusion of any additional conditions of use and potentially exposed or susceptible subpopulations. The Agency is in the process of broadly re-examining how it intends to implement these and other provisions of amended TSCA including determining how new executive orders and other direction provided by the Biden-Harris Administration will be addressed. This process would benefit greatly from stakeholder feedback. After considering comments received in response to this solicitation, EPA will determine whether to grant or deny the manufacturer request. All TSCA risk evaluations, whether EPA-initiated or manufacturer-requested, will be conducted in the same manner.

DATES: Comments must be received on or before April 5, 2021.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2020–0738, through the Federal eRulemaking Portal at *http://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html*.

Please note that due to the public health emergency the EPA Docket Center (EPA/DC) and Reading Room

were closed to public visitors on March 31, 2020. Our EPA/DC staff will continue to provide customer service via email, phone, and webform. For further information on EPA/DC services, docket contact information and the current status of the EPA/DC and Reading Room, please visit *https://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Jeffrey Putt, Existing Chemicals Risk Management Division (Mail Code 7404T), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–3703; email address: *putt.jeffrey@epa.gov*.

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

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this apply to me?

This notice is directed to the public in general and may be of interest to persons who currently or may manufacture (including import), process, distribute, use, and/or dispose of OTNE. The action may also be of interest to chemical processors, distributors in commerce, and users; non-governmental organizations in the environmental and public health sectors; state and local government agencies; and members of the public. Since other entities may also be interested in these risk evaluations, EPA has not attempted to describe all the specific entities that may be affected by this action.

B. What is EPA's authority for taking this action?

TSCA section 6(b) requires that EPA conduct risk evaluations on existing chemical substances and identifies the minimum components EPA must include in all chemical substance risk evaluations. 15 U.S.C. 2605(b). The risk evaluation must not consider costs or other non-risk factors. 15 U.S.C. 2605(b)(4)(F)(iii). The specific risk evaluation process is set out in 40 CFR part 702 and summarized on EPA's website at *https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluations-existing-chemicals-under-tsca*.

TSCA section 6(b) also allows manufacturers of a chemical substance to request an EPA-conducted risk evaluation on the chemical substance. TSCA required EPA to develop the form and manner under which these requests must be made, and the criteria for which EPA will determine whether to grant a request. These requirements and criteria are set out in 40 CFR 702.37.

Under 40 CFR 702.37(e)(3), EPA is required to assess whether the circumstances identified in a manufacturer request for a risk evaluation constitute conditions of use (as defined under TSCA section (3)(4) and implementing regulations at 40 CFR 702.33), and whether those conditions of use warrant inclusion within the scope of a risk evaluation for the chemical substance. EPA will also assess what, if any, additional conditions of use warrant inclusion within the scope of a risk evaluation for the chemical substance. EPA will conduct these assessments based on the same considerations applied in the same manner as it would for a risk evaluation in the EPA-initiated risk evaluation process.

No later than 60 business days after receiving a manufacturer request for risk evaluation that EPA has determined to be facially complete (meeting the criteria set forth in 40 CFR 702.37(e)(1)), EPA is required to submit for publication the receipt of the request in the **Federal Register**, open a public docket for the request (which must contain the manufacturer request and EPA's possible additional conditions of use), and provide no less than 45 calendar days for public comment. This notice identifies the docket containing the manufacturer request, EPA's possible additional conditions of use, and the basis for including those possible additional conditions of use. During the public comment period, the public may submit comments and information relevant to the requested risk evaluation, as well as the additional possible conditions of use EPA is including in the docket.

After the comment period closes, the Agency has up to 60 days to either grant or deny the request to conduct a risk evaluation under 40 CFR 702.37(e)(6). EPA will review the request along with any additional information received during the comment period, and grant the request if it determines the request meets all of the following requirements listed under 40 CFR 702.37(e)(6)(ii):

- The circumstances identified in the request constitute conditions of use that warrant inclusion in a risk evaluation for the chemical substance;
- EPA has all the information needed to conduct such risk evaluation on the conditions of use that were the subject of the request; and
- All other criteria and requirements of 40 CFR 702.37 have been met.

C. What action is EPA taking?

EPA is announcing the availability of and soliciting public comment on a manufacturer request for a risk evaluation of OTNE under TSCA section 6(b) that is described in detail in Unit II. Also available in the docket associated with this request are the manufacturer request and possible additional conditions of use EPA identified for inclusion in a risk evaluation of OTNE. This notice satisfies 40 CFR 702.37(e)(4).

D. What should I consider as I prepare my comments for EPA?

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

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html*.

II. Summary of This Manufacturer Request

On November 20, 2020, EPA received a complete manufacturer request for a TSCA risk evaluation of OTNE that was made by IFF, Privi, and DRT, through the OTNE Consortium. After determining the request was facially complete (*i.e.,* EPA determined that the request appeared to be consistent with the requirements in 40 CFR 702.37(b) through (d), such as including all the necessary information in those paragraphs), EPA notified the public of the receipt of the request on December 8, 2020 via a listserv announcement to stakeholders.

A. What is OTNE?

OTNE is used as a fragrance ingredient. The four chemical substances in this chemical category are listed on the TSCA Inventory as: Ethanone, 1-(1,2,3,4,5,6,7,8-octahydro-

2,3,5,5-tetramethyl-2-naphthalenyl), ethanone, 1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8-tetramethyl-2-naphthalenyl), ethanone, 1-(1,2,3,4,6,7,8,8a-octahydro-2,3,8,8-tetramethyl-2-naphthalenyl), and ethanone, 1-(1,2,3,5,6,7,8,8a-octahydro-2,3,8,8-tetramethyl-2-naphthalenyl). The associated Chemical Abstracts Service Registry Numbers (CASRNs) are 54464–59–4, 54464–57–2, 68155–67–9, and 68155–66–8, respectively. TSCA section 26(c) provides for EPA to take action on a category of chemical substances whenever authorized or required by TSCA to take action on a chemical substance. 15 U.S.C. 2625(c). EPA is treating these four CASRNs (54464–59–4, 54464–57–2, 68155–67–9, and 68155–66–8) as a category of chemical substances for purposes of this manufacturer-requested risk evaluation.

B. What are the conditions of use?

The manufacturer request for a risk evaluation of OTNE identifying conditions of use of interest to the manufacturer is included in docket EPA–HQ–OPPT–2020–0738. Subject to further analysis and public comment, EPA anticipates including activities identified in the request as conditions of use in the risk evaluation of OTNE.

EPA has identified additional conditions of use pursuant to 40 CFR 702.37(e)(3), which are also included in docket EPA–HQ–OPPT–2020–0738.

III. Request for Comment

The docket associated with this request contains the manufacturer request (excluding information claimed as CBI), EPA's possible additional conditions of use as described 40 CFR 702.37(e)(3), and the basis for these possible additions. During the comment period, the public may submit comments and information relevant to the requested risk evaluation; in particular, commenters are encouraged to identify any information not included in the request that the commenters believe would be needed to conduct a risk evaluation, and to provide any other information relevant to EPA's possible additional conditions of use, such as information on other conditions of use of the chemical substances than those included in the request or in EPA's possible additional conditions of use. 40 CFR 702.37(e)(4). In addition, at any time prior to the end of the comment period, the requesting manufacturer(s) may supplement the original request with any new information it receives. 40 CFR 702.37(e)(5).

Authority: 15 U.S.C. 2601 *et seq.*

Jane Nishida,

Acting Administrator.

[FR Doc. 2021–03383 Filed 2–18–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OW–2019–0372; FRL–10019–29–OW]

National Pollutant Discharge Elimination System (NPDES) 2021 Issuance of the Multi-Sector General Permit for Stormwater Discharges Associated With Industrial Activity

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of final permit issuance.

SUMMARY: All 10 of the Environmental Protection Agency's (EPA) Regions are finalizing the 2021 National Pollutant Discharge Elimination System (NPDES) general permit for stormwater discharges associated with industrial activity, also referred to as the ''2021 Multi-Sector General Permit (MSGP)'' or the ''final permit.'' This final permit replaces EPA's administratively continued 2015 MSGP that expired on June 3, 2020. EPA is issuing this permit for five (5) years to provide permit coverage to eligible operators in all areas of the country where EPA is the NPDES permitting authority, including Idaho (until July 1, 2021), Massachusetts, New Hampshire, New Mexico, Indian country lands, Puerto Rico, the District of Columbia, and most U.S. territories and protectorates. This **Federal Register** document summarizes the final permit. EPA encourages the public to read the final permit and accompanying fact sheet to better understand the final permit. The final permit and fact sheet can be found at *https://www.epa.gov/npdes/stormwater-discharges-industrial-activities.*

DATES: The final permit becomes effective on March 1, 2021. This effective date is necessary to provide dischargers with the immediate opportunity to comply with Clean Water Act (CWA) requirements in light of the expiration of the 2015 MSGP on June 3, 2020. In accordance with 40 CFR part 23, the 2021 MSGP shall be considered issued for the purpose of judicial review on March 5, 2021. Under CWA section 509(b), judicial review of this general permit can be requested by filing a petition for review in the United States Court of Appeals within 120 days after the permit is issued. Under CWA section 509(b)(2), the requirements in this permit may not be challenged later in civil or criminal proceedings to enforce these requirements. In addition, this permit may not be challenged in other agency proceedings. Deadlines for submittal of a Notice of Intent (NOI) are provided in Part 1.3 of the 2021 MSGP. The 2021 MSGP also provides additional dates for compliance with the terms of the permit.

FOR FURTHER INFORMATION CONTACT: For further information on the final permit, contact the appropriate EPA Regional office listed in Section I.F of this document, or Emily Halter, EPA Headquarters, Office of Water, Office of Wastewater Management (4203M), 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone number: 202–564–3324; email address: *halter.emily@epa.gov.*

SUPPLEMENTARY INFORMATION: This section is organized as follows:

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I. General Information

A. Does this action apply to me?

The final permit covers stormwater discharges to waters of the United States from industrial facilities in the 30 sectors shown below:

Sector A—Timber Products.
Sector B—Paper and Allied Products Manufacturing.
Sector C—Chemical and Allied Products Manufacturing.

Sector D—Asphalt Paving and Roofing Materials Manufactures and Lubricant Manufacturers.
Sector E—Glass, Clay, Cement, Concrete, and Gypsum Product Manufacturing.
Sector F—Primary Metals.
Sector G—Metal Mining (Ore Mining and Dressing).
Sector H—Coal Mines and Coal Mining-Related Facilities.
Sector I—Oil and Gas Extraction.
Sector J—Mineral Mining and Dressing.
Sector K—Hazardous Waste Treatment Storage or Disposal.
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Sector M—Automobile Salvage Yards.
Sector N—Scrap Recycling Facilities.
Sector O—Steam Electric Generating Facilities.
Sector P—Land Transportation.
Sector Q—Water Transportation.
Sector R—Ship and Boat Building or Repairing Yards.
Sector S—Air Transportation Facilities.
Sector T—Treatment Works.
Sector U—Food and Kindred Products.
Sector V—Textile Mills, Apparel, and other Fabric Products Manufacturing.
Sector W—Furniture and Fixtures.
Sector X—Printing and Publishing.
Sector Y—Rubber, Miscellaneous Plastic Products, and Miscellaneous Manufacturing Industries.
Sector Z—Leather Tanning and Finishing.
Sector AA—Fabricated Metal Products.
Sector AB—Transportation Equipment, Industrial or Commercial Machinery.
Sector AC—Electronic, Electrical, Photographic and Optical Goods.
Sector AD—Reserved for Facilities Not Covered Under Other Sectors and Designated by the Director.

Coverage under the final 2021 MSGP is available to operators of eligible facilities located in areas where the EPA is the CWA section 402 permitting authority. A list of eligible areas is included in Appendix C of the final 2021 MSGP.

B. How can I get copies of these documents and other related information?

1. *Docket.* EPA has established a docket for this action under Docket ID No. EPA–HQ–OW–2019–0372. Although all documents in the docket are listed in an index, some information is not publicly available, *i.e.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Publicly available docket materials are available electronically through *www.regulations.gov.* Out of an abundance of caution for members of the public and EPA staff, the EPA Docket Center and Reading Room are currently closed to the public, with limited exceptions, to reduce the risk of transmitting COVID–19. When the EPA Docket Center and Reading Room re-open, publicly available docket materials will be available in hard copy at the Water Docket in the EPA Docket Center, (EPA/DC) EPA West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Water Docket is (202) 566–2426.

2. *Electronic Access.* Electronic versions of this final permit and accompanying fact sheet are available on the EPA's NPDES website at *https://www.epa.gov/npdes/stormwater-discharges-industrial-activities.*

An electronic version of the public docket is available through the EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *https://www.regulations.gov* to view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. For additional information about the EPA's public docket, visit the Agency's Docket Center homepage at *https://www.epa.gov/dockets.* Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the Docket Facility identified in Section I.B.1.

C. Who are the EPA regional contacts for the final permit?

For the EPA Region 1, contact David Gray at: (617) 918–1577 or *gray.davidj@epa.gov.*

For the EPA Region 2, contact Stephen Venezia at: (212) 637–3856 or *venezia.stephen@epa.gov,* or for Puerto Rico contact Sergio Bosques at: (787) 977–5838 or *bosques.sergio@epa.gov.*

For the EPA Region 3, contact Carissa Moncavage at: (215) 814–5798 or *moncavage.carissa@epa.gov.*

For the EPA Region 4, contact Mike Mitchell at: (404) 562–9303 or *mitchell.michael@epa.gov.*

For the EPA Region 5, contact Andrea Schaller at: 312–886–0746 or *schaller.andrea@epa.gov.*

For the EPA Region 6, contact Nasim Jahan at: (214) 665–7522 or *jahan.nasim@epa.gov.*

For the EPA Region 7, contact Mark Matthews at: (913) 551–7635 or *matthews.mark@epa.gov.*

For the EPA Region 8, contact Paul Garrison at: (303) 312–6016 or *garrison.paul@epa.gov.*

For the EPA Region 9, contact Eugene Bromley at: (415) 972–3510 or *bromley.eugene@epa.gov.*

For the EPA Region 10, contact Margaret McCauley at: (206) 553–1772 or *mccauley.margaret@epa.gov.*

II. Background of the Industrial Stormwater Program

Section 405 of the Water Quality Act of 1987 added section 402(p) of the CWA, which directed EPA to develop a phased approach to regulate stormwater discharges under the NPDES program. EPA published a final regulation on the first phase of this program on November 16, 1990, establishing permit application requirements for ''stormwater discharges associated with industrial activity.'' See 55 FR 48065. In that final regulation, EPA defined the term ''stormwater discharge associated with industrial activity'' in a comprehensive manner to cover a wide variety of facilities. See 40 CFR 122.26(b)(14). EPA issues the 2021 MSGP under this statutory and regulatory authority.

III. Summary of the 2021 MSGP

The 2021 MSGP replaces the administratively continued 2015 MSGP, which was issued for a five-year term on June 4, 2015 and expired on June 3, 2020 (see 80 FR 34403). EPA proposed a new MSGP for a 90-day comment period from March 2 to June 1, 2020 (see 85 FR 12288). Since the new MSGP was proposed in 2020, EPA hereinafter refers to the proposed permit of the 2021 MSGP as the ''proposed 2020 MSGP.'' EPA received 195 total comment letters and 1865 unique comments on the proposed 2020 MSGP. EPA considered the comments submitted as part of this public process when finalizing 2021 MSGP. Response to comments are discussed in detail in a separate document, titled ''2021 MSGP Response to Comments,'' which can be found in the docket (Docket ID No. EPA–HQ–OW–2019–0372).

The 2021 MSGP covers stormwater discharges from industrial facilities in areas where EPA is the NPDES permitting authority in EPA Regions 1, 2, 3, 4, 5, 6, 7, 8, 9 and 10. This permit covers facilities in the state of Idaho until the transfer of NPDES Permitting Authority to Idaho for stormwater general permits on July 1, 2021. The geographic coverage of this permit is listed in Appendix C of the permit. This permit authorizes stormwater discharges from industrial facilities in 30 sectors, as shown in section I.A. of this document.

Like the 2015 MSGP, the 2021 MSGP is structured in nine parts: general

requirements that apply to all facilities (*i.e.,* eligibility requirements, effluent limitations, inspection and monitoring requirements, Stormwater Pollution Prevention Plan (SWPPP) requirements, and reporting and recordkeeping requirements) (Parts 1–7); industrial sector-specific conditions (Part 8); and state and tribal-specific requirements applicable to facilities located within individual states or Indian Country (Part 9). Additionally, the appendices provide the paper forms for the Notice of Intent (NOI), the Notice of Termination (NOT), the Conditional No Exposure Exclusion (also known as the No Exposure Certification or NEC), the Discharge Monitoring Report (DMR), and the Annual Report, as well as step-by-step procedures for determining eligibility with respect to protecting National Historic Preservation Act-protected properties and Endangered Species Act (ESA)-listed species and critical habitat, and for calculating site-specific, hardness-dependent benchmarks.

A. 2015 MSGP Litigation and National Academies Study

After the EPA issued the 2015 MSGP, numerous environmental non-governmental organizations (NGOs) [1] challenged the permit, two industry groups [2] intervened, and a Settlement Agreement was signed in 2016 with all parties. The settlement agreement did not affect the 2015 MSGP but stipulated several terms and conditions that EPA agreed to address in the proposed 2020 MSGP. One key term from the Settlement Agreement stipulated that EPA fund a study conducted by the National Academies of Sciences, Engineering, and Medicine's National Research Council (NRC) on potential permit improvements, focused primarily on monitoring requirements, for consideration in the next MSGP. In the Settlement Agreement, EPA agreed that, when drafting the proposed 2020 MSGP, the Agency would consider the recommendations suggested in the completed NRC Study.

The NRC delivered the results of their study, *Improving the EPA Multi-Sector General Permit for Industrial Stormwater Discharges,* in February 2019. In Part III of the 2021 MSGP Fact Sheet, titled ''The National Research Council (NRC) National Academies of Sciences (NAS) Industrial Stormwater Study,'' EPA outlines in detail how the Agency considered each recommendation from the NRC study in the proposed permit and which proposed requirements informed by the NRC study the Agency finalized in the 2021 MSGP. The NRC study can be found at the following website: *https://www.nap.edu/catalog/25355/improving-the-epa-multi-sector-general-permit-for-industrial-stormwater-discharges.*

B. Summary of Significant Final Permit Changes From the 2015 MSGP

The 2021 MSGP includes several new or modified requirements from the 2015 MSGP.

1. *Streamlining of permit.* EPA streamlined and simplified language throughout the final permit to present the requirements in a more clear and readable manner. Regarding the structure of the permit, Part 4 (Monitoring) was previously Part 6 in the 2015 MSGP; Part 5 (Corrective Actions and AIM) was previously Part 4 in the 2015 MSGP; and Part 6 (SWPPP) was previously Part 5 in the 2015 MSGP. Formatting the final permit in this new order (Monitoring, followed by Corrective Actions and AIM, then SWPPP requirements) provides the information in a sequential way as the latter parts often refer back to requirements in previous parts of the permit. This new structure should enhance understanding of and compliance with the permit's requirements. EPA also made a few additional edits to improve permit readability and clarity. EPA revised the wording of many eligibility requirements to be an affirmative expression of the requirement instead of assumed ineligibility unless a condition was met. For example, Part 1.1.6.2 reads ''If you discharge to an 'impaired water' . . . you must do one of the following:''. In comparison, the 2015 MSGP reads ''If you are a new discharger or a new source . . . you are ineligible for coverage under this permit to discharge to an 'impaired water' . . . unless you do one of the following:''. EPA also numbered permit conditions that were previously in bullet form to make it easier to follow and reference the permit conditions. Finally, the language of the final permit was changed from passive to active voice where appropriate (*e.g.,* ''Samples must be collected . . .'' now reads ''You must collect samples . . .'').

2. *Public sign of permit coverage.* The 2021 MSGP includes a new requirement that operators must post a sign of permit coverage at a safe, publicly accessible location in close proximity to the facility. This notice must include basic information about the facility (*e.g.,* the NPDES ID number), information that informs the public on how to request the facility's Stormwater Pollution Prevention Plan (SWPPP), and how to contact the facility and EPA if stormwater pollution is observed in the discharge. This requirement will make the procedure for requesting a SWPPP easily understandable by the public and improve transparency of the process to report possible violations. Operators are not required to post a sign of their permit coverage where other laws or local ordinances prohibit such signage. See Part 1.3.5 of the permit and fact sheet.

3. *Consideration of stormwater control measure enhancements for major storm events.* The 2021 MSGP requires that operators consider implementing enhanced stormwater control measures for facilities that could be impacted by major storm events, such as hurricanes, storm surge, and flood events. EPA is not requiring operators to implement additional controls if the operator determines such controls to be unnecessary, but EPA is requiring operators to consider the benefits of selecting and designing control measures that reduce risks to their industrial facility and the potential impact of pollutants in stormwater discharges caused by major storm events. See Part 2.1.1 of the permit and fact sheet.

4. *Monitoring changes.*

• *Indicator monitoring for pH, TSS, and COD for subsectors without benchmark monitoring.* The 2021 MSGP includes a new provision that requires certain operators to conduct indicator analytical monitoring for three parameters—pH, Total Suspended Solids (TSS), and Chemical Oxygen Demand (COD)—quarterly for the duration of the permit. This requirement applies to all operators in the following subsectors that do not have sector-specific benchmark monitoring requirements in the 2021 MSGP: B2, C5, D2, E3, F5, I1, J3, L2, N2, O1, P1, R1, T1, U3, V1, W1, X1, Y2, Z1, AB1, AC1, and AD1. Indicator monitoring is ''report-only'' and does not have a threshold or baseline value for comparison, therefore no follow-up action is triggered or required based on the sampling results. The requirement in Part 2.2.1 that the operator's discharge be controlled as necessary such that the receiving water of the United States will meet applicable water quality standards still applies. These three parameters will provide operators and EPA with a baseline and comparable understanding of industrial

[1] Environmental NGOs included Waterkeeper Alliance, Apalachicola Riverkeeper, Galveston Baykeeper, Raritan Baykeeper, Inc. d/b/a NY/NJ Baykeeper, Snake River Waterkeeper, Ecological Rights Foundation, Our Children's Earth Foundation, Puget Soundkeeper, Lake Pend Oreille Waterkeeper, and Conservation Law Foundation (collectively, ''Petitioners'').

[2] Industry intervenors included the Federal Water Quality Coalition and the Federal Storm Water Association.

stormwater discharge quality, broader water quality problems, and stormwater control measure effectiveness at these facilities. See Part 4.2.1.1.a of the permit and fact sheet.

• *Indicator monitoring for polycyclic aromatic hydrocarbons (PAHs) for certain sectors/activities.* The 2021 MSGP includes a new provision that requires certain operators to conduct report-only indicator analytical monitoring for polycyclic aromatic hydrocarbons (PAHs) bi-annually (twice per year) during their first and fourth years of permit coverage. This requirement applies to the following operators: Operators in all sectors with stormwater discharges from paved surfaces that will be sealed or re-sealed with coal-tar sealcoat where industrial activities are located during coverage under this permit; operators in sectors A (facilities that manufacture, use, or store creosote or creosote-treated wood in areas that are exposed to precipitation), C (SIC Code 2911), D, F, H, I, M, O, P (SIC Codes 4011, 4013, and 5171), Q (SIC Code 4493), R, and S. Indicator monitoring is ''report-only'' and does not have a threshold or baseline value for comparison, therefore no follow-up action is triggered or required based on the sampling results. The requirement in Part 2.2.1 that the operator's discharge be controlled as necessary such that the receiving water of the United States will meet applicable water quality standards still applies. EPA determined that the sectors and activities listed above are likely to have industrial activities with potential petroleum hydrocarbon exposure to precipitation that could result in the discharge of PAHs in stormwater based on a review of EPA's sector-specific fact sheets and a detailed literature review included in the docket (ID No. EPA–HQ–OW–2019–0372). PAH monitoring data will provide operators and EPA with a baseline and comparable understanding of industrial stormwater discharge quality with respect to discharges of PAHs at these facilities. EPA plans to use the indicator monitoring data collected to conduct an initial quantitative assessment of the levels of PAHs in industrial stormwater, further identify industrial activities with the potential to discharge PAHs in stormwater, and inform future consideration of PAH benchmark monitoring for sectors with the potential to discharge PAHs in stormwater. See Part 4.2.1.1.b of the permit and fact sheet.

• *Updating the benchmark monitoring schedule.* The 2021 MSGP requires that applicable operators conduct benchmark monitoring quarterly in their first and fourth years of permit coverage. EPA reminds operators and the public that benchmark thresholds are not effluent limitations. This permit requires benchmark monitoring as gauge of the performance of facilities' stormwater control measures. Benchmark monitoring begins in the first full quarter of permit coverage for four quarters. In the 2015 MSGP, an operator that did not exceed the four-quarter annual average for a given parameter in the first four quarters of permit coverage could discontinue benchmark monitoring for that parameter for the remainder of the permit. Under the 2021 MSGP, an operator that does not exceed the four-quarter annual average for a given parameter in the first four quarters of permit coverage can now discontinue benchmark monitoring for that parameter for the next two years (*i.e.,* the next eight quarters). Quarterly benchmark monitoring then resumes for all parameters for another four quarters in the fourth year of permit coverage, and if the operator does not exceed the four-quarter annual average for a given parameter, it can discontinue benchmark monitoring for that parameter for the remainder of their permit coverage. If, during either the first or fourth year of monitoring, the annual average for any parameter exceeds the benchmark threshold, the operator must comply with Part 5 (Additional Implementation Measures responses and deadlines) and continue quarterly benchmark monitoring for four quarters until results indicate that annual average for the parameter(s) is no longer exceeded. Under the new schedule, regardless of when the operator discontinued monitoring for any benchmark parameter, monitoring resumes for all parameters for four quarters in the fourth year of permit coverage, unless the permit has already expired. It is possible that an operator with continued benchmark exceedances in years two and three of permit coverage will be required to continue monitoring through their second and third years of permit coverage. In the scenario where the operator receives results in their third year of permit coverage that the benchmark threshold is no longer exceeded, the operator is still required to monitor again in their fourth year of permit coverage.

The principle underpinning this schedule is that the relief period from benchmark monitoring between the first and fourth year decreases if benchmark exceedances continue and additional monitoring is required. During this time, operators may also be conducting continued benchmark monitoring in compliance with AIM for certain parameters that have ongoing exceedances. The extended benchmark monitoring schedule under the 2021 MSGP will ensure that operators have current data on their industrial stormwater discharges and stormwater control measure effectiveness throughout their permit coverage and will help identify potential adverse effects from modifications in facility operations and personnel over time. See Part 4.2.2.3 of the permit and fact sheet.

• *Updating benchmark values.* EPA updated the benchmark monitoring thresholds in the 2021 MSGP for aluminum, copper for discharges to freshwater, selenium for discharges to freshwater, and cadmium based on revised current CWA section 304(a) national recommended aquatic life water quality criteria and suspended the benchmark monitoring thresholds for magnesium and iron based on lack of documented acute toxicity. The 2021 MSGP also allows operators who exceed the revised benchmark thresholds for discharges to freshwater for aluminum and copper to demonstrate to EPA that their discharges do not result in an exceedance of a facility-specific value calculated by the operator using the national recommended water quality criteria multi-variable models in-lieu of the applicable 2021 MSGP benchmark threshold. See Parts 4.2.2 and 8 of the permit and fact sheet.

EPA also received some comments related to developing wet-weather criteria. At this time, EPA does not plan to develop wet-weather criteria as the Agency believes aquatic life water quality criteria are appropriate protective values for ambient waters and MSGP's benchmark thresholds. The Agency may consider the validity of exploring a wet-weather criteria approach in the future, however.

• *Additional Implementation Measures.* The 2021 MSGP includes revisions to the Additional Implementation Measures (AIM) requirements for benchmark monitoring exceedances that were included in the proposed 2020 MSGP. EPA revised these provisions to address concerns raised in public comments. Both the proposed 2020 MSGP and the final 2021 MSGP maintain a three-level structure of advancement and responses triggered by benchmark exceedances and keep follow-up actions clear, timely, and proportional to exceedance frequency and duration. The final 2021 MSGP AIM requirements reduce costs and complexity from the proposal by creating stepwise, sequential advancement through the AIM levels

with clear ''resetting'' to baseline status if benchmark thresholds and responses are met within the required deadlines. EPA reminds operators and the public that benchmark thresholds are not effluent limitations. This permit requires benchmark monitoring as a gauge of the performance of facilities' stormwater control measures. The other corrective action conditions, subsequent action deadlines, and documentation requirements in Part 5.1 remain the same as in the 2015 MSGP.

In Part 5.2, AIM is triggered by an exceedance of a benchmark monitoring parameter, which can occur from two ''triggering events'': Either an exceedance of the four-quarterly annual average for a parameter, or from fewer than four quarterly samples if a single sample or the sum of any sample results within the sampling year exceeds the benchmark threshold by more than four times for a parameter (this result indicates that an exceedance of the annual average is mathematically certain).

There are three AIM levels in the 2021 MSGP: AIM Level 1, Level 2, and Level 3. All operators subject to benchmark monitoring requirements begin in baseline status at the start of their permit coverage. An operator would progress linearly through the three AIM levels if an exceedance triggering event occurs and continues. If an exceedance triggering event occurs while in baseline status, an operator would enter AIM Level 1. If a triggering event occurs while in Level 1, an operator proceeds to AIM Level 2. If a triggering event occurs while in Level 2, an operator proceeds to AIM Level 3. The operator is required to respond with increasingly robust control measures and continued benchmark monitoring with each subsequent AIM level. The operator is ''reset'' to baseline status from any AIM level if benchmark thresholds and responses are met within the required deadlines.

After an exceedance triggering event occurs, an operator must continue quarterly monitoring for the parameter(s) that caused the AIM triggering event at all affected stormwater discharge points, until four additional quarters of monitoring do not result in an exceedance triggering event. The deadlines for implementing AIM responses remains the same as in the proposed permit for Levels 1 and 2 (within 14 days of receipt of lab results, unless infeasible, then within 45 days). The deadline for Level 3 has been extended to allow time for scheduling and completing installation of stormwater control measures (identify the schedule for installing controls within 14 days; install controls within 60 days, unless infeasible, then within 90 days). EPA may grant an extension to the specified deadlines for AIM Level 2 and AIM Level 3 based on an appropriate demonstration by the operator as outlined in Parts 5.2.4.2 (AIM Level 2 Deadlines) and 5.3.5.2 (AIM Level 3 Deadlines).

The following five exceptions to the AIM requirements are available for an exceedance triggering event at any AIM level: (1) Natural background sources, (2) run-on, (3) a one-time abnormal event, (4) a demonstration that discharges of copper and aluminum do not result in an exceedance of facility-specific criteria using the national recommended water quality criteria in-lieu of the applicable MSGP benchmark threshold, and 5) a demonstration that the benchmark exceedance does not result in any exceedance of an applicable water quality standard. AIM requirements increase regulatory certainty while ensuring that discharges are sufficiently controlled to protect water quality. See Part 5.2 of the permit and fact sheet.

• *Impaired waters monitoring.* Under the 2021 MSGP, operators discharging to impaired waters without an EPA-approved or -established total maximum daily load (TMDL) must complete annual monitoring for discharges of certain pollutants to impaired waters. Impaired waters monitoring begins in the first year of permit coverage, starting in the first full quarter of permit coverage. Monitoring is required for one year at each discharge point for all pollutants for which the waterbody is impaired, just as in the 2015 MSGP, after which the operator can discontinue monitoring for the next two years for any pollutant that is not detected. Annual monitoring must continue for any pollutant that is detected in the discharge. Required annual monitoring then resumes in the fourth year of permit coverage for one year for those pollutants that are both causing impairments and are associated with the industrial activity and/or are a required benchmark parameter for the operator's subsector(s), including any pollutant(s) for which the operator previously discontinued monitoring. After monitoring in the fourth year of permit coverage is completed, the operator can discontinue monitoring for the duration of their permit coverage for any pollutant that is not detected. Again, annual monitoring must continue for any pollutant that is detected in the stormwater discharge. For waters identified as impaired by acidity or heat, annual monitoring must continue where the measured pH or temperature exceeds the range of acceptable values assigned to the water consistent with applicable water quality standards. The extended impaired waters monitoring schedule under the 2021 MSGP will ensure that operators affirmatively determine in their first year of permit coverage that a parameter causing an impairment is not present at the facility before narrowing the list of monitored parameters in the fourth year. The updated schedule ensures operators periodically check on their potential contributions to impairments in their industrial stormwater discharges throughout their permit coverage. See Part 4.2.5.1.a of the permit and fact sheet.

C. Summary of Changes From Proposed 2020 MSGP

After considering information and comments received, the following proposed requirements were either not finalized or have been modified in the 2021 MSGP relative to the proposed 2020 MSGP:

1. *Expanding the permit eligibility requirement for discharges to a federal CERCLA site beyond EPA Region 10.* EPA is limiting this eligibility criterion to MSGP facilities in EPA Region 10 states and Indian Country. EPA has extensive information that stormwater discharges are a source of CERCLA site recontamination in Region 10. EPA Region 10 has seen both the actual recontamination of Superfund Sites from stormwater discharge points and the potential for recontamination from source control information gathered at Superfund Sites not yet cleaned up. EPA adds in the 2021 MSGP that such facilities in Region 10 submit the required information to the EPA Regional Office in their NOI via the NPDES eReporting Tool (NeT) for the MSGP, which will be reviewed for 30 days prior to the standard 30-day review period for all NOIs.

2. Adding an eligibility criterion regarding coal-tar sealcoat. EPA is not finalizing the eligibility criterion regarding coal-tar sealcoat that was included in the proposed 2020 MSGP. EPA is instead implementing a holistic activity-based approach for addressing discharges of PAHs in stormwater associated with industrial activity. The 2021 MSGP requires industrial facilities to complete ''report-only'' indicator analytical monitoring bi-annually (*i.e.,* sample twice per year) during the first and fourth year of permit coverage for PAHs if the facilities initially seal or re-seal coal-tar sealcoat on paved surfaces where industrial activities are located, as well other specific sectors with potential petroleum hydrocarbon

exposure to stormwater. The indicator monitoring, specified in Part 4.2.1 of the 2021 MSGP, is ''report-only'' and does not have a threshold or baseline value for comparison nor does it trigger follow-up actions. This pollutant focused approach to evaluating activities and sectors that may contribute PAHs to stormwater discharges will allow the Agency to use the indicator monitoring data collected to conduct an initial quantitative assessment of the levels of PAHs in industrial stormwater, further identify industrial activities with the potential to discharge PAHs in stormwater, and inform future consideration of potential PAH benchmark monitoring for sectors with the potential to discharge PAHs in stormwater.

3. Modifying the permit authorization timeframe if a new facility had a pending enforcement action. EPA is not finalizing the proposed extended authorization timeframe that would have extended the review period for new NOIs for facilities that have a pending enforcement action. However, EPA updates the NOI form in the 2021 MSGP to include new questions specifically to identify if there is a pending enforcement action related to stormwater.

4. Providing an inspection-only option in lieu of benchmark monitoring. EPA is not finalizing an inspection-only option in the 2021 MSGP. EPA acknowledges the validity of the NRC Study recommendation to provide an alternative compliance option for low-risk facilities; however, the Agency does not currently have sufficient information or a fully-vetted approach to identify which facilities should be considered ''low-risk.'' EPA will continue to collect information, including the indicator monitoring data required in the 2021 MSGP, to support future consideration of an inspection-only option for low-risk facilities.

5. Requiring universal benchmark monitoring for pH, TSS, and COD applicable to all sectors. EPA is not finalizing universal benchmark monitoring for pH, TSS, and COD as proposed. Instead, the 2021 MSGP includes a new provision that requires certain operators to conduct indicator analytical monitoring for pH, TSS, and COD quarterly for the duration of the permit. This ''indicator monitoring'' requirement applies to all operators in subsectors that do not have sector-specific benchmark monitoring requirements in the 2021 MSGP. For the final permit, indicator monitoring is ''report-only'' and does not have a threshold or baseline value for comparison, therefore no follow-up action is triggered or required.

Requiring sector-specific benchmark monitoring for Sector I (Oil and Gas Extraction), Sector P (Land Transportation and Warehousing), and Sector R (Ship and Boat Building and Repair Yards). EPA is not finalizing benchmark monitoring requirements for Sectors I, P, and R as proposed. Upon reconsidering the recommendations of the NRC regarding ''Sectors Not Subject to Benchmark Monitoring'' and the ''Need for Periodic Monitoring Reviews,'' EPA now acknowledges that the NRC highlighted Sectors I, P, and R as ''examples [to] show that monitoring requirements within the MSGP are not consistently applied'' and that ''[s]ector-specific monitoring requirements for all sectors should be rigorously reviewed to assess whether the monitoring requirements are appropriate to ensure control of stormwater pollution and determine whether benchmark monitoring requirements should be adjusted.'' Contrary to the proposed 2020 MSGP Fact Sheet, which incorrectly interpreted the NRC study as ''recommend[ing] that EPA require benchmark monitoring for Sectors I, P, and R,'' EPA now recognizes that the NRC did not recommend the Agency require benchmarks for these sectors, but rather provided them as examples of ''Sectors Not Subject to Benchmark Monitoring'' and for highlighting the ''Need for Periodic Monitoring Reviews.'' The NRC notes that these examples ''highlight the need for updated evaluations of pollutant potential and opportunities for pollutant reduction through implementation of additional SCMs.''

EPA recognizes it misinterpreted the actual recommendations of the NRC report in this instance, and the Agency acknowledges the NRC Study's recommendation for additional sector-specific data-gathering efforts. EPA commits to address the specific recommendations of the NRC regarding ''Sectors Not Subject to Benchmark Monitoring'' and the ''Need for Periodic Monitoring Reviews'' in future proposals of the MSGP. At this time, EPA is requiring indicator monitoring for pH, TSS, and COD for facilities in subsectors that do not have sector-specific benchmark monitoring requirements in the 2021 MSGP, which includes subsectors I1, P1, and R1. The indicator monitoring will provide operators and EPA with a baseline and comparable understanding of industrial stormwater discharge quality, broader water quality problems, and stormwater control effectiveness at these facilities, as recommended by NRC. EPA will use the results of the indicator monitoring to re-assess the need for additional chemical-specific benchmark monitoring for the next reissuance of the MSGP.

6. Modifying the method for determining natural background pollutant contributions from the 2015 MSGP. In the 2021 MSGP, EPA retains the 2015 MSGP no net contribution method to applying the natural background exception for several reasons. The 2015 MSGP method is consistent with existing EPA policy concerning the establishment of site-specific water quality criteria based on natural background conditions. See EPA's Office of Science and Technology memorandum, Establishing Site Specific Aquatic Life Criteria Equal to Natural Background (November 5, 1997). Additionally, the 2015 MSGP response to comments stated that ''the CWA does not allow EPA or states to set a site-specific criteria equal to the natural background plus an otherwise protective level . . . since doing so could raise the level of the pollutant in the water body that might [be] above the natural background, which would not be protective of aquatic life, at a minimum.'' See Natural Background Exception to Benchmark Monitoring (p. 5–6) in Response to Public Comments—EPA NPDES 2015 Multi-Sector General Permit (MSGP), June 4, 2015. Public comments also raised a variety of concerns to EPA that the proposed subtraction method is counter to the ''solely attributable'' standard and is not appropriate for the MSGP.

7. Requiring sector-specific fact sheet checklists to be used as part of AIM Tier 2 in Appendix Q. EPA is not finalizing Appendix Q in the 2021 MSGP. Instead, EPA maintains the existing industrial stormwater fact sheet series as guidance. In the 2021 MSGP, after AIM Level 2 is triggered, the Level 2 response requires the operator to generally implement additional pollution prevention/good housekeeping measures. EPA encourages facilities to consult the existing MSGP industrial stormwater fact sheet series for guidance on recommended stormwater control measures appropriate to comply with AIM Level 2. EPA plans to work with external stakeholders to thoroughly revise the sector-specific fact sheets.

IV. Implementation Assistance

Following issuance of the 2021 MSGP, EPA plans to provide further assistance to industrial operators and other interested parties on various aspects of this new permit. The following activities or documents are planned:

1. National webcast—EPA will host at least one webcast in February 2021 that will provide an overview of the 2021 MSGP and an opportunity for participants to ask questions. EPA will announce details of all webcasts and post webcast recordings on the industrial stormwater website at *https://www.epa.gov/npdes/stormwater-discharges-industrial-activities.*

2. Revisions to sector-specific fact sheets for PFAS (guidance)—To recognize that industrial facilities can conduct activities that use, store, manufacture, transfer, and/or dispose of PFAS-containing materials and in alignment with EPA's ''Interim Strategy for Per- and Polyfluoroalkyl Substances in Federally Issued National Pollutant Discharge Elimination System Permits: Recommendations from the PFAS NPDES Regional Coordinators Committee,'' EPA revised each of the sector-specific fact sheet guidance documents to include practices that could be used by operators to minimize PFAS in stormwater discharges. EPA will continue to work with stakeholders to further update these sector-specific fact sheets with additional emerging stormwater control measures that could be used by industrial operators.

3. Other templates and guidance—EPA will also update existing forms and guidance for developing SWPPPs, conducting monitoring, performing inspections and visual assessments, and provide tutorials and training materials for how to submit forms and data to EPA via NeT–MSGP.

4. Benchmark monitoring tracking spreadsheet—EPA will also develop a spreadsheet that industrial operators may use to calculate whether their quarterly benchmark monitoring data results in an exceedance (AIM triggering condition).

V. Paperwork Reduction Act (PRA)

The information collection activities in this permit have been submitted for approval to the Office of Management and Budget (OMB) under the PRA. The Information Collection Request (ICR) document that EPA prepared has been assigned EPA ICR number 2612.02, OMB Control No. 2040–0300. You can find a copy of the ICR in the docket for this permit (Docket ID No EPA–HQ–OW–2019–0372), and it is briefly summarized here.

CWA section 402 and the NPDES regulations require collection of information primarily used by permitting authorities, permittees (operators), and EPA to make NPDES permitting decisions. The burden and costs associated with the entire NPDES program are accounted in an approved ICR (EPA ICR number 0229.23, OMB control no. 2040–0004). Certain changes in this permit require revisions to the ICR to reflect changes to the forms and other information collection requirements. EPA is reflecting the paperwork burden and costs associated with this permit in a separate ICR instead of revising the existing ICR for the entire program for administrative reasons.

EPA is collecting new information as part of the 2021 MSGP. The NOI form was updated from the 2015 MSGP to collect new information related to the following: Added two questions to determine if PAH indicator monitoring in Part 4.2.1.1.b should apply; added questions for operators in New Mexico only (based on CWA section 401 conditions specific to operators in New Mexico in Part 9 of the permit); added the SIC code field for co-located activities; added an additional option for Sector G ore answer selections; added an additional option for operators to upload/attach their SWPPP (in additional to the existing options from the 2015 MSGP); for new dischargers only, added a question to indicate if the facility has a pending enforcement action related to industrial stormwater by EPA, a state, or a citizen; and added questions related to endangered species protection criterion determination and Criterion C3 form information, historic properties determination, new dischargers to impaired waters eligibility information, and CERCLA-related eligibility information to the NOI form in NeT–MSGP in lieu of providing information to EPA via email communication or in another form to streamline or reduce burden.

EPA made no changes to the Notice of Termination (NOT) requirements. For the Annual Report form, EPA added the requirement to include AIM responses for the 2021 MSGP. For the No Exposure Certification form, EPA made no changes to the information collected, but finalized a change of the acronym for the No Exposure Certification from NOE to NEC.

For the Discharge Monitoring Report (DMR) form, EPA updated the form to match the language included in the permit as follows: Updated Part 3.d of the form to allow operators to indicate if monitoring was for indicator monitoring; updated Part 3.l of the form to match the abnormal event exception; added Part 3.n (demonstration that discharges of copper do not result in an exceedance of facility-specific criteria) and Part 3.o (demonstration that discharges of aluminum do not result in an exceedance of facility-specific criteria) to match the permit.

Respondents/affected entities: Industrial facilities in the 30 sectors shown in section I.A of this document in the areas where EPA is the NPDES permitting authority.

Respondent's obligation to respond: Compliance with the MSGP's information collection and reporting requirements is mandatory for MSGP operators.

Estimated number of respondents: EPA estimates that approximately 2,508 operators will receive coverage under the 2021 MSGP.

Frequency of response: Response frequencies in the 2021 MSGP vary from once per permit term to quarterly.

Total estimated burden: EPA estimates that the information collection burden of the 2021 MSGP is 68,460 hours per year. Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: EPA estimates that the final information collection cost of the 2021 MSGP is $2,461,813 per year.

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 OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9. EPA responded to ICR-related comments in the final permit.

VI. 2021 MSGP Incremental Cost Analysis and Future Cost-Benefit Considerations

The cost analysis accompanying this final permit monetizes and quantifies certain incremental cost impacts of the final permit changes as compared to the 2015 MSGP. EPA analyzed each change in the 2021 MSGP considering the previous permit's (*i.e.,* the 2015 MSGP) requirements. The objective of this cost analysis is to show where or to what extent the 2021 MSGP requirements impose an incremental increase in administrative and compliance costs (such as sampling and monitoring costs) on operators in relation to costs that are already accounted for in the 2015 MSGP.

More broadly, EPA notes that additional unquantified costs and benefits result from this action. In developing the next MSGP (or another NPDES general permit, as appropriate), EPA plans to estimate the broader impacts arising from these actions, including costs and benefits. Estimates under consideration may include: (1) Assessing how costs and benefits are attributed between the MSGP and applicable water quality standards (including TMDLs) that may be in effect; (2) developing a new modeling

framework to assess how regulated entities understand and implement control measures relating to existing and new permit obligations; (3) examining whether any underlying cost and benefit assumptions need to be updated; (4) examining more broadly how EPA can analyze benefits when developing permits; (5) developing more robust approaches to assessing uncertainties associated with the analytic approaches, including how to quantitatively assess uncertainties of key assumptions; and (6) developing a framework to analyze the effect of cooperative federalism.

EPA expects the incremental cost impact on entities that will be covered under the 2021 MSGP, including small businesses, to be minimal. EPA anticipates the incremental administrative and compliance cost for new or modified permit requirements will be $338–$632 per operator per year; or $1,690–$3,157 per operator over the 5-year permit term. A copy of EPA's incremental cost analysis for the final permit, titled ''Cost Analysis for the Final 2021 Multi-Sector General Permit (MSGP),'' is available in the docket (Docket ID No. EPA–HQ–OW–2019–0372). The cost analysis indicates that while there will be an incremental increase in the costs of complying with the 2021 MSGP, these costs will not have a significant economic impact on a substantial number of small entities.

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

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is a ''significant regulatory action.'' Accordingly, EPA submitted this action to OMB for review under Executive Orders 12866 and 13563 (76 FR 3821, January 21, 2011), and any changes made in response to OMB recommendations will be documented in the docket for this action (Docket ID No. EPA–HQ–OW–2019–0372).

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

Executive Order 12898 (59 FR 7629, February 16, 1994) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

This action does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations and/or indigenous peoples, as specified in Executive Order 12898. EPA has determined that the 2021 MSGP will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because the requirements in the permit apply equally to industrial facilities in areas where EPA is the permitting authority, and the provisions increase the level of environmental protection for all affected populations.

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

This action has tribal implications. However, it will neither impose substantial direct compliance costs on federally recognized tribal governments, nor preempt tribal law. With limited exceptions, EPA directly implements the NPDES program in Indian country as no tribe has yet obtained EPA authorization to administer the NPDES program. As a result, almost all eligible facilities with stormwater discharges associated with industrial activities in Indian country fall under EPA's MSGP or may be covered under an individual NPDES permit issued by EPA.

EPA consulted with tribal officials under EPA's Policy on Consultation and Coordination with Indian Tribes early in the process of developing this permit to have meaningful and timely input into its development to gain an understanding of and, where necessary, to address the tribal implications of the permit. A summary of that consultation and coordination follows.

- June 26, 2019—EPA initiated a tribal consultation and coordination process for this action by sending a ''Notice of Consultation and Coordination'' letter to all 573 federally recognized tribes. The letter invited tribal leaders and designated consultation representative(s) to participate in the tribal consultation and coordination process. The consultation period was from July 8 to September 9, 2019.
- July 10, 2019—EPA presented an overview of the current 2015 MSGP and potential changes for the reissuance of the MSGP to the National Tribal Water Council.
- August 1, 2019—EPA held an informational webinar for tribal representatives. A total of 19 tribal representatives participated in the webinar.

EPA solicited comment from federally recognized tribes early in the reissuance process. Tribes and tribal organizations submitted one letter and three emails to EPA, and EPA addressed those comments in the final permit and/or sent the requested information to the tribes. Records of the tribal informational webinar and a consultation summary summarizing the written comments submitted by tribes are included in the docket for this action (Docket ID No. EPA–HQ–OW–2019–0372). EPA also notes that the Agency completed the CWA section 401 certification procedures with all authorized tribes where this permit applies. EPA will provide email notification to tribes of the final 2021 MSGP.

X. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use

This action is not a ''significant energy action'' because it is not likely to have a significant adverse effect on the supply, distribution or use of energy and has not otherwise been designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action.

Authority: Clean Water Act, 33 U.S.C. 1251 *et seq.*

This notice of final permit issuance of the Environmental Protection Agency was signed on January 15, 2021, by Dennis Deziel, Regional Administrator, EPA Region 1, pursuant to the settlement agreement entered in *Waterkeeper Alliance, Inc. et al.* v. *U.S. EPA,* No. 15–2091 (2d Cir.). That notice of final permit issuance with the original signature and date is maintained by EPA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned EPA Official re-signs the notice of final permit issuance for publication, as an official document of the Environmental Protection Agency. This administrative process in no way alters the legal effect of this notice of final permit issuance upon publication in the **Federal Register**.

Dated: February 11, 2021.

Deborah Szaro,

Acting Regional Administrator, EPA Region 1.

This notice of final permit issuance of the Environmental Protection Agency was signed on January 15, 2021, by Jeffrey Gratz, Deputy Director, Water

Division, EPA Region 2, pursuant to the settlement agreement entered in *Waterkeeper Alliance, Inc. et al.* v. *U.S. EPA,* No. 15–2091 (2d Cir.). That notice of final permit issuance with the original signature and date is maintained by EPA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned EPA Official re-signs the notice of final permit issuance for publication, as an official document of the Environmental Protection Agency. This administrative process in no way alters the legal effect of this notice of final permit issuance upon publication in the **Federal Register**.

Dated: February 11, 2021.

Jeffrey Gratz,

Deputy Director, Water Division, EPA Region 2.

This notice of final permit issuance of the Environmental Protection Agency was signed on January 15, 2021, by Carmen Guerrero-Perez, Director, Caribbean Environmental Protection Division, EPA Region 2, pursuant to the settlement agreement entered in *Waterkeeper Alliance, Inc. et al.* v. *U.S. EPA,* No. 15–2091 (2d Cir.). That notice of final permit issuance with the original signature and date is maintained by EPA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned EPA Official re-signs the notice of final permit issuance for publication, as an official document of the Environmental Protection Agency. This administrative process in no way alters the legal effect of this notice of final permit issuance upon publication in the **Federal Register**.

Dated: February 11, 2021.

Carmen Guerrero-Perez,

Director, Caribbean Environmental Protection Division, EPA Region 2.

This notice of final permit issuance of the Environmental Protection Agency was signed on January 15, 2021, by Catherine Libertz, Director, Water Division, EPA Region 3, pursuant to the settlement agreement entered in *Waterkeeper Alliance, Inc. et al.* v. *U.S. EPA,* No. 15–2091 (2d Cir.). That notice of final permit issuance with the original signature and date is maintained by EPA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned EPA Official re-signs the notice of final permit issuance for publication, as an official document of the Environmental Protection Agency. This administrative process in no way alters the legal effect of this notice of final permit issuance upon publication in the **Federal Register**.

Dated: February 11, 2021.

Catherine Libertz,

Director, Water Division, EPA Region 3.

This notice of final permit issuance of the Environmental Protection Agency was signed on January 15, 2021, by Jeaneanne Gettle, Director, Water Division, EPA Region 4, pursuant to the settlement agreement entered in *Waterkeeper Alliance, Inc. et al.* v. *U.S. EPA,* No. 15–2091 (2d Cir.). That notice of final permit issuance with the original signature and date is maintained by EPA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned EPA Official re-signs the notice of final permit issuance for publication, as an official document of the Environmental Protection Agency. This administrative process in no way alters the legal effect of this notice of final permit issuance upon publication in the **Federal Register**.

Dated: February 11, 2021.

Jeaneanne Gettle,

Director, Water Division, EPA Region 4.

This notice of final permit issuance of the Environmental Protection Agency was signed on January 15, 2021, by Tera Fong, Director, Water Division, EPA Region 5, pursuant to the settlement agreement entered in *Waterkeeper Alliance, Inc. et al.* v. *U.S. EPA,* No. 15–2091 (2d Cir.). That notice of final permit issuance with the original signature and date is maintained by EPA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned EPA Official re-signs the notice of final permit issuance for publication, as an official document of the Environmental Protection Agency. This administrative process in no way alters the legal effect of this notice of final permit issuance upon publication in the **Federal Register**.

Dated: February 11, 2021.

Tera Fong,

Director, Water Division, EPA Region 5.

This notice of final permit issuance of the Environmental Protection Agency was signed on January 15, 2021, by Charles Maguire, Director, Water Division, EPA Region 6, pursuant to the settlement agreement entered in *Waterkeeper Alliance, Inc. et al.* v. *U.S. EPA,* No. 15–2091 (2d Cir.). That notice of final permit issuance with the original signature and date is maintained by EPA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned EPA Official re-signs the notice of final permit issuance for publication, as an official document of the Environmental Protection Agency. This administrative process in no way alters the legal effect of this notice of final permit issuance upon publication in the **Federal Register**.

Dated: February 11, 2021.

Charles Maguire,

Director, Water Division, EPA Region 6.

This notice of final permit issuance of the Environmental Protection Agency was signed on January 15, 2021, by Jeffery Robichaud, Director, Water Division, EPA Region 7, pursuant to the settlement agreement entered in *Waterkeeper Alliance, Inc. et al.* v. *U.S. EPA,* No. 15–2091 (2d Cir.). That notice of final permit issuance with the original signature and date is maintained by EPA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned EPA Official re-signs the notice of final permit issuance for publication, as an official document of the Environmental Protection Agency. This administrative process in no way alters the legal effect of this notice of final permit issuance upon publication in the **Federal Register**.

Dated: February 11, 2021.

Jeffery Robichaud,

Director, Water Division, EPA Region 7.

This notice of final permit issuance of the Environmental Protection Agency was signed on January 15, 2021, by Darcy O'Connor, Director, Water Division, EPA Region 8, pursuant to the settlement agreement entered in *Waterkeeper Alliance, Inc. et al.* v. *U.S. EPA,* No. 15–2091 (2d Cir.). That notice of final permit issuance with the original signature and date is maintained by EPA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned EPA Official re-signs the notice of final permit issuance for publication, as an official document of the Environmental Protection Agency. This administrative process in no way alters the legal effect of this notice of final permit issuance upon publication in the **Federal Register**.

Dated: February 11, 2021.

Humberto Garcia,

Acting Director, Water Division, EPA Region 8.

This notice of final permit issuance of the Environmental Protection Agency was signed on January 15, 2021, by Tomás Torres, Director, Water Division, EPA Region 9, pursuant to the settlement agreement entered in *Waterkeeper Alliance, Inc. et al.* v. *U.S. EPA,* No. 15–2091 (2d Cir.). That notice of final permit issuance with the original signature and date is maintained by EPA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned EPA Official re-signs the notice of final permit issuance for publication, as an official document of the Environmental Protection Agency. This administrative process in no way alters the legal effect of this notice of final permit issuance upon publication in the **Federal Register**.

Dated: February 11, 2021.

Tomás Torres,

Director, Water Division, EPA Region 9.

This notice of final permit issuance of the Environmental Protection Agency was signed on January 15, 2021, by Daniel Opalski, Director, Water Division, EPA Region 10, pursuant to the settlement agreement entered in *Waterkeeper Alliance, Inc. et al.* v. *U.S. EPA,* No. 15–2091 (2d Cir.). That notice of final permit issuance with the original signature and date is maintained by EPA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned EPA Official re-signs the notice of final permit issuance for publication, as an official document of the Environmental Protection Agency. This administrative process in no way alters the legal effect of this notice of final permit issuance upon publication in the **Federal Register**.

Dated: February 11, 2021.

Daniel Opalski,

Director, Water Division, EPA Region 10.

[FR Doc. 2021–03391 Filed 2–18–21; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[FRS 17437; PS Docket No. 13–42]

Reallocation of 470–512 MHz (T-Band) Spectrum

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: In this document, the Public Safety and Homeland Security Bureau and Wireless Telecommunications Bureau (collectively the Bureaus) jointly terminate PS Docket No. 13–42 entitled Reallocation of 470–512 MHz (T-Band) Spectrum.

DATES: January 13, 2021.

FOR FURTHER INFORMATION CONTACT: Brian Marenco, Electronics Engineer, Policy and Licensing Division, Public Safety and Homeland Security Bureau, (202) 418–0838 or via email at *Brian.Marenco@fcc.gov,* and Thomas Eng, Electronics Engineer, Policy and Licensing Division, Public Safety and Homeland Security Bureau, (202) 418–0019 or via email at *Thomas.Eng@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Order,* DA 21–52, adopted on January 13, 2021, and released on January 13, 2021. The complete text of this document is available for inspection and copying during normal business hours in the FCC Reference Information Center, 45 L Street NE, Washington, DC 20554. Effective March 19, 2020, and until further notice, the Commission no longer accepts any hand or messenger delivered filings. This is a temporary measure taken to help protect the health and safety of individuals, and to mitigate the transmission of COVID–19. See *FCC Announces Closure of FCC Headquarters Open Window and Change in Hand-Delivery Policy,* Public Notice, DA 20–304 (March 19, 2020). *https://www.fcc.gov/document/fcc-closes-headquarters-open-window-and-changes-hand-delivery-policy.* During the time the Commission's building is closed to the general public and until further notice.

1. On January 13, 2021, the Bureaus released an Order terminating the proceeding for PS Docket No. 13–42 as a result of the signing of the Don't Break Up the T-Band Act (T-Band Act) into law as part of the Consolidated Appropriations Act, 2021. The T-Band Act repealed section 6103 of the Middle Class Tax Relief and Job Creation Act of 2012, which mandated the Commission reallocate and auction frequencies used by public safety eligibles in the 470–512 MHz spectrum (T-Band Mandate).

2. The Commission adopted a Notice of Proposed Rulemaking in June 2020 to meet its statutory deadlines and directives. Since the T-Band Act repealed the T-Band Mandate in its entirety, the Bureaus terminated the proceeding since there is no longer a statutory mandate to reallocate and auction frequencies in the T-Band.

Federal Communications Commission.

Marlene Dortch,

Secretary,Office of the Secretary.

[FR Doc. 2021–03425 Filed 2–18–21; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[FRS 17438]

Wireless Telecommunications Bureau and Public Safety and Homeland Security Bureau Modify Suspensions of Acceptance and Processing of Certain Part 22 and Part 90 Applications for 470–512 MHz (T-Band) Spectrum

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: In this Public Notice, the Public Safety and Homeland Security Bureau and Wireless Telecommunications Bureau (collectively the Bureaus) modify suspensions of acceptance and processing of certain Part 22 and Part 90 applications for 470–512 MHz (T-Band) spectrum.

DATES: The Bureaus issued the Public Notice on January 19, 2021.

FOR FURTHER INFORMATION CONTACT: Brian Marenco, Electronics Engineer, Policy and Licensing Division, Public Safety and Homeland Security Bureau, (202) 418–0838 or via email at *Brian.Marenco@fcc.gov,* and Joshua Smith, Mobility Division, Wireless Telecommunications Bureau, (717) 338–2502 or via email at *Joshua.Smith@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Public Notice,* DA 21–82, released on January 19, 2021. The complete text of this document is available for inspection and copying during normal business hours in the FCC Reference Information Center, 45 L Street NE, Washington, DC 20554. Effective March 19, 2020, and until further notice, the Commission no longer accepts any hand or messenger delivered filings. This is a temporary measure taken to help protect the health and safety of individuals, and to mitigate the transmission of COVID–19. See *FCC Announces Closure of FCC Headquarters Open Window and Change in Hand-Delivery Policy,* Public Notice, DA 20–304 (March 19, 2020). *https://www.fcc.gov/document/fcc-closes-headquarters-open-window-and-*

changes-hand-delivery-policy. During the time the Commission's building is closed to the general public and until further notice.

1. On January 19, 2021, the Bureaus released a Public Notice seeking to ensure the orderly resumption of application and licensing processes in the T-Band since the Commission is no longer required to reallocate and auction certain frequencies in the T-Band after the signing of the Don't Break Up the T-Band Act into law as part of the Consolidated Appropriations Act, 2021. The Bureaus announced that in the 30 days immediately following release of the Public Notice, they would resume processing T-Band applications for renewal of license and all other pending T-Band applications; but dismiss without prejudice any pending application that includes a request for waiver of the application freeze.

2. The Bureaus also indicated that following the 30-day processing period, applicants and frequency coordinators will have a 30-day period to prepare and begin pre-coordination of certain new applications. Immediately thereafter, for a ninety-day period, *i.e.,* from March 22, 2021 until June 21, 2021, the Bureaus announced that they will accept certain types of applications but only from incumbent licensees.

3. Band applications established in the Public Notice are procedural in nature, and therefore not subject to the notice and comment and effective date requirements of the Administrative Procedure Act. Moreover, the Bureaus found good cause for not delaying the effect of the modifications until after publication of the Public Notice in the **Federal Register**. The Bureaus indicated that such a delay is unnecessary and contrary to the public interest because, without good reason, it would impede timely access to T-Band channels to applicants that require new or enhanced communications services.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2021–03426 Filed 2–18–21; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[17490]

Open Commission Meeting Wednesday, February 17, 2021

February 10, 2021.

The Federal Communications Commission will hold an Open Meeting on the subjects listed below on Wednesday, February 17, 2021, which is scheduled to commence at 10:30 a.m.

Due to the current COVID–19 pandemic and related agency telework and headquarters access policies, this meeting will be in a wholly electronic format and will be open to the public on the internet via live feed from the FCC's web page at *www.fcc.gov/live* and on the FCC's YouTube channel.

Item No.	Bureau	Subject
1	WIRELINE COMPETITION	*Title:* Presentation on the Emergency Broadband Benefit Program. *Summary:* The Commission will hear a presentation on the creation of an Emergency Broadband Benefit Program. Congress charged the FCC with developing a new $3.2 billion program to help struggling Americans to pay for broadband internet service during the pandemic.
2	WIRELINE COMPETITION	*Title:* Presentation on COVID–19 Telehealth Program. *Summary:* The Commission will hear a presentation about the next steps for the agency's COVID–19 Telehealth program. Congress recently provided an additional $249.95 million to support the FCC's efforts to expand connected care throughout the country and help more patients receive health care safely.
3	OFFICE OF ECONOMICS AND ANALYTICS, WIRELINE COMPETITION AND WIRELESS TELE-COMMUNICATIONS.	*Title:* Presentation on Collection of Broadband Deployment Data. *Summary:* The Commission will hear a presentation on the work the agency is doing to collect precise and accurate fixed and mobile broadband deployment data as part of its mission to close the digital divide.
4	PUBLIC SAFETY & HOMELAND SECURITY.	*Title:* 911 Fee Diversion (PS Docket No. 20–291); New and Emerging Technologies 911 Improvement Act of 2008 (PS Docket No. 09–14). *Summary:* The Commission will consider a Notice of Proposed Rulemaking that would implement section 902 of the Don't Break Up the T-Band Act of 2020, which requires the Commission to take action to help address the diversion of 911 fees by states and other jurisdictions for purposes unrelated to 911.
5	WIRELINE COMPETITION	*Title:* Implementing the Secure and Trusted Communications Networks Act (WC Docket No. 18–89). *Summary:* The Commission will consider a Third Further Notice of Proposed Rulemaking that proposes to modify FCC rules consistent with changes that were made to the Secure and Trusted Communications Networks Act in the Consolidated Appropriations Act, 2021.

* * * * *

The meeting will be webcast with open captioning at: *www.fcc.gov/live*. Open captioning will be provided as well as a text only version on the FCC website. Other reasonable accommodations for people with disabilities are available upon request. In your request, include a description of the accommodation you will need and a way we can contact you if we need more information. Last minute requests will be accepted but may be impossible to fill. Send an email to: *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530.

Additional information concerning this meeting may be obtained from the Office of Media Relations, (202) 418–0500. Audio/Video coverage of the meeting will be broadcast live with open captioning over the internet from the FCC Live web page at *www.fcc.gov/live*.

Federal Communications Commission.

Marlene Dortch,

Secretary.

[FR Doc. 2021–03313 Filed 2–18–21; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[IB Docket No. 20–205; DA 21–81; FRS 17434]

Notice of 90-Day Period To Submit Affirmation of Continued Operation of the Identified Earth Station Antennas and of Intent To Participate in the C-Band Transition

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: In this document, the International Bureau (Bureau) provides the following notice to (1) operators of incumbent Fixed Satellite Service (FSS) C-band earth station antennas that have been reported as no longer operational and (2) incumbent FSS C-band earth station operators that have not responded to communications from RSM US LLP (RSM), the C-band Relocation Coordinator, and/or incumbent C-band satellite operators: Failure to submit a filing to the Bureau by no later than 90 days after the release of the Bureau's Notice (April 19, 2021) affirming the continued operation of the identified earth station antennas and the intent to participate in the C-band transition will result in a Bureau announcement that the authorizations identified in the attached documents filed by RSM in IB Docket No. 20–205 on January 14, 2021 have automatically terminated by operation of rule, and that those authorizations will be terminated in the International Bureau Filing System (IBFS) and removed from the incumbent earth station list.

DATES: Identified earth station operators must provide notice of operational status by April 19, 2021.

FOR FURTHER INFORMATION CONTACT: Kerry Murray, International Bureau, Satellite Division, at (202) 418–0734, *Kerry.Murray@fcc.gov* or *IBFSINFO@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's document, DA 21–81, released January 19, 2021. The full text of this document, along with the attachments identifying the specific earth station antennas subject to automatic termination, is available for public inspection and can be downloaded at *https://www.fcc.gov/document/ib-identifies-inactiveunresponsive-c-band-incumbent-earth-stations* or by using the search function for Docket No. 20–205 on the Commission's ECFS page at *www.fcc.gov/ecfs.*

Background. Under the Commission's *3.7 GHz Band Report and Order,* RSM is responsible for coordinating with the five incumbent C-band satellite operators—Eutelsat, Intelsat, SES, StarOne, and Telesat—to ensure that all incumbent earth stations are accounted for in the transition.[1] The overwhelming majority of incumbent earth stations have been claimed by the satellite operator from which they receive service and will be transitioned to the upper 200 megahertz of the band. Because the incumbent satellite operators do not necessarily have a direct customer relationship with each earth station receiving from their satellites, the satellite operators have conducted significant outreach to earth station operators to build, refine, and maintain their lists of claimed stations, which have been identified in each of the satellite operators' transition plans to the Commission.[2] A limited number of incumbent earth stations, however, remain unclaimed by any of the satellite operators. In these cases, RSM, as the C-band Relocation Coordinator, has conducted outreach and research to determine whether the earth station is still active and, if so, the satellite(s) from which the earth station receives its service so that it may assign, if possible, that earth station to a satellite operator for transition purposes.[3] RSM states that it and the incumbent satellite operators regularly share the results of their respective outreach efforts to better coordinate the transition of incumbent earth stations.

On January 14, 2021, RSM submitted an *ex parte* filing that includes two lists of incumbent earth stations. The e*x parte* letter is provided as Attachment C to DA 21–81. In one list, Attachment A to DA 21–81, RSM identifies various individual earth station antennas that it reports, based on communications with earth station operators by RSM or satellite operators or both, as no longer operational at the site address and GPS coordinates provided in the latest incumbent earth station list.[4] In the other list, Attachment B to DA 21–81, RSM identifies earth station operators (and associated antennas) that it reports as unresponsive to multiple and varied C-band transition outreach efforts by RSM, the satellite operators, or both, via email, phone, and, in some cases, certified mail.

Reported inactive earth station antennas. RSM and/or the incumbent satellite operators have reported that, based on their communications with the relevant earth station operators, the incumbent earth station antennas identified in Attachment A are no longer operational. Under the Commission's rules, antennas must continue to be operational to qualify for incumbent status.[5]

We hereby presume that earth station antennas reported to us as inactive on Attachment A are no longer operational. Section 25.161(c) of the Commission's rules provides that an earth station authorization is automatically terminated if the station is not operational for more than 90 days.[6] We also note that the Commission's rules require earth station operators to take the steps necessary to remove non-operational antennas from the active records in the International Bureau Filing System (IBFS).[7]

We direct earth station operators with incumbent earth station antennas reported to Commission staff as inactive to make either of two filings no later than 90 days after release of this Notice (April 19, 2021): (1) File to remove those antennas from IBFS as no longer operational as required by Commission rule, or (2) file in Electronic Comment Filing System (ECFS) IB Docket No. 20–205 to assert that those antennas are still operational. An earth station operator may contact Bureau staff at *IBFSINFO@fcc.gov* if it wants advice on how to make a filing in ECFS, if it needs instructions on how to surrender entire Callsigns in IBFS or how to remove an inactive earth station antenna from a Callsign that includes other operational earth station antennas, or if it has other questions about the above.

[1] *See Expanding Flexible Use of the 3.7 to 4.2 GHz Band,* Report and Order and Order of Proposed Modification, 35 FCC Rcd 2343, 2391, paras. 116–23 (2020) (*3.7 GHz Band Report and Order*).

[2] *See* 47 CFR 27.1412(d) (transition plan requirements). The most recent status information on the satellite operators' transitions plans can be found in their respective quarterly reports filed in GN Docket No. 20–173 on December 31, 2020.

[3] *3.7 GHz Band Report and Order,* 35 FCC Rcd 2343, 2460, para. 313. To the extent an earth station antenna cannot be assigned to a satellite operator, RSM is ultimately responsible for recommending an earth station transition plan for that antenna and to assist, when necessary, the earth station by installing filters or hiring third parties to install such filters. 47 CFR 27.1413(c)(3)(ii).

[4] See *International Bureau Releases Updated List of Incumbent Earth Stations in the 3.7–4.2 GHz Band in the Contiguous United States,* Public Notice, DA 20–1424, IB Docket No. 20–205 (rel. Nov. 30, 2020) and *Erratum to International Bureau Releases Updated List of Incumbent Earth Stations in the 3.7–4.2 GHz Band in the Contiguous United States,* Public Notice, DA 20–1448, IB Docket No. 20–205 (rel. Dec. 3, 2020) for the current incumbent earth station list and an explanation of the criteria applied to be included on the list.

[5] 47 CFR 25.138(c)(1).

[6] *See* 47 CFR 25.161(c). The Bureau has delegated authority to enforce the Part 25 rules. 47 CFR 0.261(a)(15).

[7] 47 CFR 25.115(b)(8).

Earth station operators that do not respond by April 19, 2021 to affirm the continued operation of the identified earth station antennas will be deemed to have had the authorizations for those antennas automatically terminated by rule. Those authorizations will be terminated in IBFS, *i.e.,* the IBFS records for those antennas will be shown with a terminated status. Such terminated earth stations will also be removed from the incumbent earth station list and will not be entitled to protection from interference from the network deployments of new wireless licenses or be eligible for reimbursement of any transition costs, including the cost of any filters, that those earth stations may decide to incur.

Unresponsive earth station operators (and associated antennas). Based on their failure to respond to multiple contact attempts by RSM and the incumbent satellite operators, we hereby presume that the incumbent earth station antennas identified in Attachment B as associated with unresponsive earth station operators have ceased operations. Section 25.161(c) of the Commission's rules provide that an earth station authorization is automatically terminated if the station is not operational for more than 90 days.[8]

To confirm whether or not these unresponsive station operators have discontinued the operation of these earth station antennas, we direct the operators of earth stations on the list whose facilities continue to be operational to submit a notification, by no later than 90 days after release of this Public Notice (*i.e.,* no later than April 19, 2021), affirming that these facilities remain operational and that they intend to participate in the C-band transition. Operators should submit this notification to the Bureau in ECFS IB Docket No. 20–205. In providing this response, an earth station operator affirming that the identified earth station antennas remain operational should identify the satellite from which each antenna is receiving service. Commission staff will forward all affirmations of continued operation to the Relocation Coordinator and/or relevant satellite operator(s), who will contact affirming earth station operators directly to initiate the transition. An earth station operator may contact Bureau staff at *IBFSINFO@fcc.gov* if it wants advice on how to make a filing in ECFS.

Earth station operators that do not respond by April 19, 2021 to affirm the continued operation of the identified earth station antennas will be deemed to have had the authorizations for those antennas automatically terminated by rule. Those authorizations will be terminated in IBFS. Such terminated earth stations will also be removed from the incumbent earth station list and will not be entitled to protection from interference from the network deployments of new wireless licenses or be eligible for reimbursement of any transition costs, including the cost of any filters, that those earth stations may decide to incur.

Federal Communications Commission.

Troy Tanner,

Deputy Chief, International Bureau.

[FR Doc. 2021–03408 Filed 2–18–21; 8:45 am]

BILLING CODE 6712–01–P

[8] 47 CFR 25.161(c).

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0678; FRS 17488]

Information Collection Being Submitted for Review and Approval to Office of Management and Budget

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal Agencies to take this opportunity to comment on the following information collection. Pursuant to the Small Business Paperwork Relief Act of 2002, the FCC seeks specific comment on how it can further reduce the information collection burden for small business concerns with fewer than 25 employees.

DATES: Written comments and recommendations for the proposed information collection should be submitted on or before March 22, 2021.

ADDRESSES: Comments should be sent to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Your comment must be submitted into *www.reginfo.gov* per the above instructions for it to be considered. In addition to submitting in *www.reginfo.gov* also send a copy of your comment on the proposed information collection to Cathy Williams, FCC, via email to *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.* Include in the comments the OMB control number as shown in the **SUPPLEMENTARY INFORMATION** below.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection, contact Cathy Williams at (202) 418–2918. To view a copy of this information collection request (ICR) submitted to OMB: (1) Go to the web page *http://www.reginfo.gov/public/do/PRAMain,* (2) look for the section of the web page called ''Currently Under Review,'' (3) click on the downward-pointing arrow in the ''Select Agency'' box below the ''Currently Under Review'' heading, (4) select ''Federal Communications Commission'' from the list of agencies presented in the ''Select Agency'' box, (5) click the ''Submit'' button to the right of the ''Select Agency'' box, (6) when the list of FCC ICRs currently under review appears, look for the Title of this ICR and then click on the ICR Reference Number. A copy of the FCC submission to OMB will be displayed.

SUPPLEMENTARY INFORMATION: The Commission may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

As part of its continuing effort to reduce paperwork burdens, as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the FCC invited the general public and other Federal Agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimates; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology. Pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, see 44 U.S.C. 3506(c)(4), the FCC seeks specific comment on how it might ''further reduce the information collection burden for small business concerns with fewer than 25 employees.''

OMB Control No.: 3060–0678.

Title: Part 25 of the Commission's Rules Governing the Licensing of, and Spectrum Usage by, Satellite Network Stations and Space Stations.

Form No: FCC Form 312, FCC Form 312–EZ, FCC Form 312–R and Schedules A, B and S.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit entities and Not-for-profit institutions.

Number of Respondents: 6,524 respondents; 6,573 responses.

Estimated Time per Response: 0.5–80 hours.

Frequency of Response: On occasion, one time, and annual reporting requirements; third-party disclosure requirement; recordkeeping requirement.

Obligation to Respond: Required to obtain or retain benefits. The Commission has statutory authority for the information collection requirements under 47 U.S.C. 154, 301, 302, 303, 307, 309, 310, 319, 332, 605, and 721.

Total Annual Burden: 44,988 hours.

Total Annual Cost: $16,612,586.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: There is no need for confidentiality pertaining to the information collection requirements in this collection.

Needs and Uses: On March 3, 2020, the Commission released a Report and Order and Order of Proposed Modification, FCC 20–22, GN Docket No. 18–122, titled ''Expanding Flexible Use of the 3.7 to 4.2 GHz Band.'' In this Report and Order and Order of Proposed Modification, the Commission updated its rules by reforming the use of the 3.7–4.2 GHz band, also known as the C-Band. The new rules repack existing satellite operations into the upper 200 megahertz of the band (and reserve a 20 megahertz guard band), making a significant amount of spectrum—280 megahertz or more than half of the band—available for flexible use throughout the contiguous United States. The relevant rule revisions for purposes of this information collection are the addition of sections 25.138 and 25.147 of the Commission's rules. In updating this information collection, we are not accounting for any changes to the number of respondents, burden hours, and annual cost related to these rule revisions since the addition of sections 25.138 and 25.147 set forth rules for transition of operations from one frequency band to another.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2021–03321 Filed 2–18–21; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10752]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by March 22, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

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. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Submissions of 1135 Waiver Request Automated Process; *Use:* Waivers under Section 1135 of the Social Security Act (the Act) and certain flexibilities allow the CMS to relax certain requirements, known as the Conditions of Participation (CoPs) or Conditions of Coverage to promote the health and safety of beneficiaries. Under Section 1135 of the Act, the Secretary may temporarily waive or modify certain Medicare, Medicaid, and Children's Health Insurance Program (CHIP) requirements to ensure that sufficient health care services are available to meet the needs of individuals enrolled in Social Security Act programs in the emergency area and time periods. These waivers ensure that providers who provide such services in good faith can be reimbursed and exempted from sanctions.

During emergencies, such as the current COVID–19 public health emergency (PHE), CMS must be able to apply program waivers and flexibilities under section 1135 of the Social Security Act, in a timely manner to respond quickly to unfolding events. In

a disaster or emergency, waivers and flexibilities assist health care providers/suppliers in providing timely healthcare and services to people who have been affected and enables states, Federal districts, and U.S. territories to ensure Medicare and/or Medicaid beneficiaries have continued access to care. During disasters and emergencies, it is not uncommon to evacuate Medicare-participating facilities and relocate patients/residents to other provider settings or across state lines, especially, during hurricane and tornado events. CMS must collect relevant information for which a provider is requesting a waiver or flexibility to make proper decisions about approving or denying such requests. Collection of this data aids in the prevention of gaps in access to care and services before, during, and after an emergency. CMS must also respond to inquiries related to a PHE from providers and beneficiaries. CMS is not collecting information from these inquiries; we are merely responding to them.

Prior to this request, CMS did not have a standard process or OMB approval for providers/suppliers impacted to submit 1135 waiver/flexibility requests or inquiries, as these were generally seen on a smaller scale (natural disasters) prior to the COVID–19 public health emergency. CMS has provided general guidance to Medicare-participating facilities which can be viewed at *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/1135-Waivers.* The requests and inquiries would be sent directly, via email, to the Survey Operations Group in each CMS Location (previously known as CMS Regional Offices) and the entity would provide a brief summary to CMS for a waiver/flexibility request or an answer to an inquiry. We are now developing a streamlined, automated process to standardize the 1135 waiver requests and inquiries submitted based on lessons learned during COVID–19 PHE, primarily based on the volume of requests to ensure timely response to facility needs. The waiver request form was approved under an Emergency information collection request on October 15, 2020.

Furthermore, the normal operations of a healthcare provider are disrupted by emergencies or disasters occasionally. When this occurs, State Survey Agencies (SA) deliver a provider/beneficiary tracking report regarding the current status of all affected healthcare providers and their beneficiaries. This report includes demographic information about the provider, their operational status, beneficiary status, and planned resumption of normal operations. This information is provided whether or not a PHE has been declared. We are now developing a streamlined, automated process to standardize submission of this information directly by the provider during emergencies and eliminating the need for SA to provide it. It will consist of a public facing web form.

This information will be used by CMS to receive, triage, respond to and report on requests and/or inquiries for Medicare, Medicaid, and CHIP beneficiaries. This information will be used to make decisions about approving or denying waiver and flexibility requests and may be used to identify trends that inform CMS Conditions for Coverage or Conditions for Participation policies during public health emergencies, when declared by the President and the HHS Secretary.

Subsequent to the Emergency information collection request, we revised the package to include a second form, Healthcare Facility Status Workflow, which is for operational status information which will be used to assist providers in delivering critical care to beneficiaries during emergencies. Subsequent to the 60-day **Federal Register** notice which published on October 21, 2020 (85 FR 66990), we conducted user acceptance testing, resulting in enhancements to the public-facing web form that streamline the submission process and improve the flow and readability of the web form. These enhancements make the automated process easier to use for healthcare providers. We are also remediating a violation of the Paperwork Reduction Act by adding the Acute Hospital Care at Home waiver to this package. The initiative was established on November 23, 2020, in response to the unprecedented strain on hospital capacity due to the severe national increase in coronavirus disease 2019 (COVID–19). There is an increase in burden due to adding this waiver initiative to this package. *Form Number:* CMS–10752 (OMB control number: 0938–1384); *Frequency:* Occasionally; *Affected Public:* Private Sector: Business or other for-profits and Not-for-profit institutions and State, Local or Tribal Governments; *Number of Respondents:* 5,729; *Total Annual Responses:* 5,729; *Total Annual Hours:* 5,729. (For policy questions regarding this collection, contact Adriane Saunders at 404–562–7484.)

Dated: February 16, 2021.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2021–03419 Filed 2–18–21; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[CFDA Numbers: 93.581, 93.587, 93.612]

Notice for Public Comment on Administration for Native Americans' Program Policies and Procedures

AGENCY: Administration for Native Americans (ANA), Administration for Children and Families (ACF), Department of Health and Human Services (HHS).

ACTION: Notice for public comment.

SUMMARY: Pursuant to Section 814 of the Native American Programs Act of 1974 (NAPA), as amended, ANA is required to provide members of the public an opportunity to comment on proposed changes in interpretive rules and general statements of policy and to give notice of the proposed changes no less than 30 days before such changes become effective. In accordance with notice requirements of NAPA, ANA herein describes proposed interpretive rules and general statements of policy that relate to ANA's funding opportunities in Fiscal Year (FY) 2021. Changes to FY 2021 funding opportunity announcements (FOAs) will be based on the following previously published programs: Environmental Regulatory Enhancement (ERE), HHS–2021–ACF–ANA–NR–1907; Native American Language Preservation and Maintenance-Esther Martinez Immersion (EMI), HHS–2021–ACF–ANA–NB–1958; Native American Language Preservation and Maintenance (P&M), HHS–2021–ACF–ANA–NL–1924; Social and Economic Development Strategies (SEDS), HHS–2021–ACF–ANA–NA–1906; Social and Economic Development Strategies-Alaska (SEDS–AK), HHS–2021–ACF–ANA–NK–1902; and Social and Economic Development Strategies-Growing Organizations (SEDS–GO), HHS–2021–ACF–ANA–NN–1918.

DATES: Comments are due by March 22, 2021. If ANA does not receive any significant comments within the 30-day comment period, ANA will proceed with the proposed changes in the respective published FOAs. The FOAs

will serve as the final notice of these proposed changes.

ADDRESSES: Comments may be submitted to Carmelia Strickland, Director of Program Operations, Administration for Native Americans, 330 C Street SW, Washington, DC 20201 or via email to *ANAComments@acf.hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Carmelia Strickland, Director, Division of Program Operations, Administration for Native Americans, 330 C Street SW, Washington, DC 20201. Telephone: (877) 922–9262; Email: *ANAComments@acf.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 814 of NAPA, as amended, (42 U.S.C. 2992b–1) incorporates provisions of the Administrative Procedure Act that require ANA to provide notice of its proposed interpretive rules and statements of policy, and to seek public comment on such proposals. This notice serves to fulfill the statutory notice and public comment requirement. ANA voluntarily includes rules of practice and procedures in this notice in an effort to be transparent. The proposed interpretive rules, statements of policy, and rules of ANA practice and procedure reflected in clarifications, modifications, and new text will appear in the following six FY 2021 FOAs: ERE, EMI, P&M, SEDS, SEDS–AK, and SEDS–GO.

ANA's past FOAs can be accessed at *https://ami.grantsolutions.gov/index.cfm?switch=searchresult&type=office&param=ANA&page=ANA.* Synopses and application forms will be available on *https://www.grants.gov.*

A. *Interpretive rules, statements of policy, procedures, and practice.* The proposals below reflect ANA's proposed changes in rules, policy, or procedures that will take effect in the FY 2021 FOAs.

1. Letter of Intent—ANA will include a provision in all of its FOAs to ask potential applicants to submit a Letter of Intent within 30 days of publication, but it is not mandatory. By doing so, respondents will receive information about ANA's training and technical assistance support for applicants. This will also enable ANA to estimate the number of applications that will be submitted in order to plan for the peer review process.

2. Intellectual Property—Based on feedback from grantees and through tribal consultations, ANA is concerned about the protection of intellectual property of materials created with grant funding. Therefore, ANA will include information in all FOAs that encourages applicants to educate themselves on intellectual property rights and the protection of ownership of Native language materials, ceremonies, music and dance, and other forms of knowledge and cultural practices that originate from Native communities.

3. Previously Funded Projects—ANA has a long-standing policy in place that it provides project-specific funding and not ongoing program funding. There is existing authority for ANA to choose not to fund a project that is essentially identical or similar in whole or in part to previously funded projects proposed by the same applicant or activities or projects proposed by a consortium that duplicate activities for which any consortium member also receives or has received funding from ANA. It will be clarified in the FOAs this year that applicants that propose a project similar to a previously funded ANA grant should acknowledge past funding and explain what was accomplished. In addition, the applicant should be explicit and provide a detailed description of how the new project is different and is not duplicative of the past project.

4. Eligibility—In December, Congress passed the Indian Community Economic Enhancement Act of 2020, which reauthorized certain sections of NAPA related to funding for economic development projects including adding Native community development financial institutions (CDFIs) as an eligible entity; therefore, ANA will add Native CDFIs to the list of eligible applicants. In addition, during tribal consultation in 2020, a comment was received that asked ANA to ensure that Urban Indian Organizations were eligible to apply for ANA grants. Therefore, ANA will clarify in the FOAs that Urban Indian Organizations (UIOs), as defined by 25 U.S.C.1603(29), are eligible under current regulations (45 CFR1336.33) as ''incorporated non-profit multi-purpose community-based Indian organizations'' and as ''urban Indian centers''. However, Native CDFIs and UIOs are not eligible to apply for the ERE program, which is limited to tribes and tribal entities. Additionally, like all applicants that are not tribes or Alaska Native Villages, Native CDFIs and UIOs must also meet the ANA's Assurance of Community Representation on the Board of Directors.

5. Application Requirements and Evaluation Criteria Scores—Sections 803 and 806 of NAPA, 42 U.S.C. 2991b; 2991d–1. In FY 2018, ANA made substantial revisions to the application requirements and evaluation criteria included in our FOAs. The purpose of the revisions was to shift from a deficit-based to a strengths-based approach for application planning and development, to design each project to follow the ANA Project Framework, and to emphasize a community-based approach to project planning and implementation. ANA stands behind the revisions made in FY 2018 and does not plan to change the information being requested; however, efforts have been made to reduce redundancy and number of scoring criteria. ANA proposes the following evaluation criteria scores for the SEDS, SEDS–AK, ERE, and P&M FOAs for FY 2021:

Approach for a maximum of 73 points, to consist of the following: Long Term Community Goal (2 points), Current Community Condition (3 points); Project Goal (2 points); Objectives (6 points); Outcomes and Indicators (5 points); Outputs (3 points); Outcome Tracker and Outcome Tracking Strategy (7 points). Community-Based Strategy (10 points), Readiness and Implementation Strategy (20 points); and the Objective Work Plan (OWP) (15 points).

Organizational Capacity for a maximum of 12 points.

Budget and Budget Justification for a maximum of 15 points, to consist of the following: Line Item Budget (5 points) and Budget Justification (10 points).

These changes are meant to streamline the information required for a successful grant application and provide specific point allotments in order to make ANA's evaluation criterion more approachable. In addition, it is intended to provide greater guidance to panel reviewers on how to allocate scores.

6. Changes to the SEDS–FOA—Priorities and bonus points—Sections 803 and 803B of NAPA, 42 U.S.C. 2991b; 2991b–2. As previously mentioned, recently passed legislation requires ANA to prioritize applications seeking assistance for the following: (1) The development of a tribal code or courts system for purposes of economic development, including commercial codes, training for court personnel, and the development of nonprofit subsidiaries or other tribal business structures; (2) the development of a native community development financial institution, including training and administrative expenses; (3) the development of a tribal master plan for community and economic development and infrastructure. The new economic development legislative priorities will be incorporated into the new program areas of interest for the SEDS FOA. Ten bonus points will be awarded to applications that address one or more of these priority areas. Applications that

propose a legislative priority project should include the priority area(s) in the project goal, all objectives and indicators as reflected in the project's framework, project approach, Objective Work Plan and Outcome Tracker. Reviewers should provide 10 points if all elements are included in the application to address one or more of the economic development priority areas.

In addition, during tribal consultation, additional social development priorities areas were identified by Native communities to potentially fund through the SEDS program. Therefore, 5 bonus points will be awarded to applications that address one or more of the following Native community priority areas: Native Veterans, Missing and Murdered Native Americans (MMNA), or Emergency Preparedness and Response. Applications that address one of more of these priorities areas should include the priority area in the project goal, all objectives, indicator(s), and target population (either as participants or beneficiaries). Reviewers should provide 5 points if all elements are included in the application to address one or more priority areas. Since social and economic development projects have different project goals, no application will be eligible to receive both sets of bonus points. In addition, the SEDS program areas of interest will be expanded to include MMNA and Anti-Human Trafficking.

7. Changes to SEDS–AK FOA—Section 803 of NAPA, 42 U.S.C. 2991b. ANA will also incorporate the new legislative economic development priorities into the SEDS–AK FOA. Therefore, new program areas of interest for SEDS–AK will include the following: (1) The development of a Tribal code or court system for purposes of economic development, including commercial codes, training for court personnel, and the development of nonprofit subsidiaries or other tribal business structures; (2) the development of native community development financial institutions, including training and administrative expenses; (3) the development of a tribal master plans for community and economic development and infrastructure. Therefore, 10 bonus points will be awarded to applications that address one or more of these priority areas. Applications that propose a legislative priority project should have it included in the project goal, all objectives and indicators as reflected in the project's framework, the project approach, and the Objective Work Plan and Outcome Tracker. Reviewers should provide 10 points if all elements are included in the application to address one or more of the economic development priority areas. In addition, ANA plans to modify the description of the program purpose for the SEDS–AK FOA to provide a competitive advantage for smaller Alaska Native villages or organizations that have never received ANA funding. Therefore, the FOA will state that reviewers should award 5 bonus points in the scoring criteria if an eligible entity has never received an ANA award. ANA staff will confirm during the objective review process if an applicant organization for SEDS–AK has received a past ANA award.

8. Changes to EMI FOA—Section 803C of NAPA, 42 U.S.C. 2991b–3. In accordance with 42 U.S.C. 2991b–3(c)(7), applicants for an EMI grant must submit an official document that certifies the applicant has at least 3 years of experience in operating and administering a Native American language survival school, a Native American language nest, or any other educational program in which instruction is conducted in a Native American language, in accordance with Public Law 109–394. Therefore, the EMI FOA will have a new evaluation criterion to score 10 points to ensure the application includes a certification document that demonstrates the applicant has at least 3 years of experience in operating a language nest, survival school, or other native language educational program. As a result, the EMI FOA's scoring criteria will change as follows:

Approach for a maximum of 75 points, to consist of the following: Nest or Survival School Certification (10 points); Long Term Community Goal (2 points); Current Community Condition (3 points); Project Goal (2 points); Objectives (6 points); Outcomes and Indicators (5 points); Outputs (3 points); Outcome Tracker and Outcome Tracking Strategy (7 points); Community-Based Strategy (8 points); Readiness and Implementation Strategy (16 points); and the Objective Work Plan (OWP) (13 points).

Organizational Capacity for a maximum of 10 points.

Budget and Budget Justification for a maximum of 15 points, to consist of the following: Line Item Budget (5 points) and Budget Justification (10 points).

9. Changes to SEDS–GO FOA—Sections 803 and 803B of NAPA, 42 U.S.C. 2991b; 2991b–2. In FY 2020, ANA introduced a new FOA as a special initiative under the SEDS program to support growing organizations to provide funding to enhance their internal capacity and infrastructure to better serve their members or their communities. There will be no substantive changes to application requirements in the FY 2021 SEDS–GO FOA. There will be slight changes to the evaluation scoring criteria, which will be as follows:

Approach (for a maximum of 70 points) to consist of the following: Introduction to the Applicant Organization (6 points); Targeted Challenge (6 points); Project Goal (6 points); SMART Objectives (6 points); Outcomes and Indicators (6 points); Description of Project Implementation Strategy (25 points); Objective Work Plan (OWP) (15 points).

Organizational Capacity—15 points.

Budget and Budget Justification (for a maximum of 15 points) to consist of a Line Item Budget (5 points) and a Budget Justification (10 points).

Bonus Points—5 bonus points may be provided to applicants that have never received an ANA grant award.

Statutory Authority: Section 814 of the Native American Programs Act of 1974, as amended.

Elizabeth Leo,

Senior Grant Policy Specialist, Office of Administration, Administration for Children and Families.

[FR Doc. 2021–03345 Filed 2–18–21; 8:45 am]

BILLING CODE 4184–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1136]

Guidance Documents Related to Coronavirus Disease 2019; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of FDA guidance documents related to the Coronavirus Disease 2019 (COVID–19) public health emergency (PHE). This notice of availability (NOA) is pursuant to the process that FDA announced, in the **Federal Register** of March 25, 2020, for making available to the public COVID–19-related guidances. The guidances identified in this notice address issues related to the COVID–19 PHE and have been issued in accordance with the process announced in the March 25, 2020, notice. The guidances have been implemented without prior comment, but they remain subject to comment in accordance with the Agency's good guidance practices.

DATES: The announcement of the guidances is published in the **Federal Register** on February 19, 2021.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, 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 name of the guidance document that the comments address and the docket number for the guidance (see table 1). Received comments will be placed in the docket(s) 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, 240–402–7500.

• 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.govinfo.gov/content/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, 240–402–7500.

You may submit comments on any guidance at any time (see § 10.115(g)(5) (21 CFR 10.115(g)(5))).

Submit written requests for single copies of these guidances to the address noted in table 1. Send two self-addressed adhesive labels to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Stephen Ripley, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911, Kimberly Thomas, Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6220, Silver Spring, MD 20993–0002, 301–796–2357, or Erica Takai, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5456, Silver Spring, MD 20993–0002, 301–796–6353.

SUPPLEMENTARY INFORMATION:

I. Background

On January 31, 2020, as a result of confirmed cases of COVID–19, and after consultation with public health officials as necessary, the Secretary of Health and Human Services (HHS), pursuant to the authority under section 319 of the Public Health Service Act (42 U.S.C. 247d), determined that a PHE exists and has existed since January 27, 2020, nationwide.[1] On March 13, 2020, there was a Presidential declaration that the COVID–19 outbreak in the United States constitutes a national emergency, beginning March 1, 2020.[2]

In the **Federal Register** of March 25, 2020 (85 FR 16949) (the March 25, 2020, notice) (available at *https://www.govinfo.gov/content/pkg/FR-2020-03-25/pdf/2020-06222.pdf*), FDA announced procedures for making available FDA guidances related to the COVID–19 PHE. These procedures, which operate within FDA's established good guidance practices regulations, are intended to allow FDA to rapidly disseminate Agency recommendations and policies related to COVID–19 to industry, FDA staff, and other stakeholders. The March 25, 2020, notice stated that due to the need to act quickly and efficiently to respond to the COVID–19 PHE, FDA believes that prior public participation will not be feasible or appropriate before FDA implements COVID–19-related guidances. Therefore, FDA will issue COVID–19-related guidances for immediate implementation without prior public comment (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(h)(1)(C)) and § 10.115(g)(2)). The guidances are available on FDA's web pages entitled ''COVID–19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders'' (available at *https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-*

[1] Secretary of Health and Human Services, ''Determination that a Public Health Emergency Exists'' (originally issued on January 31, 2020, and subsequently renewed), available at: *https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx.*

[2] Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID–19) Outbreak (March 13, 2020), available at: *https://trumpwhitehouse.archives.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/.*

stakeholders) and ''Search for FDA Guidance Documents'' (available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents)*.

The March 25, 2020, notice further stated that, in general, rather than publishing a separate NOA for each COVID–19-related guidance, FDA intends to publish periodically a consolidated NOA announcing the availability of certain COVID–19-related guidances that FDA issued during the relevant period, as included in table 1. This notice announces COVID–19-related guidances that are posted on FDA's website.

II. Availability of COVID–19-Related Guidance Documents

Pursuant to the process described in the March 25, 2020, notice, FDA is announcing the availability of the following COVID–19-related guidances:

TABLE 1—GUIDANCES RELATED TO THE COVID–19 PUBLIC HEALTH EMERGENCY

Docket No.	Center	Title of guidance	Contact information to request single copies
FDA–2020–D–1825	CBER	Investigational COVID–19 Convalescent Plasma (Updated January 2021).	Office of Communication, Outreach and Development, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002, 1–800–835–4709 or 240–402–8010; email *ocod@fda.hhs.gov.*
FDA–2020–D–1137	CBER	Manufacturing Considerations for Licensed and Investigational Cellular and Gene Therapy Products During COVID–19 Public Health Emergency (January 2021).	Office of Communication, Outreach and Development, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002, 1–800–835–4709 or 240–402–8010; email *ocod@fda.hhs.gov.*
FDA–2020–D–1136	CDER	Review Timelines for Applicant Responses to Complete Response Letters When a Facility Assessment Is Needed During the COVID–19 Public Health Emergency (December 2020).	*druginfo@fda.hhs.gov.* Please include the docket number FDA–2020–D–1136 and complete title of the guidance in the request.
FDA–2020–D–1136	CDER	Protecting Participants in Bioequivalence Studies for Abbreviated New Drug Applications During the COVID–19 Public Health Emergency (January 2021).	*druginfo@fda.hhs.gov.* Please include the docket number FDA–2020–D–1136 and complete title of the guidance in the request.
FDA–2020–D–1136	CDER	COVID–19: Potency Assay Considerations for Monoclonal Antibodies and Other Therapeutic Proteins Targeting SARS-CoV–2 Infectivity (January 2021).	*druginfo@fda.hhs.gov.* Please include the docket number FDA–2020–D–1136 and complete title of the guidance in the request.
FDA–2020–D–1138	CDRH	Coagulation Systems for Measurement of Viscoelastic Properties: Enforcement Policy During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency (January 2021).	*CDRH-Guidance@fda.hhs.gov.* Please include the document number 20041–R1 and complete title of the guidance in the request.

Although these guidances have been implemented immediately without prior comment, FDA will consider all comments received and revise the guidances as appropriate (see § 10.115(g)(3)).

These guidances are being issued consistent with FDA's good guidance practices regulation (§ 10.115). The guidances represent the current thinking of FDA. They do not establish any rights for any person and are not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

A. CBER Guidances

While these guidances contain no collection of information, they do refer to previously approved FDA collections of information (listed in table 2). Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for these guidances. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulations and guidances have been approved by OMB as listed in the following table:

TABLE 2—CBER GUIDANCES AND COLLECTIONS

COVID–19 guidance title	CFR cite referenced in COVID–19 guidance	Another guidance title referenced in COVID–19 guidance	OMB control No(s).
Investigational COVID–19 Convalescent Plasma; Guidance for Industry (Updated: January 15, 2021).	21 CFR part 312, 21 CFR parts 606 and 630.	Form FDA 3926	0910–0014, 0910–0116, 0910–0814.
Manufacturing Considerations for Licensed and Investigational Cellular and Gene Therapy Products During COVID–19 Public Health Emergency (January 2021).	21 CFR 1271.50, 21 CFR part 211, 21 CFR part 312 (INDs), 21 CFR part 601 (BLAs), 21 CFR 314.420 (Master Files).	.....	0910–0543, 0910–0139, 0910–0014, 0910–0338, 0910–0001.

B. CDER Guidances

While these guidances contain no collection of information, they do refer to previously approved FDA collections of information (listed in table 3). Therefore, clearance by OMB under the PRA (44 U.S.C. 3501–3521) is not required for these guidances. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulations and guidances have been approved by OMB as listed in the following table:

TABLE 3—CDER GUIDANCES AND COLLECTIONS

COVID–19 guidance title	CFR cite referenced in COVID–19 guidance	Another guidance title referenced in COVID–19 guidance	OMB control No(s).
Review Timelines for Applicant Responses to Complete Response Letters When a Facility Assessment Is Needed During the COVID–19 Public Health Emergency (December 2020).	21 CFR 314.3(b), 21 CFR 600.3 and 600.21, 21 CFR 601.20(d).	Manufacturing, Supply Chain, and Drug and Biological Product Inspections During COVID–19 Public Health Emergency: Questions and Answers.	0910–0001, 0910–0338, 0910–0139.
Protecting Participants in Bioequivalence Studies for Abbreviated New Drug Applications During the COVID–19 Public Health Emergency.	21 CFR 50, 21 CFR 312, 21 CFR 314.3, 21 CFR 314.101, 21 CFR 314.105, 21 CFR 320.1, 21 CFR 320.23(b), 21 CFR 320.24–26, 21 CFR 320.31, 21 CFR 314.94, 314.101, 314.105.	Referencing Approved Drug Products in ANDA Submissions. Bioequivalence Studies With Pharmacokinetic Endpoints for Drugs Submitted Under an Abbreviated New Drug Application. Conduct of Clinical Trials of Medical Products during the COVID–19 Public Health Emergency. ANDA Submissions—Content and Format of Abbreviated New Drug Application. Controlled Correspondence Related to Generic Drug Development. Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA. Use of Electronic Informed Consent in Clinical Investigations—Questions and Answers. Oversight of Clinical Investigations—A Risk-Based Approach to Monitoring.	0910–0001, 0910–0014, 0910–0130, 0910–0139, 0910–0303, 0910–0572, 0910–0755, 0910–0797.
COVID–19: Potency Assay Considerations for Monoclonal Antibodies and Other Therapeutic Proteins Targeting SARS–CoV–2 Infectivity.	21 CFR 211.165, 21 CFR 211.194, 21 CFR 601.2, 21 CFR 610.3, 21 CFR 610.10.	ICH guidance for Industry Q6B Specifications: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products. Analytical Procedures and Methods Validation for Drugs and Biologics. ICH guidance for industry Q2(R1) Validation of Analytical Procedures: Text and Methodology. Emergency Use Authorization of Medical Products and Related Authorities. Bioanalytical Method Validation. ICH guidance for industry M4Q: The CTD—Quality. ICH guidance for industry Q5C Quality of Biotechnological Products: Stability Testing of Biotechnological/Biological Products. ICH guidance for industry Q8(R2) Pharmaceutical Development.	0910–0001, 0910–0014, 0910–0338, 0910–0139, 0910–0303.

C. CDRH Guidance

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information (listed in table 4). Therefore, clearance by OMB under the PRA (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulations have been approved by OMB as listed in the following table:

TABLE 4—CDRH GUIDANCE AND COLLECTIONS

COVID–19 guidance title	CFR cite referenced in COVID–19 guidance	Another guidance title referenced in COVID–19 guidance	OMB control No(s).
Coagulation Systems for Measurement of Viscoelastic Properties: Enforcement Policy During the Coronavirus Disease 2019 (COVID–19) Public Health Emergency (January 2021).	800, 801, and 809		0910–0485.
	807, subparts A through D		0910–0625.
	807, subpart E		
	803		0910–0120.
	806		0910–0437.
	820		0910–0359.
			0910–0073.

IV. Electronic Access

Persons with access to the internet may obtain COVID–19-related guidances at:

- FDA web page entitled ''COVID–19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders,'' available at *https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders;*
- FDA web page entitled ''Search for FDA Guidance Documents'' available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents;* or
- *https://www.regulations.gov.*

Dated: February 16, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–03421 Filed 2–18–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–2253]

Medical Device User Fees; Stakeholder Meetings on Medical Device User Fee Amendments of Fiscal Years 2023 to 2027 Reauthorization; Request for Notification of Stakeholder Intention to Participate

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for notification of participation.

SUMMARY: The Food and Drug Administration (FDA or Agency) is issuing this notice to request that public stakeholders—including patient and consumer advocacy groups, healthcare professionals, and scientific and academic experts—notify FDA of their intent to participate in periodic consultation meetings on the reauthorization of the Medical Device User Fee Amendments (MDUFA). The statutory authority for MDUFA expires in September 2022. At that time, new legislation will be required for FDA to continue collecting user fees for the medical device program. The Federal Food, Drug, and Cosmetic Act (FD&C Act) requires that FDA consult with a range of stakeholders in developing recommendations for the next MDUFA program. The FD&C Act also requires that FDA hold discussions (at least every month) with patient and consumer advocacy groups during FDA's negotiations with the regulated industry. The purpose of this request for notification is to ensure continuity and progress in these monthly discussions by establishing consistent public stakeholder representation.

DATES: Submit notification of intention to participate in these series of meetings by February 26, 2021. Stakeholder meetings will be held monthly. It is anticipated that they will commence in March 2021. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The meetings will take place virtually and will be held by webcast only. Submit notification of intention to participate in monthly stakeholder meetings by email to *MDUFAVReauthorization@fda.hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Ellen Olson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1664, Silver Spring, MD 20993, 301–796–4322, *MDUFAVReauthorization@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is requesting that public stakeholders—including patient and consumer advocacy groups, healthcare professionals, and scientific and academic experts—notify the Agency of their intent to participate in periodic stakeholder consultation meetings on the reauthorization of MDUFA. MDUFA authorizes FDA to collect user fees from the regulated industry for the process for the review of medical devices. The authorization for the current program (MDUFA IV) expires in September 2022. Without new legislation, FDA will no longer be able to collect user fees for future fiscal years to fund the medical device review process.

Section 738A(b)(1) of the FD&C Act (21 U.S.C. 379j–1(b)(1)) requires that FDA consult with a range of stakeholders, including representatives from patient and consumer advocacy groups, healthcare professionals, and scientific and academic experts, in developing recommendations for the next MDUFA program. FDA initiated the reauthorization process by holding a public meeting on October 27, 2020, where stakeholders and other members of the public were given an opportunity to present their views on the reauthorization. The FD&C Act further requires that FDA continue meeting with the representatives of patient and consumer advocacy groups at least once every month during negotiations with the regulated industry to continue discussions of stakeholder views on the reauthorization and their suggestions for changes. It is anticipated that these monthly stakeholder consultation meetings will commence in March 2021.

FDA is issuing this **Federal Register** notice to request that stakeholder representatives from patient and consumer advocacy groups, healthcare professional associations, as well as

scientific and academic experts, notify FDA of their intent to participate in the periodic stakeholder consultation meetings on MDUFA reauthorization. FDA believes that consistent stakeholder representation at these meetings will be important to ensure progress in these discussions. If you wish to participate in the stakeholder consultation meetings, please designate one or more representatives from your organization who will commit to attending these meetings and preparing for the discussions. Stakeholders who identify themselves through this notice, and are otherwise eligible to attend, may participate in all stakeholder consultation discussions while FDA negotiates with the regulated industry. These stakeholder discussions will satisfy the consultation requirement in section 738A(b)(3) of the FD&C Act.

II. Notification of Intent To Participate in Periodic Stakeholder Consultation Meetings

If you intend to participate in continued periodic stakeholder consultation meetings regarding MDUFA reauthorization, please provide notification by email to *MDUFAVReauthorization@fda.hhs.gov* by February 26, 2021. Your email should contain complete contact information, including name, title, affiliation, address, email address, phone number, and notice of any special accommodations required because of disability. Stakeholders will receive confirmation and additional information about the first meeting from FDA after the Agency receives this notification.

Dated: February 16, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–03428 Filed 2–18–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–2305]

Authorizations of Emergency Use of Certain Drug and Biological Products During the COVID–19 Pandemic; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of five Emergency Use Authorizations (EUAs) (the Authorizations) under the Federal Food, Drug, and Cosmetic Act (FD&C Act) for drug and biological products for use during the COVID–19 pandemic. FDA issued one Authorization for a drug as requested by Baxter Healthcare Corporation (Baxter); one Authorization for a biological product as requested by the Office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services (ASPR/HHS); an Authorization for a drug and an Authorization for a biological product as requested by Eli Lilly and Company; and one Authorization for biological products as requested by Regeneron Pharmaceuticals, Inc. The Authorizations contain, among other things, conditions on the emergency use of the authorized products. The Authorizations follow the February 4, 2020, determination by the Secretary of HHS that there is a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and that involves a novel (new) coronavirus. The virus, now named SARS–CoV–2, causes the illness COVID–19. On the basis of such determination, the Secretary of HHS declared on March 27, 2020, that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID–19 pandemic, pursuant to the FD&C Act, subject to the terms of any authorization issued under that section. The Authorizations, which include an explanation of the reasons for issuance, are reprinted in this document.

DATES: The Authorization for Baxter is effective as of August 13, 2020; the Authorization for ASPR/HHS is effective as of August 23, 2020; the Authorizations for Eli Lilly and Company are effective as of November 9, 2020, and November 19, 2020, respectively; and the Authorization for Regeneron Pharmaceuticals, Inc. is effective as of November 21, 2020.

ADDRESSES: Submit written requests for single copies of the EUAs to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a Fax number to which the Authorizations may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorizations.

FOR FURTHER INFORMATION CONTACT: Michael Mair, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4340, Silver Spring, MD 20993–0002, 301–796–8510 (this is not a toll free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb–3) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. With this EUA authority, FDA can help ensure that medical countermeasures may be used in emergencies to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by biological, chemical, nuclear, or radiological agents when there are no adequate, approved, and available alternatives.

II. Criteria for EUA Authorization

Section 564(b)(1) of the FD&C Act provides that, before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of the following grounds: (1) A determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents; (2) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces, including personnel operating under the authority of title 10 or title 50, U.S. Code, of attack with (A) a biological, chemical, radiological, or nuclear agent or agents; or (B) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to U.S. military forces; [1] (3) a determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living

[1] In the case of a determination by the Secretary of Defense, the Secretary of HHS shall determine within 45 calendar days of such determination, whether to make a declaration under section 564(b)(1) of the FD&C Act, and, if appropriate, shall promptly make such a declaration.

abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents; or (4) the identification of a material threat by the Secretary of Homeland Security pursuant to section 319F–2 of the Public Health Service (PHS) Act (42 U.S.C. 247d–6b) sufficient to affect national security or the health and security of U.S. citizens living abroad.

Once the Secretary of HHS has declared that circumstances exist justifying an authorization under section 564 of the FD&C Act, FDA may authorize the emergency use of a drug, device, or biological product if the Agency concludes that the statutory criteria are satisfied. Under section 564(h)(1) of the FD&C Act, FDA is required to publish in the **Federal Register** a notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons for the action. Section 564 of the FD&C Act permits FDA to authorize the introduction into interstate commerce of a drug, device, or biological product intended for use when the Secretary of HHS has declared that circumstances exist justifying the authorization of emergency use. Products appropriate for emergency use may include products and uses that are not approved, cleared, or licensed under sections 505, 510(k), 512, or 515 of the FD&C Act (21 U.S.C. 355, 360(k), 360b, and 360e) or section 351 of the PHS Act (42 U.S.C. 262), or conditionally approved under section 571 of the FD&C Act (21 U.S.C. 360ccc). FDA may issue an EUA only if, after consultation with the HHS Assistant Secretary for Preparedness and Response, the Director of the National Institutes of Health, and the Director of the Centers for Disease Control and Prevention (to the extent feasible and appropriate given the applicable circumstances), FDA [2] concludes: (1) That an agent referred to in a declaration of emergency or threat can cause a serious or life-threatening disease or condition; (2) that, based on the totality of scientific evidence available to FDA, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that: (A) The product may be effective in diagnosing, treating, or preventing (i) such disease or condition; or (ii) a serious or life-threatening disease or condition caused by a product authorized under section 564, approved or cleared under the FD&C Act, or licensed under section 351 of the PHS Act, for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and (B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product, taking into consideration the material threat posed by the agent or agents identified in a declaration under section 564(b)(1)(D) of the FD&C Act, if applicable; (3) that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition; (4) in the case of a determination described in section 564(b)(1)(B)(ii), that the request for emergency use is made by the Secretary of Defense; and (5) that such other criteria as may be prescribed by regulation are satisfied.

No other criteria for issuance have been prescribed by regulation under section 564(c)(4) of the FD&C Act.

III. The Authorizations

The Authorizations follow the February 4, 2020, determination by the Secretary of HHS that there is a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and that involves a novel (new) coronavirus. The virus, now named SARS–CoV–2, causes the illness COVID–19. Notice of the Secretary's determination was provided in the **Federal Register** on February 7, 2020 (85 FR 7316). On the basis of such determination, the Secretary of HHS declared on March 27, 2020, that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID–19 pandemic, pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section. Notice of the Secretary's declaration was provided in the **Federal Register** on April 1, 2020 (85 FR 18250). Having concluded that the criteria for issuance of the Authorizations under section 564(c) of the FD&C Act are met, FDA issued five authorizations for the emergency use of drug and biological products during the COVID–19 pandemic. On August 13, 2020, FDA issued an EUA to Baxter for REGIOCIT, subject to the terms of the Authorization. On August 23, 2020, FDA issued an EUA to ASPR/HHS for COVID–19 convalescent plasma, subject to the terms of the Authorization. On November 9, 2020, FDA issued an EUA to Eli Lilly and Company for bamlanivimab, subject to the terms of the Authorization (technical correction on November 10, 2020). On November 19, 2020, FDA issued an EUA to Eli Lilly and Company for OLUMIANT (baricitinib), for use in combination with VEKLURY (remdesivir), subject to the terms of the Authorization. On November 21, 2020, FDA issued an EUA to Regeneron Pharmaceuticals, Inc. for casirivimab and imdevimab, administered together, subject to the terms of the Authorization. The Authorizations, which are included after section IV of this document in their entirety (not including the authorized versions of the fact sheets and other written materials), provide an explanation of the reasons for issuance, as required by section 564(h)(1) of the FD&C Act. Any subsequent reissuances of these Authorizations can be found on FDA's web page: *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.*

IV. Electronic Access

An electronic version of this document and the full text of the Authorizations are available on the internet at *https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.*

BILLING CODE 4164–01–P

[2] The Secretary of HHS has delegated the authority to issue an EUA under section 564 of the FD&C Act to the Commissioner of Food and Drugs.

August 13, 2020

Mr. Fortunato Aldape
Baxter Healthcare Corporation
Director, Global Regulatory Affairs, Acute Therapies
One Baxter Parkway
Deerfield, IL 60015

Dear Mr. Aldape:

This letter is in response to Baxter Healthcare Corporation's ("Baxter") request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for REGIOCIT replacement solution that contains citrate for regional citrate anticoagulation (RCA) of the extracorporeal circuit for emergency use as a replacement solution in adult patients treated with Continuous Renal Replacement Therapy (CRRT) and for whom RCA of the extracorporeal circuit is appropriate, in a critical care setting, during the Coronavirus Disease 2019 (COVID-19) pandemic, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3).

On February 4, 2020, pursuant to section 564(b)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the Act), the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19.[1] Pursuant to section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared on March 27, 2020, that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic, subject to the terms of the authorization issued under that section.[2]

The Agency has noted that SARS-CoV-2, the virus that causes COVID-19, has led to an increased population with critical illness and multiple organ failure, including acute kidney injury, increasing the need for CRRT. As a result, there is an insufficient supply of replacement solutions to meet the emergency need to provide CRRT in critically ill patients. Based on the totality of scientific evidence available, FDA has concluded that REGIOCIT may be effective for use as a replacement solution in adult patients treated with CRRT with suspected or confirmed

[1] U.S. Department of Health and Human Services, Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3, 85 FR 7316 (February 7, 2020).
[2] U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*, 85 FR 18250 (April 1, 2020).

COVID-19[3], and for whom RCA of the extracorporeal circuit is appropriate, in a critical care setting during the Coronavirus Disease 2019 (COVID-19) pandemic.

Having concluded that the criteria for issuance of this authorization under section 564(c) of the Act are met, I am authorizing the emergency use of your REGIOCIT product, as described in the Scope of Authorization (Section II) of this letter, subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of REGIOCIT, as described in the Scope of Authorization (Section II) of this letter, meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

1. SARS-CoV-2, the virus that causes COVID-19, can cause a serious or life-threatening disease or condition, including severe respiratory illness and multiple organ failure, including acute kidney injury, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that REGIOCIT may be effective for use as a replacement solution in adult patients with suspected or known COVID-19[4] in a critical care setting who are being treated with CRRTand for whom RCA is appropriate, and that, when used under the terms and conditions described in this authorization, the known and potential benefits of REGIOCIT outweigh the known and potential risks of REGIOCIT; and

3. There is no adequate, approved, and available alternative to the emergency use of REGIOCIT due to an insufficient supply of FDA-approved alternatives to meet the emergency need during the COVID-19 pandemic.[5]

II. Scope of Authorization

I have concluded, pursuant to section 564(d)(1) of the Act, that the scope of this authorization is limited as follows:

- REGIOCIT will be used as a replacement solution only in adult patients being treated with CRRT and for whom RCA is appropriate.
- REGIOCIT will be administered only by a licensed healthcare provider in a critical care setting.

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[3] As noted in the letter of authorization, in the circumstances of this public health emergency, it would not be feasible to authorize REGIOCIT only to be used for patients with suspected or confirmed COVID-19; therefore, the authorization does not limit use to such patients.

[4] In the circumstances of this public health emergency, it would not be feasible to require healthcare providers to seek to limit REGIOCIT only to be used for patients with suspected or confirmed COVID-19; therefore, this authorization does not limit use to such patients.

[5] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

- REGIOCIT will be available for use only in facilities that Baxter Healthcare Corporation has qualified[6] for receiving REGIOCIT.

REGIOCIT is a replacement solution that contains citrate for RCA of the extracorporeal circuit. REGIOCIT is authorized for emergency use as a replacement solution in adult patients treated with CRRT, and for whom RCA is appropriate, during the COVID-19 pandemic. REGIOCIT is intended for use in a critical care setting. REGIOCIT is intended to be used in continuous venovenous hemofiltration (CVVH), and continuous venovenous hemodiafiltration (CVVHDF) modalities.

Authorized Product Details

REGIOCIT is supplied as a 5000 mL sterile solution of 0.503% sodium chloride and 0.529% sodium citrate in water for injection in a polyolefin clear plastic bag.

REGIOCIT is authorized under the terms and conditions of this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

REGIOCIT is authorized to be accompanied by the following product-specific information pertaining to the emergency use, which is required to be made available to healthcare providers and patients:

- Fact Sheet for Healthcare Providers: Emergency Use of REGIOCIT during the COVID-19 Pandemic
- REGIOCIT Package Insert- EUA
- Fact Sheet for Patients and Caregivers: Emergency Use of REGIOCIT during the COVID-19 Pandemic

I have concluded, pursuant to section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of REGIOCIT, when used consistent within the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of REGIOCIT.

I have concluded, pursuant to section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that REGIOCIT may be effective for the uses described within the Scope of Authorization of this letter (Section II), pursuant to section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that REGIOCIT, when used as described in the Scope of Authorization of this letter (Section II), meets the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.

[6] Baxter Healthcare Corporation will determine whether an individual facility is qualified, for the purposes of receiving REGIOCIT, in accordance with the process and criteria submitted in Baxter's EUA request.

The emergency use of the authorized product under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under section 564(b)(1), the REGIOCIT, with the required labeling set forth in this section (Section II), are authorized for the uses described above.

III. Conditions of Authorization

Pursuant to Section 564 of the Act, I am establishing the following conditions on this authorization:

Baxter Healthcare Corporation

A. Baxter Healthcare Corporation may request changes to the authorized labeling as described in the Scope of Authorization (Section II) of this letter. Such requests will be made in consultation with, and require concurrence of, the Division of Cardiology and Nephrology (DCN)/Office of Cardiology, Hematology, Endocrinology and Nephrology (OCHEN)/Office of New Drugs (OND)/Center for Drug Evaluation and Research (CDER).

B. Baxter Healthcare Corporation may request changes to the Scope of Authorization (Section II in this letter) of the product. Such requests will be made in consultation with, and require concurrence of, the Office of Counterterrorism and Emerging Threats (OCET)/Office of the Chief Scientist (OCS)/Office of the Commissioner (OC) and DCN/OCHEN/OND/CDER.

C. Baxter Healthcare Corporation will manufacture REGIOCIT in conformance with Current Good Manufacturing Practices.

D. Baxter Healthcare Corporation will manufacture and test REGIOCIT per the process and methods, including in-process sampling and testing and finished product testing (release and stability) to meet all specifications as referenced in Baxter's EUA request.

E. REGIOCIT will have an 18-month expiry period when stored at room temperature or refrigerated conditions.

F. Baxter Healthcare Corporation will conduct additional endotoxin testing as detailed in Baxter Healthcare Corporation's response, dated July 13, 2020, to FDA's information request, dated July 10, 2020.

G. Baxter Healthcare Corporation will not implement any changes to the description of the product, manufacturing process, facilities and equipment, and elements of the associated control strategy that assure process performance and quality of the authorized product without notification to and concurrence by the Agency.

H. Baxter Healthcare Corporation will determine whether an individual facility is qualified, for the purposes of receiving REGIOCIT, in accordance with the process and criteria submitted in Baxter Healthcare Corporation's EUA request. Baxter Healthcare Corporation will maintain documentation on its qualification activities for each individual facility.

I. Baxter Healthcare Corporation will submit information to the Agency within three working days of receipt of any information concerning any batch of REGIOCIT (whether the batch is distributed or not), as follows: (1) information concerning any incident that causes the drug product or its labeling to be mistaken for, or applied to, another article; and (2) information concerning any bacteriological or microscopic contamination, or any significant chemical, physical, or other change in deterioration in the drug product, or any failure of one or more batches of the drug product to meet the established specifications.

J. Baxter Healthcare Corporation will report to FDA serious adverse events and all medication errors associated with the use of REGIOCIT of which they become aware during the pandemic, to the extent practicable given emergency circumstances, using either of the following options.

Option 1: Submit reports through the Safety Reporting Portal (SRP) as described on the FDA SRP web page.

Option 2: Submit reports directly through the Electronic Submissions Gateway (ESG) as described on the FAERS electronic submissions web page.

Submitted reports under both options should state: "use of REGIOCIT was under an EUA". For reports submitted under Option 1, include this language at the beginning of the question "Describe Event" for further analysis. For reports submitted under Option 2, include this language at the beginning of the "Case Narrative" field.

Baxter Healthcare Corporation and Authorized Distributors[7]

K. Baxter Healthcare Corporation will notify FDA of any authorized distributor(s) of the product, including the name, address, and phone number of any authorized distributor(s), and provide authorized distributor(s) with a copy of this EUA.

L. Baxter Healthcare Corporation and authorized distributor(s) will make REGIOCIT available with the authorized labeling as described in the Scope of Authorization (Section II) of this letter.

[7] "Authorized Distributor(s)" are identified by the sponsor in EUA requests as an entity allowed to distribute the product.

M. Baxter Healthcare Corporation and authorized distributor(s) will make available on their website(s) the Fact Sheet for Healthcare Providers, the Fact Sheet for Patients, and the REGIOCIT Package Insert for EUA.

N. Through a process of inventory control, Baxter Healthcare Corporation and authorized distributor(s) will maintain records of the healthcare settings to which they distribute REGIOCIT and the number of bags of REGIOCIT distributed.

O. Baxter Healthcare Corporation and authorized distributor(s) will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

P. Baxter Healthcare Corporation and authorized distributor(s) are authorized to make available additional information relating to the emergency use of the product that is consistent with, and does not exceed, the terms of this letter of authorization.

Hospitals and Other Healthcare Facilities to Whom the Authorized REGIOCIT Is Distributed and Healthcare Providers Administering the Authorized REGIOCIT

Q. Healthcare facilities and healthcare providers will ensure that they are aware of the letter of authorization, and the terms herein, and that the authorized labeling (as described in the Scope of Authorization (Section II) of this letter) is made available to healthcare providers and to patients and caregivers through appropriate means.

R. Through a process of inventory control, healthcare facilities will maintain records regarding the dispensed authorized REGIOCIT (i.e., lot numbers, quantity, receiving site, receipt date), and product storage.

S. Healthcare facilities will ensure that any records associated with this EUA are maintained until notified by Baxter Healthcare Corporation and/or FDA. Such records will be made available to Baxter Healthcare Corporation, HHS, and FDA for inspection upon request.

T. Healthcare facilities and prescribing health care providers or their designee receiving REGIOCIT will track all medication errors associated with the use of and all serious adverse events that are considered to be potentially attributable to REGIOCIT use and must report these to FDA in accordance with the Fact Sheet for Healthcare Providers using one of the following methods:

Option 1: Complete and submit a MedWatch form online (www.fda.gov/medwatch/report.htm)

Option 2: Complete and submit FDA Form 3500 (health professional) by fax (1-800-FDA-0178) (this form can be found via link above).

Call 1-800-FDA-1088 for questions. Submitted reports should state, "use of REGIOCIT was under an EUA" at the beginning of the question "Describe Event" for further

analysis.

Conditions Related to Printed Matter, Advertising and Promotion

U. All descriptive printed matter, including advertising and promotional material, relating to the use of REGIOCIT shall be consistent with the authorized labeling, as well as the terms set forth in this EUA and the applicable requirements set forth in the Act and FDA regulations.

V. No descriptive printed matter, including advertising or promotional material, relating to the use of REGIOCIT may represent or suggest that such products are safe or effective.

W. All descriptive printed matter, including advertising and promotional material, relating to the use of REGIOCIT clearly and conspicuously shall state that:

- REGIOCIT is not FDA-approved;
- REGIOCIT has been authorized by FDA for use under an EUA;
- REGIOCIT is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

IV. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of REGIOCIT during the COVID-19 pandemic is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Sincerely,

--/S/--

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures

August 23, 2020

Robert P. Kadlec, MD, MTM&H, MS
Assistant Secretary for Preparedness and Response
Office of the Assistant Secretary for Preparedness and Response
Office of the Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Dr. Kadlec:

This letter is in response to your request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of COVID-19 convalescent plasma for the treatment of hospitalized patients with Coronavirus Disease 2019 (COVID-19), as described in the Scope of Authorization (Section II) of this letter, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3).

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19 (the virus was later named SARS-CoV-2).[1] On March 27, 2020, on the basis of such determination, the Secretary of HHS declared that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic, pursuant to Section 564 of the Act, subject to the terms of any authorization issued under that section.[2]

COVID-19 convalescent plasma is human plasma collected from individuals whose plasma contains anti-SARS-CoV-2 antibodies, and who meet all donor eligibility requirements (21 CFR 630.10 and 21 CFR 630.15) and qualifications. It is an investigational product and is not currently approved or licensed for any indication. Based on review of historical evidence using convalescent plasma in prior outbreaks of respiratory viruses, certain preclinical evidence, results from small clinical trials of convalescent plasma conducted during the current outbreak, and data obtained from the ongoing National Convalescent Plasma Expanded Access Protocol (EAP)

[1] U.S. Department of Health and Human Services (HHS). *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3.* February 4, 2020.
[2] HHS. *Emergency Use Authorization Declaration.* 85 FR 18250 (April 1, 2020). https://www.govinfo.gov/content/pkg/FR-2020-04-01/pdf/2020-06905.pdf.

sponsored by the Mayo Clinic,[3] it is reasonable to believe that the known and potential benefits of COVID-19 convalescent plasma outweigh the known and potential risks of the drug for the treatment of patients hospitalized with COVID-19.[4]

Current data suggest the largest clinical benefit is associated with high-titer units administered early in the course of disease. COVID-19 convalescent plasma units containing antibodies to SARS-CoV-2 but not qualified as high-titer by a test found acceptable for this purpose by FDA (see Section II) are considered Low Titer units and are acceptable for use based on an individualized assessment of patient benefit-risk. Adequate and well-controlled randomized trials remain necessary for a definitive demonstration of COVID-19 convalescent plasma efficacy and to determine the optimal product attributes and appropriate patient populations for its use. Given that the clinical evidence supporting this EUA was not obtained from prospective, well-controlled randomized clinical trials (RCTs), additional RCTs are needed. COVID-19 convalescent plasma should not be considered a new standard of care for the treatment of patients with COVID-19. Additional data will be forthcoming from other analyses and ongoing, well-controlled clinical trials in the coming months. These ongoing clinical trials of COVID-19 convalescent plasma should not be amended based on the issuance of this EUA; providers are encouraged to enroll patients in those trials.

Having concluded that the criteria for issuance of this authorization under 564(c) of the Act are met, I am authorizing the emergency use of COVID-19 convalescent plasma for treatment of hospitalized patients with COVID-19, as described in the Scope of Authorization section of this letter (Section II) and subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of COVID-19 convalescent plasma for the treatment of hospitalized patients with COVID-19 when administered as described in the Scope of Authorization (Section II) meet the criteria for issuance of an authorization under Section 564(c) of the Act, because:

1. SARS-CoV-2 can cause COVID-19, a serious or life-threatening disease or condition, including severe respiratory illness, in humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that COVID-19 convalescent plasma may be effective in treating COVID-19, and that, when used under the conditions described in this authorization, the known and potential benefits of COVID-19 convalescent plasma when used to treat COVID-19 outweigh the known and potential risks of such products; and

[3] A national expanded access protocol (EAP) sponsored by the Mayo Clinic was established in April 2020 and has enrolled ~90,000 subjects as of August 13, 2020. The goal of this uncontrolled, single-arm study is to provide access to COVID-19 convalescent plasma in hospitalized subjects with severe or life-threatening COVID-19 or judged by the treating provider to be at high risk of progression to severe or life-threatening disease.

[4] Information derived from ongoing clinical trials of COVID-19 convalescent plasma (particularly randomized controlled trials), as well as clinical trial results from studies of other investigational medical products to treat COVID-19, will continue to inform the risk-benefit assessment for this EUA.

3. There is no adequate, approved, and available alternative to the emergency use of COVID-19 convalescent plasma for the treatment of COVID-19.[5]

II. Scope of Authorization

I have concluded, pursuant to section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of the authorized COVID-19 convalescent plasma for the treatment of hospitalized patients with COVID-19. The emergency use of the authorized COVID-19 convalescent plasma under this EUA must be consistent with, and may not exceed, the terms of this letter, including the scope and the conditions of authorization set forth below.

The Authorized COVID-19 Convalescent Plasma (Product Description):

I am authorizing the use of COVID-19 convalescent plasma, a biologic product to be used for the treatment of hospitalized patients with COVID-19.

COVID-19 convalescent plasma is human plasma collected from individuals whose plasma contains SARS-CoV-2 antibodies and who meet all donor eligibility requirements (21 CFR 630.10 and 21 CFR 630.15) and qualifications. Under this EUA, authorized COVID-19 convalescent plasma will be obtained from registered or licensed blood establishments from donors in the United States or its territories in accordance with applicable regulations, policies, and procedures. Testing for relevant transfusion-transmitted infections (21 CFR 610.40) must be performed and the donation must be found suitable (21 CFR 630.30).

Plasma donations must be tested by registered or licensed blood establishments for anti-SARS-CoV-2 antibodies as a manufacturing step to determine suitability before release. Units tested by the Ortho VITROS SARS-CoV-2 IgG test and found to have a signal-to-cutoff (S/C) value of 12 or greater qualify as high titer COVID-19 convalescent plasma. If a blood establishment is considering using an alternative test in manufacturing in order to qualify high titer COVID-19 convalescent plasma, they should contact the FDA Center for Biologics Evaluation and Research (CBER) to determine acceptability of the proposed test, which if accepted, would require an amendment to this EUA.

Units containing anti-SARS-CoV-2 antibodies but not qualified as high titer by the test described above are considered low titer units and must be labeled accordingly. The health care provider may assess whether units with a S/C value of less than 12 are acceptable for use based on an individualized assessment of benefit-risk. FDA will continue to evaluate this recommendation based on additional data that become available.

Health care providers will administer the authorized COVID-19 convalescent plasma with anti-SARS-CoV-2 antibodies according to standard hospital procedures and institutional medical and nursing practices. Clinical dosing may first consider starting with one COVID-19 convalescent plasma unit (about 200 mL), with administration of additional COVID-19 convalescent plasma units based on the prescribing physician's medical judgment and the patient's clinical response.

[5] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

COVID-19 convalescent plasma is authorized to be accompanied by the following product-specific information pertaining to emergency use, which is required to be made available to health care providers and patients respectively:

- Fact Sheet for Health Care Providers: Emergency Use Authorization (EUA) of COVID-19 Convalescent Plasma for Treatment of COVID-19 in Hospitalized Patients
- Fact Sheet for Patients and Parents Caregivers: Emergency Use Authorization (EUA) of COVID-19 Convalescent Plasma for Treatment of COVID-19 in Hospitalized Patients.

Changes to the authorized Fact Sheets may be requested by the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR) and are authorized to be made in consultation with, and with concurrence of, the Office of Blood Research and Review (OBRR) Center for Biologics Evaluation and Research (CBER), Counterterrorism Office (CT) Office of the Center Director (OD) CBER, and Office of Counterterrorism and Emerging Threats (OCET) Office of the Chief Scientist (OCS) Office of the Commissioner (OC), as appropriate.

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of COVID-19 convalescent plasma, when used for the treatment of hospitalized patients with COVID-19 and used in accordance with this Scope of Authorization (Section II), outweigh its known and potential risks.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that COVID-19 convalescent plasma may be effective for the treatment of hospitalized patients with COVID-19 when used in accordance with this Scope of Authorization (Section II), pursuant to Section 564(c)(2)(A) of the Act.

Having reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, I have concluded that COVID-19 convalescent plasma (as described in this Scope of Authorization (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of your product under an EUA must be consistent with, and may not exceed, the terms of the Authorization, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section III). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1), COVID-19 convalescent plasma is authorized for the treatment of hospitalized patients with COVID-19 as described in the Scope of Authorization (Section II) under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

III. Conditions of Authorization

Pursuant to section 564 of the Act, I am establishing the following conditions on this authorization:

ASPR

A. ASPR will ensure that the terms of this EUA are made available to all relevant stakeholders (e.g., U.S. government agencies, state and local government authorities, registered or licensed blood establishments, hospitals, health care providers) involved in distributing or receiving authorized COVID-19 convalescent plasma. ASPR will provide to all relevant stakeholders a copy of this letter of authorization and communicate any subsequent amendments that might be made to this letter of authorization and its authorized accompanying materials (i.e., Fact Sheets).

B. ASPR may request changes to this authorization, and such changes may be permitted without amendment of this EUA upon concurrence of OBRR/CBER, CT/OD/CBER, and OCET/OCS/OC.

C. ASPR may request changes to the authorized Fact Sheets for COVID-19 convalescent plasma, and such changes may be permitted without amendment of this EUA upon concurrence of OBRR/CBER, CT/OD/CBER, and OCET/OCS/OC.

D. ASPR will report to FDA serious adverse events and all medication errors associated with the use of the authorized COVID-19 convalescent plasma that are reported to ASPR, or of which ASPR otherwise becomes aware, during the pandemic.

E. ASPR will make available to FDA upon request any records maintained in connection with this EUA.

Registered or Licensed Blood Establishments

F. Registered or licensed blood establishments will ensure that the authorized COVID-19 convalescent plasma, accompanied with the authorized labeling (i.e., Fact Sheets), is distributed to hospitals consistent with the terms of this letter, and that such hospitals are aware of the letter of authorization.

G. Registered or licensed blood establishments will ensure that appropriate storage and cold chain is maintained. The authorized COVID-19 convalescent plasma should be frozen after collection and stored at -18°C or colder. Once thawed, it can be refrigerated for up to 5 days prior to patient transfusion.

H. Through a process of inventory control, registered or licensed blood establishments will maintain records regarding distribution of the authorized COVID-19 convalescent plasma (i.e., donor records, quantity, receiving site, receipt date).

I. Registered or licensed blood establishments will make available to FDA upon request any records maintained in connection with this EUA.

Hospitals to Whom the Authorized COVID-19 Convalescent Plasma Is Distributed, and Health Care Providers Administering the Authorized COVID-19 Convalescent Plasma

J. Hospitals and health care providers receiving authorized COVID-19 convalescent plasma will ensure that they are aware of the letter of authorization, and the terms herein, and that the authorized Fact Sheets are made available to health care providers and to patients and caregivers, respectively, through appropriate means.

K. The authorized COVID-19 convalescent plasma must be stored frozen at -18°C or colder. Once thawed and refrigerated, the authorized COVID-19 convalescent plasma must be used within 5 days for patient transfusion.

L. Hospitals and health care providers administering COVID-19 convalescent plasma will track serious adverse events that are considered to be potentially attributable to COVID-19 convalescent plasma use and must report these to FDA in accordance with the Fact Sheet for Health Care Providers. Health care providers must maintain records and conduct a thorough investigation of adverse reactions after transfusion of convalescent plasma, and must report fatalities related to transfusion, as required under 21 CFR 606.170.

M. Through a process of inventory control, hospitals will maintain records regarding the administered authorized COVID-19 convalescent plasma (e.g., donation identification number, quantity, receiving site, receipt date), product storage, and maintain patient information (e.g., patient name, age, disease manifestation, number of doses administered per patient, other drugs administered).

N. Hospitals will ensure that any records associated with this EUA are maintained until notified by ASPR and/or FDA. Such records will be made available to ASPR, HHS, and FDA for inspection upon request.

Conditions Related to Printed Matter, Advertising, and Promotion

O. All descriptive printed matter, including advertising and promotional material, relating to the use of the authorized COVID-19 convalescent plasma shall be consistent with the authorized labeling, as well as the terms set forth in this EUA and the applicable requirements set forth in the Act and FDA regulations.

P. No descriptive printed matter, including advertising or promotional material, relating to the use of COVID-19 convalescent plasma may represent or suggest that such product is safe or effective.

Q. All descriptive printed matter, including advertising and promotional material, relating to the use of COVID-19 convalescent plasma clearly and conspicuously shall state that:

- COVID-19 convalescent plasma has not been approved or licensed by FDA;
- COVID-19 convalescent plasma has been authorized by FDA under an EUA;
- COVID-19 convalescent plasma is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

IV. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

/s/

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures

November 10, 2020

Eli Lilly and Company
Attention: Christine Phillips, PhD, RAC
Advisor Global Regulatory Affairs - US
Lilly Corporate Center
Drop Code 2543
Indianapolis, IN 46285

Dear Ms. Phillips:

This letter is in response to Eli Lilly and Company's ("Lilly") request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of bamlanivimab for the treatment of mild to moderate coronavirus disease 2019 (COVID-19), as described in the Scope of Authorization (Section II) of this letter, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3).

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19.[1] On the basis of such determination, the Secretary of HHS on March 27, 2020, declared that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3), subject to terms of any authorization issued under that section.[2]

Bamlanivimab is a neutralizing IgG1 monoclonal antibody that binds to the receptor binding domain of the spike protein of SARS-CoV-2. It is an investigational drug and is not currently approved for any indication.

Based on review of the topline data from the planned interim analysis of Trial J2W-MC-PYAB, also called BLAZE-1 (NCT04427501), an ongoing randomized, double-blind, placebo-controlled, Phase 2 dose finding trial of bamlanivimab monotherapy in outpatients with mild to moderate COVID-19, it is reasonable to believe that bamlanivimab may be effective for the treatment of mild to moderate COVID-19 in adults and pediatric patients with positive results of direct SARS-CoV-2 viral testing who are 12 years of age and older weighing at least 40 kg, and who are at high risk for progressing to severe COVID-19 and/or hospitalization, and that, when

[1] U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*, February 4, 2020.
[2] U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*, 85 FR 18250 (April 1, 2020).

used under the conditions described in this authorization, the known and potential benefits of bamlanivimab outweigh the known and potential risks of such product.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of bamlanivimab for treatment of COVID-19, as described in the Scope of Authorization section of this letter (Section II) and subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of bamlanivimab for the treatment of COVID-19 when administered as described in the Scope of Authorization (Section II) meets the criteria for issuance of an authorization under Section 564(c) of the Act, because:

1. SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that bamlanivimab may be effective in treating mild to moderate COVID-19 in adults and pediatric patients with positive results of direct SARS-CoV-2 viral testing who are 12 years of age and older weighing at least 40 kg, and who are at high risk for progressing to severe COVID-19 and/or hospitalization, and that, when used under the conditions described in this authorization, the known and potential benefits of bamlanivimab outweigh the known and potential risks of such product; and

3. There is no adequate, approved, and available alternative to the emergency use of bamlanivimab for the treatment of mild to moderate COVID-19 in adults and pediatric patients with positive results of direct SARS-CoV-2 viral testing who are 12 years of age and older weighing at least 40 kg, and who are at high risk for progressing to severe COVID-19 and/or hospitalization.[3]

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited as follows:

- Distribution of the authorized bamlanivimab will be controlled by the United States (U.S.) Government for use consistent with the terms and conditions of this EUA. Lilly will supply bamlanivimab to authorized distributors[4], who will distribute to healthcare facilities or healthcare providers as directed by the U.S. Government, in collaboration with state and local government authorities, as needed;

[3] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.
[4] "Authorized Distributor(s)" are identified by Lilly as an entity or entities allowed to distribute authorized bamlanivimab.

- The bamlanivimab covered by this authorization will be used only by healthcare providers to treat mild to moderate COVID-19 in adults and pediatric patients with positive results of direct SARS-CoV-2 viral testing who are 12 years of age and older weighing at least 40 kg, and who are at high risk for progressing to severe COVID-19 and or hospitalization;

- Bamlanivimab is not authorized for use in the following patient populations [5]:

  - Adults or pediatric patients who are hospitalized due to COVID-19, or
  - Adults or pediatric patients who require oxygen therapy due to COVID-19, or
  - Adults or pediatric patients who require an increase in baseline oxygen flow rate due to COVID-19 in those patients on chronic oxygen therapy due to underlying non-COVID-19-related comorbidity.

- Bamlanivimab may only be administered in settings in which health care providers have immediate access to medications to treat a severe infusion reaction, such as anaphylaxis, and the ability to activate the emergency medical system (EMS), as necessary.

- The use of bamlanivimab covered by this authorization must be in accordance with the dosing regimens as detailed in the authorized Fact Sheets.

Product Description

Bamlanivimab is a neutralizing IgG1 monoclonal antibody that binds to the receptor binding domain of the spike protein of SARS-CoV-2. Bamlanivimab, injection, 700 mg/20 mL, is a sterile, preservative-free aqueous solution that is to be diluted by using a 250 mL prefilled 0.9% Sodium Chloride Injection infusion solution, withdrawing and discarding 70 mL of 0.9% Sodium Chloride Injection from the infusion bag, and then transferring 20mL of 700mg/20mL bamlanivimab to the 0.9% Sodium Chloride Injection infusion bag. The authorized bamlanivimab includes a vial label and/or carton labeling that is clearly marked for "emergency use authorization".

Bamlanivimab, injection, 700 mg/20 mL, vials should be stored in unopened vials under refrigerated temperature at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light until time of use. Diluted bamlanivimab infusion solution can be stored for up to 24 hours at refrigerated temperature (2°C to 8°C [36°F to 46°F]) or up to 7 hours at room temperature (20°C to 25°C [68°F to 77°F]) including infusion time.

[5] Benefit of treatment with bamlanivimab has not been observed in patients hospitalized due to COVID-19. Monoclonal antibodies, such as bamlanivimab, may be associated with worse clinical outcomes when administered to hospitalized patients with COVID-19 requiring high flow oxygen or mechanical ventilation.

Bamlanivimab is authorized for emergency use with the following product-specific information required to be made available to healthcare providers and patients/caregivers, respectively, through Lilly's website at www.bamlanivimab.com:

- Fact Sheet for Health Care Providers: Emergency Use Authorization (EUA) of Bamlanivimab
- Fact Sheet for Patients, Parents and Parent Caregivers: Emergency Use Authorization (EUA) of Bamlanivimab for Coronavirus Disease 2019 (COVID-19)

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of bamlanivimab, when used for the treatment of COVID-19 and used in accordance with this Scope of Authorization (Section II), outweigh its known and potential risks.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that bamlanivimab may be effective for the treatment of COVID-19 when used in accordance with this Scope of Authorization (Section II), pursuant to Section 564(c)(2)(A) of the Act.

Having reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, I have concluded that bamlanivimab (as described in this Scope of Authorization (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of your product under an EUA must be consistent with, and may not exceed, the terms of the Authorization, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section III). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1), bamlanivimab is authorized to treat mild to moderate COVID-19 illness in adults and pediatric patients 12 years of age and older weighing at least 40 kg, who are at high risk for progressing to severe COVID-19 illness and/or hospitalization as described in the Scope of Authorization (Section II) under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

III. Conditions of Authorization

Pursuant to Section 564 of the Act, I am establishing the following conditions on this authorization:

Eli Lilly and Company (Lilly) and Authorized Distributors

A. Lilly and authorized distributor(s) will ensure that the authorized bamlanivimab is distributed, as directed by the U.S. government, and the authorized labeling (i.e., Fact Sheets) will be made available to healthcare facilities and or healthcare providers consistent with the terms of this letter.

B. Lilly and authorized distributor(s) will ensure that appropriate storage and cold chain is maintained until the product is delivered to healthcare facilities and/or healthcare providers.

C. Lilly and authorized distributor(s) will ensure that the terms of this EUA are made available to all relevant stakeholders (e.g., U.S. government agencies, state and local government authorities, authorized distributors, healthcare facilities, healthcare providers) involved in distributing or receiving authorized bamlanivimab. Lilly will provide to all relevant stakeholders a copy of this letter of authorization and communicate any subsequent amendments that might be made to this letter of authorization and its authorized accompanying materials (i.e., Fact Sheets).

D. Lilly may request changes to this authorization, including to the authorized Fact Sheets for bamlanivimab, that do not alter the analysis of benefits and risks that underlies this authorization and FDA may determine that such changes may be permitted without amendment of this EUA. That determination must be made by joint decision of the Office of Infectious Diseases Office of New Drugs Center for Drug Evaluation and Research (CDER), the Counter-Terrorism and Emergency Coordination Staff Office of the Center Director CDER, and Office of Counterterrorism and Emerging Threats Office of the Chief Scientist Office of the Commissioner.

E. Lilly will report to FDA serious adverse events and all medication errors associated with the use of the authorized bamlanivimab that are reported to Lilly using either of the following options.

Option 1: Submit reports through the Safety Reporting Portal (SRP) as described on the FDA SRP web page.

Option 2: Submit reports directly through the Electronic Submissions Gateway (ESG) as described on the FAERS electronic submissions web page.

Submitted reports under both options should state: "use of bamlanivimab was under an EUA." For reports submitted under Option 1, include this language at the beginning of the question "Describe Event" for further analysis. For reports submitted under Option 2, include this language at the beginning of the "Case Narrative" field.

F. All manufacturing facilities will comply with Current Good Manufacturing Practice requirements.

G. Lilly will retain an independent third party (i.e., not affiliated with Lilly) to conduct a review of the batch records and any underlying data and associated discrepancies of bamlanivimab drug substance manufactured at Lilly Branchburg, NJ.

- For all batches manufactured prior to the effective date of this authorization, these batches can be released while review is ongoing.
- For all batches manufactured after the effective date of this authorization, the third party review can be performed concurrent to Lilly's batch release process.

If the independent review finds, prior to release, a discrepancy with significant potential to affect critical quality attributes, the product must not be released unless and until the issue is satisfactorily resolved. Any discrepancies found by the independent review, whether prior to or after release, must be reported to the Agency in a summary report, submitted every 14 calendar days, and include Lilly's corrective and preventive action plans for each discrepancy, including whether market action is required. The plans must include an appropriate evaluation of each discrepancy's potential impact on any released drug substance and associated drug product.

H. Lilly will retain an independent third-party (i.e., not affiliated with Lilly) to conduct laboratory release testing of bamlanivimab drug substance manufactured at Lilly, Branchburg (excluding bioburden and endotoxin testing). Due to implementation timelines, independent third-party potency testing will commence on February 1, 2021. Until February 1, 2021, the Lilly Indianapolis, IN facility may conduct the equivalent of third-party potency testing. Any discrepancies found by Lilly Indianapolis, IN or the independent laboratory must be reported to the Agency in a summary report, submitted every 14 calendar days, and include Lilly's corrective and preventive action plans for each discrepancy. The plans must include an appropriate evaluation of each discrepancy's potential impact on any released drug substance and associated drug product.

I. Lilly will submit information to the Agency within three working days of receipt of any information concerning any batch of bamlanivimab (whether the batch is distributed or not), as follows: (1) information concerning any incident that causes the drug product or its labeling to be mistaken for, or applied to, another article; and (2) information concerning any bacteriological or microscopic contamination, or any significant chemical, physical, or other change in deterioration in the drug product, or any failure of one or more batches of the drug product to meet the established specifications. Lilly will include in its notification to the Agency whether the batch, or batches, in question will be recalled. If FDA requests that these, or any other batches, at any time, be recalled, Lilly must recall them.

J. Lilly will not implement any changes to the description of the product, manufacturing process, facilities and equipment, and elements of the associated control strategy that assure process performance and quality of the authorized product without notification to and concurrence by the Agency.

K. Lilly will manufacture and test bamlanivimab per the process and methods, including in-process sampling and testing and finishing product testing (release and stability) to meet all specifications as detailed in Lilly's EUA request.

L. Lilly will list bamlanivimab with a unique product NDC under the marketing category of Unapproved Drug- Other. Further, the listing will include each establishment where manufacturing is performed for the drug and the type of operation performed at each such establishment.

M. Through a process of inventory control, Lilly and authorized distributor(s) will maintain records regarding distribution of the authorized bamlanivimab (i.e., lot numbers, quantity, receiving site, receipt date).

N. Lilly and authorized distributor(s) will make available to FDA upon request any records maintained in connection with this EUA.

Healthcare Facilities to Whom the Authorized Bamlanivimab Is Distributed and Healthcare Providers Administering the Authorized Bamlanivimab

O. Healthcare facilities and healthcare providers will ensure that they are aware of the letter of authorization, and the terms herein, and that the authorized Fact Sheets are made available to healthcare providers and to patients and caregivers, respectively, through appropriate means, prior to administration of bamlanivimab.

P. Healthcare facilities and healthcare providers receiving bamlanivimab will track serious adverse events that are considered to be potentially attributable to bamlanivimab use and must report these to FDA in accordance with the Fact Sheet for Healthcare Providers. Complete and submit a MedWatch form (www.fda.gov/medwatch/report.htm), or Complete and submit FDA Form 3500 (health professional) by fax (1-800-FDA-0178) (these forms can be found via link above). Call 1-800-FDA-1088 for questions. Submitted reports should state, "use of bamlanivimab was under an EUA" at the beginning of the question "Describe Event" for further analysis.

Q. Healthcare facilities and healthcare providers will ensure that appropriate storage and cold chain is maintained until the product is administered consistent with the terms of this letter.

R. Through a process of inventory control, healthcare facilities will maintain records regarding the dispensed authorized bamlanivimab (i.e., lot numbers, quantity, receiving site, receipt date), product storage, and maintain patient information (e.g., patient name, age, disease manifestation, number of doses administered per patient, other drugs administered).

S. Healthcare facilities will ensure that any records associated with this EUA are maintained until notified by Lilly and or FDA. Such records will be made available to Lilly, HHS, and FDA for inspection upon request.

Conditions Related to Printed Matter, Advertising and Promotion

T. All descriptive printed matter, as well as advertising and promotional material, relating to the use of the bamlanivimab under this authorization shall be consistent with the authorized labeling, as well as the terms set forth in this EUA and the applicable requirements set forth in the Act and FDA regulations.

U. No descriptive printed matter, as well as advertising or promotional material, relating to the use of bamlanivimab may represent or suggest that such products are safe or effective when used for the treatment of mild to moderate COVID-19 in adults and pediatric patients with

positive results of direct SARS-CoV-2 viral testing who are 12 years of age and older weighing at least 40 kg, and who are at high risk for progressing to severe COVID-19 and or hospitalization.

V. All descriptive printed matter, as well as advertising and promotional material, relating to the use of the bamlanivimab clearly and conspicuously shall state that:

- the bamlanivimab has not been approved, but has been authorized for emergency use by FDA, to treat mild to moderate COVID-19 in adults and pediatric patients with positive results of direct SARS-CoV-2 viral testing who are 12 years of age and older weighing at least 40 kg, and who are at high risk for progressing to severe COVID-19 and or hospitalization.

- the bamlanivimab is authorized for the treatment of mild to moderate COVID-19 in adults and pediatric patients with positive results of direct SARS-CoV-2 viral testing who are 12 years of age and older weighing at least 40 kg, and who are at high risk for progressing to severe COVID-19 and or hospitalization only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of the bamlanivimab under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

IV. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

--/S/--

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

November 19, 2020

Eli Lilly and Company
Attention: Jillian Venci Fuhs, JD, PharmD
Advisor, Global Regulatory Affairs – North America
Lilly Corporate Center
Drop Code 2543
Indianapolis, IN 46285

Dear Dr. Fuhs:

This letter is in response to Eli Lilly and Company's ("Lilly") request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of baricitinib (Olumiant), in combination with remdesivir (Veklury), for the treatment of suspected or laboratory confirmed coronavirus disease 2019 (COVID-19) in certain hospitalized patients requiring supplemental oxygen, invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO), as described in the Scope of Authorization (Section II) of this letter, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3).

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19.[1] On the basis of such determination, the Secretary of HHS on March 27, 2020, declared that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3), subject to terms of any authorization issued under that section.[2]

Baricitinib is a Janus kinase (JAK) inhibitor. JAKs are intracellular enzymes which transmit signals arising from cytokine or growth factor-receptor interactions on the cellular membrane to influence cellular processes of hematopoiesis and immune cell function. Baricitinib (Olumiant) is approved by FDA for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more tumor necrosis factor antagonist therapies. Baricitinib has not been approved by FDA for the treatment of COVID-19.

[1] U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*, February 4, 2020.
[2] U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*, 85 FR 18250 (April 1, 2020).

Based on review of the data from the randomized, double-blind, placebo-controlled trial conducted by the National Institute of Allergy and Infectious Diseases (NIAID) comparing baricitinib in combination with remdesivir to remdesivir alone, also called ACTT-2 (NCT04401579), data for baricitinib that FDA reviewed for the FDA-approved indication of rheumatoid arthritis (NDA 207924), and data from populations studied for other indications, including pediatric patients, it is reasonable to believe that baricitinib may be effective, in combination with remdesivir, for the treatment of suspected or laboratory confirmed COVID-19 in hospitalized adults and pediatric patients 2 years of age or older requiring supplemental oxygen, invasive mechanical ventilation, or ECMO, and that, when used under the conditions described in this authorization, the known and potential benefits of baricitinib when used to treat COVID-19 in such patients outweigh the known and potential risks of such product.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of baricitinib for treatment of COVID-19, as described in the Scope of Authorization section of this letter (Section II) and subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of baricitinib for the treatment of COVID-19 when administered as described in the Scope of Authorization (Section II) meets the criteria for issuance of an authorization under Section 564(c) of the Act, because:

1. SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that baricitinib, in combination with remdesivir, may be effective in treating suspected or laboratory confirmed COVID-19 in hospitalized adults and pediatric patients 2 years of age or older requiring supplemental oxygen, invasive mechanical ventilation, or ECMO, and that, when used under the conditions described in this authorization, the known and potential benefits of baricitinib when used in combination with remdesivir to treat COVID-19 in such patients outweigh the known and potential risks of such product; and

3. There is no adequate, approved, and available alternative to the emergency use of baricitinib, in combination with remdesivir, for treatment of suspected or laboratory confirmed COVID-19 in hospitalized adults and pediatric patients 2 years of age or older requiring supplemental oxygen, invasive mechanical ventilation, or ECMO.[3, 4]

[3] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

[4] On October 22, 2020, remdesivir was approved to treat COVID-19 in adults and pediatric patients (12 years of age and older and weighing at least 40 kg) requiring hospitalization. Remdesivir is a nucleoside ribonucleic acid polymerase inhibitor that has demonstrated antiviral activity against SARS-COV-2. Baricitinib is a Janus kinase (JAK) inhibitor, a class of drugs that block extracellular signals from multiple cytokines that are involved in inflammatory diseases and thought to contribute to inflammation and worsening of COVID-19. The Adaptive COVID-19 Treatment Trial 2 (ACTT-2) trial provided scientific evidence that the combination of baricitinib plus

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited as follows:

- The baricitinib covered by this authorization will be used only by healthcare providers, in combination with remdesivir, to treat suspected or laboratory confirmed COVID-19 in hospitalized[5] adults and pediatric patients 2 years of age or older requiring supplemental oxygen, invasive mechanical ventilation, or ECMO; and

- The use of baricitinib covered by this authorization must be in accordance with the dosing regimens as detailed in the authorized Fact Sheets.

Product Description

Baricitinib is a Janus kinase (JAK) inhibitor. Baricitinib is available as debossed, film-coated, immediate-release tablets. Each tablet contains a recessed area on each face of the tablet surface. Baricitinib tablets are to be taken orally or can be crushed, dispersed in water, and given via a gastrostomy tube. The authorized baricitinib includes commercially available[6] Olumiant (baricitinib) supplied in 30 count bottles as follows:

- OLUMIANT (baricitinib) 1 mg (NDC 0002-4732-30)
- OLUMIANT (baricitinib) 2 mg (NDC 0002-4182-30)

Baricitinib should be stored at 20° to 25°C (68° to 77°F) with excursions permitted to 15° to 30°C (59° to 86°F).

Baricitinib is authorized for emergency use with the FDA-approved package insert and the following product-specific information required to be made available to healthcare providers and patients/caregivers, respectively, through Lilly's website at *www.baricitinibemergencyuse.com*:

- Fact Sheet for Health Care Providers: Emergency Use Authorization (EUA) of Baricitinib

- Fact Sheet for Patients, Parents and Caregivers: Emergency Use Authorization (EUA) of Baricitinib

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remdesivir provided a potential clinically meaningful benefit as compared to remdesivir alone in time to recovery, NIAID Ordinal Scale outcome at Day 15, and progression to ventilation or death at Day 29. Veklury's FDA-approved indication is for a narrower population than the use authorized for baricitinib under this EUA.

[5] Individuals determined as being appropriate for acute inpatient hospitalization and who are admitted or transferred to an alternate care site (ACS) that is capable of providing acute care that is comparable to general inpatient hospital care are within the terms and conditions of this Letter of Authorization. An ACS is intended to provide additional hospital surge capacity and capability for communities overwhelmed by patients with COVID-19.

[6] For the purposes of this Letter of Authorization, commercially available Olumiant (baricitinib) tablets refers to product in United States distribution under the approved New Drug Application 207924.

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of baricitinib, when used for the treatment of COVID-19 and used in accordance with this Scope of Authorization (Section II), outweigh its known and potential risks.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that baricitinib may be effective for the treatment of COVID-19 when used in accordance with this Scope of Authorization (Section II), pursuant to Section 564(c)(2)(A) of the Act.

Having reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, I have concluded that baricitinib (as described in this Scope of Authorization (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of your product under an EUA must be consistent with, and may not exceed, the terms of the Authorization, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section III). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1), baricitinib is authorized, in combination with remdesivir, to treat suspected or laboratory confirmed COVID-19 in hospitalized adults and pediatric patients 2 years of age or older requiring supplemental oxygen, invasive mechanical ventilation, or ECMO as described in the Scope of Authorization (Section II) under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

III. Conditions of Authorization

Pursuant to Section 564 of the Act, I am establishing the following conditions on this authorization:

Eli Lilly and Company (Lilly) and Authorized Distributors[7]

A. Lilly and authorized distributor(s) will ensure that the authorized baricitinib is distributed and the FDA-approved package insert and authorized labeling (i.e., Fact Sheets) will be made available to healthcare facilities and/or healthcare providers consistent with the terms of this letter.

B. Lilly and authorized distributor(s) will ensure that appropriate storage is maintained until the authorized product is delivered to healthcare facilities and/or healthcare providers.

C. Lilly and authorized distributor(s) will ensure that the terms of this EUA are made available to all relevant stakeholders (e.g., U.S. government agencies, state and local government authorities, authorized distributors, healthcare facilities, healthcare providers) involved in distributing or receiving authorized baricitinib. Lilly will provide to all relevant

[7] "Authorized Distributor(s)" are identified by Lilly as an entity or entities allowed to distribute authorized baricitinib.

stakeholders a copy of this letter of authorization and communicate any subsequent amendments that might be made to this letter of authorization and its authorized accompanying materials (i.e., Fact Sheets).

D. Lilly may request changes to this authorization, including to the authorized Fact Sheets for baricitinib, that do not alter the analysis of benefits and risks that underlies this authorization and FDA may determine that such changes may be permitted without amendment of this EUA. That determination must be made by joint decision of the Office of Infectious Diseases/Office of New Drugs/Center for Drug Evaluation and Research (CDER), the Counter-Terrorism and Emergency Coordination Staff/Office of the Center Director/CDER, and Office of Counterterrorism and Emerging Threats/Office of the Chief Scientist/Office of the Commissioner.

E. Lilly will report to FDA serious adverse events and all medication errors associated with the use of the authorized baricitinib that are reported to Lilly using either of the following options.

Option 1: Submit reports through the Safety Reporting Portal (SRP) as described on the FDA SRP web page.

Option 2: Submit reports directly through the Electronic Submissions Gateway (ESG) as described on the FAERS electronic submissions web page.

Submitted reports under both options should state: "Baricitinib treatment under Emergency Use Authorization (EUA)." For reports submitted under Option 1, include this language at the beginning of the question "Describe Event" for further analysis. For reports submitted under Option 2, include this language at the beginning of the "Case Narrative" field.

F. All manufacturing facilities will comply with Current Good Manufacturing Practice requirements.

G. Lilly will submit information to the Agency within three working days of receipt of any information concerning any batch of authorized baricitinib (whether the batch is distributed or not), as follows: (1) information concerning any incident that causes the drug product or its labeling to be mistaken for, or applied to, another article; and (2) information concerning any bacteriological or microscopic contamination, or any significant chemical, physical, or other change in deterioration in the drug product, or any failure of one or more batches of the drug product to meet the established specifications. Lilly will include in its notification to the Agency whether the batch, or batches, in question will be recalled.

H. Lilly will not implement any changes to the description of the authorized product, manufacturing process, facilities and equipment, and elements of the associated control strategy that assure process performance and quality of the authorized product without notification to and concurrence by the Agency.

I. Lilly will manufacture and test authorized baricitinib per the process and methods, including in-process sampling and testing and finishing product testing (release and stability) to meet all specifications as detailed in Lilly's EUA request.

J. Through a process of inventory control, Lilly and authorized distributor(s) will maintain records regarding distribution of the authorized baricitinib (i.e., lot numbers, quantity, receiving site, receipt date).

K. Lilly and authorized distributor(s) will make available to FDA upon request any records maintained in connection with this EUA.

Healthcare Facilities to Whom the Authorized Baricitinib Is Distributed and Healthcare Providers Administering the Authorized Baricitinib

L. Healthcare facilities and healthcare providers will ensure that they are aware of the letter of authorization, and the terms herein, and that the authorized Fact Sheets are made available to healthcare providers and to patients and caregivers, respectively, through appropriate means, prior to administration of baricitinib for the authorized use.

M. Healthcare facilities and healthcare providers will track serious adverse events that are considered to be potentially attributable to the authorized baricitinib use and must report these to FDA in accordance with the Fact Sheet for Healthcare Providers. Complete and submit a MedWatch form (www.fda.gov/medwatch/report.htm), or Complete and submit FDA Form 3500 (health professional) by fax (1-800-FDA-0178) (these forms can be found via link above). Call 1-800-FDA-1088 for questions. Submitted reports should state, "Baricitinib treatment under Emergency Use Authorization (EUA)" at the beginning of the question "Describe Event" for further analysis.

N. Healthcare facilities and healthcare providers will ensure that appropriate storage is maintained until the authorized product is administered consistent with the terms of this letter.

O. Through a process of inventory control, healthcare facilities will maintain records regarding the dispensed authorized baricitinib (i.e., lot numbers, quantity, receiving site, receipt date), product storage, and maintain patient information (e.g., patient name, age, disease manifestation, number of doses administered per patient, other drugs administered).

P. Healthcare facilities will ensure that any records associated with this EUA are maintained until notified by Lilly and/or FDA. Such records will be made available to Lilly, HHS, and FDA for inspection upon request.

Conditions Related to Printed Matter, Advertising and Promotion

Q. All descriptive printed matter, advertising, and promotional material relating to the use of the baricitinib under this authorization shall be consistent with the authorized labeling, as

well as the terms set forth in this EUA and the applicable requirements set forth in the Act and FDA regulations.

R. No descriptive printed matter, advertising, or promotional material relating to the use of baricitinib under this authorization may represent or suggest that such products are safe or effective when used, in combination with remdesivir, for the treatment of suspected or laboratory confirmed COVID-19 in hospitalized adults and pediatric patients 2 years of age or older requiring supplemental oxygen, invasive mechanical ventilation, or ECMO.

S. All descriptive printed matter, advertising, and promotional material relating to the use of the baricitinib under this authorization clearly and conspicuously shall state that:

- the baricitinib has not been approved, but has been authorized for emergency use by FDA, in combination with remdesivir, for the treatment of suspected or laboratory confirmed COVID-19 in hospitalized adults and pediatric patients 2 years of age or older requiring supplemental oxygen, invasive mechanical ventilation, or ECMO.

- the baricitinib is authorized, in combination with remdesivir, for the treatment of suspected or laboratory confirmed COVID-19 in hospitalized adults and pediatric patients 2 years of age or older requiring supplemental oxygen, invasive mechanical ventilation, or ECMO only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of the baricitinib under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

IV. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

--/S/--

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

November 21, 2020

Regeneron Pharmaceuticals, Inc.
Attention: Yunji Kim, PharmD
Director, Regulatory Affairs
777 Old Saw Mill River Road
Tarrytown, NY 10591

Dear Dr. Kim:

This letter is in response to Regeneron Pharmaceutical, Inc's ("Regeneron") request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of casirivimab and imdevimab, administered together, for the treatment of mild to moderate coronavirus disease 2019 (COVID-19), as described in the Scope of Authorization (Section II) of this letter, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3).

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19.[1] On the basis of such determination, the Secretary of HHS on March 27, 2020, declared that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3), subject to terms of any authorization issued under that section.[2]

Casirivimab and imdevimab are recombinant human IgG1 monoclonal antibodies that target the receptor binding domain of the spike protein of SARS-CoV-2. They are investigational drugs and are not approved for any indication.

Based on review of the analysis of phase 1 and 2 data from the ongoing trial R10933-10987-COV-2067 (NCT04425629), a phase 1/2/3, randomized, double-blind, placebo-controlled trial evaluating the safety and efficacy of casirivimab and imdevimab 2400 mg IV or casirivimab and imdevimab 8000 mg IV or placebo in outpatients (non-hospitalized) with SARS-CoV-2 infection, it is reasonable to believe that casirivimab and imdevimab, administered together, may be effective for the treatment of mild to moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral

[1] U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*, February 4, 2020.
[2] U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*, 85 FR 18250 (April 1, 2020).

testing, and who are at high risk for progressing to severe COVID-19 and/or hospitalization, and that, when used under the conditions described in this authorization, the known and potential benefits of casirivimab and imdevimab, administered together, outweigh the known and potential risks of such product.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of casirivimab and imdevimab, to be administered together, for treatment of COVID-19, as described in the Scope of Authorization section of this letter (Section II) and subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of casirivimab and imdevimab for the treatment of COVID-19 when administered as described in the Scope of Authorization (Section II) meets the criteria for issuance of an authorization under Section 564(c) of the Act, because:

1. SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that casirivimab and imdevimab, administered together, may be effective in treating mild to moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progressing to severe COVID-19 and/or hospitalization, and that, when used under the conditions described in this authorization, the known and potential benefits of casirivimab and imdevimab outweigh the known and potential risks of such products; and

3. There is no adequate, approved, and available alternative to the emergency use of casirivimab and imdevimab, administered together, for the treatment of mild to moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progressing to severe COVID-19 and/or hospitalization.[3]

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited as follows:

- Distribution of the authorized casirivimab and imdevimab will be controlled by the United States (U.S.) Government for use consistent with the terms and conditions of this EUA. Regeneron will supply casirivimab and imdevimab to authorized distributor(s)[4], who will distribute to healthcare facilities or healthcare providers as

[3] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.
[4] "Authorized Distributor(s)" are identified by Regeneron as an entity or entities allowed to distribute authorized casirivimab and imdevimab.

directed by the U.S. Government, in collaboration with state and local government authorities, as needed;

- The casirivimab and imdevimab covered by this authorization will be used only by healthcare providers to treat mild to moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progressing to severe COVID-19 and or hospitalization;

- Casirivimab and imdevimab may only be administered together;

- Casirivimab and imdevimab is not authorized for use in the following patient populations [5]:

  - Adults or pediatric patients who are hospitalized due to COVID-19, or
  - Adults or pediatric patients who require oxygen therapy due to COVID-19, or
  - Adults or pediatric patients who require an increase in baseline oxygen flow rate due to COVID-19 in those patients on chronic oxygen therapy due to underlying non-COVID-19-related comorbidity.

- Casirivimab and imdevimab may only be administered in settings in which health care providers have immediate access to medications to treat a severe infusion reaction, such as anaphylaxis, and the ability to activate the emergency medical system (EMS), as necessary.

- The use of casirivimab and imdevimab covered by this authorization must be in accordance with the dosing regimens as detailed in the authorized Fact Sheets.

Product Description

Casirivimab and imdevimab are recombinant neutralizing human IgG1 monoclonal antibodies that target the receptor binding domain of the spike protein of SARS-CoV-2. Casirivimab and imdevimab are each supplied in individual single use vials. Casirivimab is available as 300 mg/2.5 mL (120 mg/mL) or 1332 mg/11.1 mL (120 mg/mL) sterile, preservative-free aqueous solution to be diluted prior to infusion. Imdevimab is available as 300 mg/2.5 mL (120 mg/mL) or 1332 mg/11.1 mL (120 mg/mL) sterile, preservative-free aqueous solution to be diluted prior to infusion. For dilution, 20 mL of 0.9% Sodium Chloride Injection are withdrawn and discarded from the infusion bag, and 10 mL of casirivimab and 10 mL of imdevimab from each respective vial are transferred to the 0.9% Sodium Chloride Injection fusion bag.

[5] Benefit of treatment with casirivimab and imdevimab has not been observed in patients hospitalized due to COVID-19. Monoclonal antibodies, such as casirivimab and imdevimab, may be associated with worse clinical outcomes when administered to hospitalized patients with COVID-19 requiring high flow oxygen or mechanical ventilation.

The authorized casirivimab and imdevimab vial label and carton labeling may be clearly marked with either "Caution: New Drug- limited by Federal law (or United States) to Investigational use" or with "For use under Emergency Use Authorization (EUA)". Some vial labels and carton labeling of casirivimab and imdevimab may be instead labeled with the Investigational New Drug (IND) clinical trial code name as "REGN10933" and "REGN10987", respectively.

Casirivimab injection and imdevimab injection unopened vials should be stored under refrigerated temperature at 2°C to 8°C (36°F to 46°F) in the individual original carton to protect from light. Diluted casirivimab and imdevimab infusion solution can be stored in the refrigerator between 2°C to 8°C (36°F to 46°F) for no more than 36 hours and at room temperature up to 25°C (77°F) for no more than 4 hours, including infusion time.

Casirivimab and imdevimab is authorized for emergency use with the following product-specific information required to be made available to healthcare providers and patients/caregivers, respectively, through Regeneron's website at www.regencov2.com:

- Fact Sheet for Health Care Providers: Emergency Use Authorization (EUA) of casirivimab and imdevimab
- Fact Sheet for Patients, Parents and Caregivers: Emergency Use Authorization (EUA) of casirivimab and imdevimab for Coronavirus Disease 2019 (COVID-19)
- Information Sheet ("Fact Sheet Directions")

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of casirivimab and imdevimab, when used for the treatment of COVID-19 and used in accordance with this Scope of Authorization (Section II), outweigh the known and potential risks.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that casirivimab and imdevimab may be effective for the treatment of COVID-19 when used in accordance with this Scope of Authorization (Section II), pursuant to Section 564(c)(2)(A) of the Act.

Having reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, I have concluded that casirivimab and imdevimab (as described in this Scope of Authorization (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of your product under an EUA must be consistent with, and may not exceed, the terms of the Authorization, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section III). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1), casirivimab and imdevimab is authorized to treat mild to moderate COVID-19 illness in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, who

are at high risk for progressing to severe COVID-19 illness and/or hospitalization as described in the Scope of Authorization (Section II) under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

III. Conditions of Authorization

Pursuant to Section 564 of the Act, I am establishing the following conditions on this authorization:

Regeneron and Company (Regeneron) and Authorized Distributors

A. Regeneron and authorized distributor(s) will ensure that the authorized casirivimab and imdevimab is distributed as directed by the U.S. government, and the authorized labeling (i.e., Fact Sheets) will be made available to healthcare facilities and/or healthcare providers consistent with the terms of this letter.

B. Regeneron and authorized distributor(s) will ensure that appropriate storage and cold chain is maintained until the product is delivered to healthcare facilities and/or healthcare providers.

C. Regeneron and authorized distributor(s) will ensure that the terms of this EUA are made available to all relevant stakeholders (e.g., U.S. government agencies, state and local government authorities, authorized distributors, healthcare facilities, healthcare providers) involved in distributing or receiving authorized casirivimab and imdevimab. Regeneron will provide to all relevant stakeholders a copy of this letter of authorization and communicate any subsequent amendments that might be made to this letter of authorization and its authorized accompanying materials (i.e., Fact Sheets).

D. Regeneron may request changes to this authorization, including to the authorized Fact Sheets for casirivimab and imdevimab, that do not alter the analysis of benefits and risks that underlies this authorization and FDA may determine that such changes may be permitted without amendment of this EUA. That determination must be made by joint decision of the Office of Infectious Diseases/Office of New Drugs/Center for Drug Evaluation and Research (CDER), the Counter-Terrorism and Emergency Coordination Staff/Office of the Center Director/CDER, and Office of Counterterrorism and Emerging Threats/Office of the Chief Scientist/Office of the Commissioner.

E. Regeneron will report to FDA serious adverse events and all medication errors associated with the use of the authorized casirivimab and imdevimab that are reported to Regeneron using either of the following options.

   Option 1: Submit reports through the Safety Reporting Portal (SRP) as described on the FDA SRP web page.

   Option 2: Submit reports directly through the Electronic Submissions Gateway (ESG) as described on the FAERS electronic submissions web page.

Submitted reports under both options should state: "Casirivimab and imdevimab treatment under Emergency Use Authorization (EUA)." For reports submitted under Option 1, include this language at the beginning of the question "Describe Event" for further analysis. For reports submitted under Option 2, include this language at the beginning of the "Case Narrative" field.

F. All manufacturing facilities will comply with Current Good Manufacturing Practice requirements.

G. Regeneron will submit information to the Agency within three working days of receipt of any information concerning any batch of casirivimab or imdevimab (whether the batch is distributed or not), as follows: (1) information concerning any incident that causes the product or its labeling to be mistaken for, or applied to, another article; and (2) information concerning any bacteriological or microscopic contamination, or any significant chemical, physical, or other change in deterioration in the product, or any failure of one or more batches of the product to meet the established specifications. Regeneron will include in its notification to the Agency whether the batch, or batches, in question will be recalled. If FDA requests that these, or any other batches, at any time, be recalled, Regeneron must recall them.

H. Regeneron will not implement any changes to the description of the product, manufacturing process, facilities and equipment, and elements of the associated control strategy that assure process performance and quality of the authorized product without notification to and concurrence by the Agency.

I. Regeneron will manufacture and test casirivimab and imdevimab per the process and methods, including in-process sampling and testing and finishing product testing (release and stability) to meet all specifications as detailed in Regeneron's EUA request.

J. Regeneron will list casirivimab and imdevimab with a unique product NDC for each presentation of each antibody under the marketing category of Unapproved Drug- Other. Further, the listing will include each establishment where manufacturing is performed for the drug and the type of operation performed at each such establishment.

K. Through a process of inventory control, Regeneron and authorized distributor(s) will maintain records regarding distribution of the authorized casirivimab and imdevimab (i.e., lot numbers, quantity, receiving site, receipt date).

L. Regeneron and authorized distributor(s) will make available to FDA upon request any records maintained in connection with this EUA.

Healthcare Facilities to Whom the Authorized Casirivimab and Imdevimab Is Distributed and Healthcare Providers Administering the Authorized Casirivimab and Imdevimab

M. Healthcare facilities and healthcare providers will ensure that they are aware of the letter of authorization, and the terms herein, and that the authorized Fact Sheets are made available

to healthcare providers and to patients and caregivers, respectively, through appropriate means, prior to administration of casirivimab and imdevimab.

N. Healthcare facilities and healthcare providers receiving casirivimab and imdevimab will track serious adverse events that are considered to be potentially attributable to casirivimab and imdevimab use and must report these to FDA in accordance with the Fact Sheet for Healthcare Providers. Complete and submit a MedWatch form (www.fda.gov/medwatch/report.htm), or Complete and submit FDA Form 3500 (health professional) by fax (1-800-FDA-0178) (these forms can be found via link above). Call 1-800-FDA-1088 for questions. Submitted reports should state, "Casirivimab and imdevimab treatment under Emergency Use Authorization" at the beginning of the question "Describe Event" for further analysis.

O. Healthcare facilities and healthcare providers will ensure that appropriate storage and cold chain is maintained until the product is administered consistent with the terms of this letter.

P. Through a process of inventory control, healthcare facilities will maintain records regarding the dispensed authorized casirivimab and imdevimab (i.e., lot numbers, quantity, receiving site, receipt date), product storage, and maintain patient information (e.g., patient name, age, disease manifestation, number of doses administered per patient, other drugs administered).

Q. Healthcare facilities will ensure that any records associated with this EUA are maintained until notified by Regeneron and/or FDA. Such records will be made available to Regeneron, HHS, and FDA for inspection upon request.

Conditions Related to Printed Matter, Advertising and Promotion

R. All descriptive printed matter, advertising, and promotional materials relating to the use of the casirivimab and imdevimab under this authorization shall be consistent with the authorized labeling, as well as the terms set forth in this EUA and the applicable requirements set forth in the Act and FDA regulations.

S. No descriptive printed matter, advertising, or promotional materials relating to the use of casirivimab and imdevimab may represent or suggest that such products are safe or effective when used for the treatment of mild to moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progressing to severe COVID-19 and/or hospitalization.

T. All descriptive printed matter, advertising, promotional material, relating to the use of the casirivimab and imdevimab clearly and conspicuously shall state that:

- the casirivimab and imdevimab has not been approved, but has been authorized for emergency use by FDA under an EUA, to treat mild to moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least

40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progressing to severe COVID-19 and or hospitalization.

- the emergency use of casirivimab and imdevimab is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization revoked sooner.

IV. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

--/S/--

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Dated: February 16, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–03429 Filed 2–18–21; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; RFP–NIH–NIAID–DAIT–75N93020R00018: Transplantation Statistical and Clinical Coordinating Center (T–SCCC).

Date: March 18, 2021.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G53, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Konrad Krzewski, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G53, Rockville, MD 20852, 240–747–7526, *konrad.krzewski@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: February 12, 2021.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–03387 Filed 2–18–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Microbiology, Infectious Diseases and AIDS Initial Review Group; Microbiology and Infectious Diseases B Subcommittee MID–B Review Committee 03/2021.

Date: March 15–17, 2021.

Time: 11:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F30, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Ellen S. Buczko, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F30, Rockville, MD 20852, 301–451–2676, *ebuczko1@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: February 12, 2021.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–03388 Filed 2–18–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute of Neurological Disorders and Stroke Special Emphasis Panel; Advancing Careers of Diverse Research, February 25, 2021, 10:00 a.m. to February 26, 2021, 06:00 p.m., National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 which was published in the **Federal Register** on January 14, 2021, 86 FR 3164.

This notice is being amended to change the dates of this two-day meeting from February 25, 2021 and February 26, 2021 to April 14, 2021 and April 15, 2021. The meeting time remains the same. The meeting is closed to the public.

Dated: February 12, 2021.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–03386 Filed 2–18–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2021–0047]

Information Collection Request to Office of Management and Budget; OMB Control Number: 1625–0043

AGENCY: Coast Guard, DHS.

ACTION: Sixty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for the following collection of information: 1625–0043, Ports and Waterways Safety; without change.

Our ICR describes the information we seek to collect from the public. Before submitting this ICR to OIRA, the Coast Guard is inviting comments as described below.

DATES: Comments must reach the Coast Guard on or before April 20, 2021.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG–2021–0047] to the Coast Guard using the Federal eRulemaking Portal at *https://www.regulations.gov.* See the ''Public participation and request for comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

A copy of the ICR is available through the docket on the internet at *https://www.regulations.gov.* Additionally, copies are available from: COMMANDANT (CG–6P), ATTN: PAPERWORK REDUCTION ACT MANAGER, U.S. COAST GUARD, 2703 MARTIN LUTHER KING JR. AVE. SE, STOP 7710, WASHINGTON, DC 20593–7710.

FOR FURTHER INFORMATION CONTACT: A.L. Craig, Office of Privacy Management, telephone 202–475–3528, or fax 202–372–8405, for questions on these documents.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology.

In response to your comments, we may revise this ICR or decide not to seek an extension of approval for the Collection. We will consider all comments and material received during the comment period.

We encourage you to respond to this request by submitting comments and related materials. Comments must contain the OMB Control Number of the ICR and the docket number of this request, [USCG–2021–0047], and must be received by April 20, 2021.

Submitting Comments

We encourage you to submit comments through the Federal eRulemaking Portal at *https://www.regulations.gov.* If your material cannot be submitted using *https://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at *https://www.regulations.gov* and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. All comments received will be posted without change to *https://www.regulations.gov* and will include any personal information you have provided. For more about privacy and submissions in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

Information Collection Request

Title: Ports and Waterways Safety—Title 33 CFR Subchapter P.

OMB Control Number: 1625–0043.

Summary: This collection of information allows the master, owner, or agent of a vessel affected by these rules to request a deviation from the requirements governing navigation safety equipment to the extent that there is no reduction in safety.

Need: Provisions in Title 33 CFR Subchapter P, allow any person directly affected by the rules in that subchapter to request a deviation from any of the requirements as long as it does not compromise safety. This collection enables the Coast Guard to evaluate the information the respondent supplies, to determine whether it justifies the request for a deviation.

Forms: None.

Respondents: Master, owner, or agent of a vessel.

Frequency: On occasion.

Hour Burden Estimate: The estimated burden remains 2,033 hours a year.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended.

Dated: February 11, 2021.

Kathleen Claffie,

Chief, Office of Privacy Management, U.S. Coast Guard.

[FR Doc. 2021–03335 Filed 2–18–21; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[Docket No. USCBP–2021–0006]

Commercial Customs Operations Advisory Committee (COAC)

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security (DHS).

ACTION: Committee management; notice of Federal Advisory Committee Meeting.

SUMMARY: The Commercial Customs Operations Advisory Committee (COAC) will hold its quarterly meeting on Wednesday, March 17, 2021. The meeting will be open to the public via webinar only. There is no on-site, in-person option for this quarterly meeting.

DATES: The COAC will meet on Wednesday, March 17, 2021, from 1:00 p.m. to 5:00 p.m. EDT. Please note that the meeting may close early if the committee has completed its business. Comments must be submitted in writing no later than March 16, 2021.

ADDRESSES: The meeting will be held via webinar. The webinar link and conference number will be provided to all registrants by 5:00 p.m. EDT on March 16, 2021. For information on facilities or services for individuals with disabilities or to request special assistance at the meeting, contact Ms. Florence Constant-Gibson, Office of Trade Relations, U.S. Customs and Border Protection, at (202) 344–1440 as soon as possible.

FOR FURTHER INFORMATION CONTACT: Ms. Florence Constant-Gibson, Office of Trade Relations, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW, Room 3.5A, Washington, DC 20229; or Ms. Valarie M. Neuhart, Designated Federal Officer at (202) 344–1440.

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the authority of the Federal Advisory Committee Act, 5 U.S.C. Appendix. The Commercial Customs Operations Advisory Committee (COAC) provides advice to the Secretary of Homeland Security, the Secretary of the Treasury, and the Commissioner of U.S. Customs and Border Protection (CBP) on matters pertaining to the commercial operations of CBP and related functions within the Department of Homeland Security and the Department of the Treasury.

Pre-registration: For members of the public who plan to participate via webinar, please register online at *https://teregistration.cbp.gov/index.asp?w=219* by 5:00 p.m. EDT by March 16, 2021. For members of the public who are pre-registered to attend the webinar and later need to cancel, please do so by March 15, 2021 utilizing the following link: *https://teregistration.cbp.gov/cancel.asp?w=219.*

Please feel free to share this information with other interested members of your organization or association.

To facilitate public participation, we are inviting public comment on the issues the committee will consider prior to the formulation of recommendations as listed in the Agenda section below.

Comments must be submitted in writing no later than March 16, 2021, and must be identified by Docket No. USCBP–2021–0006, and may be submitted by one (1) of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: tradeevents@cbp.dhs.gov.* Include the docket number in the subject line of the message.
- *Mail:* Ms. Florence Constant-Gibson, Office of Trade Relations, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW, Room 3.5A, Washington, DC 20229.

Instructions: All submissions received must include the words ''Department of Homeland Security'' and the docket number (USCBP–2021–0006) for this action. Comments received will be posted without alteration at *http://www.regulations.gov.* Please do not submit personal information to this docket.

Docket: For access to the docket or to read background documents or comments, go to *http://www.regulations.gov* and search for Docket Number USCBP–2021–0006. To submit a comment, click the ''Comment Now!'' button located on the top-right hand side of the docket page.

There will be multiple public comment periods held during the meeting on March 17, 2021. Speakers are requested to limit their comments to two (2) minutes or less to facilitate greater participation. Please note that the public comment period for speakers may end before the time indicated on the schedule that is posted on the CBP web page, *http://www.cbp.gov/trade/stakeholder-engagement/coac.*

Agenda

The COAC will hear from the current subcommittees on the topics listed below and then will review, deliberate, provide observations, and formulate recommendations on how to proceed:

1. The Next Generation Facilitation Subcommittee will provide an update on the following working groups: The Unified Entry Processes Working Group will provide an update on the current status of the development of objectives for the future entry environment to enable faster and more secure entry processing; the Emerging Technologies Working Group will provide an update on the University of Houston's block chain assessment report; and, the One U.S. Government Working Group will provide an update on several key projects, including the Partner Government Agency Disclaim Handbook and the automation of currently required original/hard copy documents at time of entry.

2. The Rapid Response Subcommittee will provide an update on the progress of the Broker Exam Modernization Working Group efforts to improve the testing experience for the April 2021 exam, as well as future broker exams. The U.S.-Mexico-Canada Agreement (USMCA) Working Group has reconvened and will provide an update regarding its goals and objectives.

3. The Intelligent Enforcement Subcommittee will provide updates on the following Working Groups: The Bond Working Group will report on the continued work with CBP on the Monetary Guidelines of Setting Bond Amounts as part of a larger risk-based bonding initiative; the Anti-Dumping and Countervailing Duty (AD/CVD) Working Group will report on the discussions surrounding non-resident importers and the impact this has on AD/CVD enforcement along with recommended solutions; the Intellectual Property Rights (IPR) Process Modernization Working Group will provide updates on development of several recommendations put forth during the April 2020 COAC meeting and will submit recommendations furthering the modernization of the IPR Process; and, the Forced Labor Working Group will provide a summary of the areas of focus that will be in its scope for the upcoming quarter.

4. The Secure Trade Lanes Subcommittee will present updates on the following Working Groups: The

Trusted Trader Working Group's progress in developing the CBP White Paper for the Implementation of C–TPAT Trade Compliance Requirements for Forced Labor; the In-Bond Working Group's ongoing work with the technical enhancements that have been shared with the Trade Support Network, as well as the review of regulatory recommendations for future development; the Export Modernization Working Group's progress in developing the Export Operations for the 21st Century White Paper mentioned during the October 7, 2020 COAC meeting; and, the Remote and Autonomous Cargo Processing Working Group's progress reviewing the various modes of conveyance and automation opportunities.

Meeting materials will be available by March 15, 2021, at: *http://www.cbp.gov/trade/stakeholder-engagement/coac/coac-public-meetings.*

Dated: February 15, 2021.

Valarie M. Neuhart,

Deputy Executive Director, Office of Trade Relations.

[FR Doc. 2021–03365 Filed 2–18–21; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2020–0010; OMB No. 1660–0033]

Agency Information Collection Activities: Submission for OMB Review; Comment Request; Residential Basement Floodproofing Certification

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: 30 Day reinstatement notice and request for comments.

SUMMARY: The Federal Emergency Management Agency (FEMA), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public to take this opportunity to comment on a reinstatement, without change, of a previously approved information collection for which approval has expired. FEMA will submit the information collection abstracted below to the Office of Management and Budget (OMB) for review and clearance in accordance with the requirements of the Paperwork Reduction Act of 1995. The submission will describe the nature of the information collection, the categories of respondents, the estimated burden (*i.e.,* the time, effort and resources used by respondents to respond) and cost, and the actual data collection instruments used.

DATES: Comments must be submitted on or before March 22, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection should be made to Director, Information Management Division, email address *FEMA-Information-Collections-Management@fema.dhs.gov* or Joycelyn Collins, Underwriting Branch Program Analyst, Federal Insurance Directorate, *Joycelyn.Collins@fema.dhs.gov,* 202–701–3383.

SUPPLEMENTARY INFORMATION: Congress created the National Flood Insurance Program (NFIP) through enactment of the National Flood Insurance Act of 1968 (NFIA) (Title XIII of Pub. L. 90–448, 82 Stat. 476), found at 42 U.S.C. 4001 *et seq.* The NFIP is a Federal program enabling property owners in participating communities to purchase insurance as a protection against flood losses in exchange for state and community floodplain management requirements that reduce the risk of future flood damages. Communities participate in the NFIP based on an agreement between the community and FEMA. If a community adopts and enforces a floodplain management ordinance to reduce future flood risk to new construction in floodplains, FEMA will make flood insurance available within the community as a financial protection against flood losses. Accordingly, the NFIP is comprised of three key activities: Flood insurance, floodplain management, and flood hazard mapping.

As part of the minimum floodplain management requirements established by FEMA, NFIP participating communities generally must require that all new construction and substantial improvements of residential structures within areas identified by FEMA as Special Flood Hazard Areas (SFHA) Zones A1–30, AE and AH zones have the lowest floor, including the basement, elevated to or above the base flood level. *See* 44 CFR 60.3(c)(2). However, FEMA may grant exceptions to this requirement to communities that are not subject to tidal flooding, given the communities adopt standards for floodproofed residential basements below the base flood. 44 CFR 60.6(c). Communities requesting this exception must demonstrate that ''areas of special flood hazard in which basements will be permitted are subject to shallow and low velocity flooding and that there is adequate flood warning time to ensure that all residents are notified of impending floods.'' 44 CFR 60.6(c)(1).

Communities seeking the exception must also adopt certain floodplain management measures regarding the floodproofing of basements. *See* 44 CFR 60.6(c)(2). Such measures include that a professional engineer or architect inspect new or substantially improved buildings with basements and ''certify that the basement design and methods of construction proposed are in accordance with accepted standards of practice for meeting the [residential basement floodproofing requirements]. 44 CFR 60.6(c)(2)(iv). This proposed information collection consists of the ''Residential Basement Floodproofing Certificate,'' which is used to document compliance with 44 CFR 60.6(c)(2)(iv).

This proposed information collection previously published in the **Federal Register** on April 7, 2020, at 85 FR 19496 with a 60-day public comment period. FEMA received three comments germane to this information collection (FEMA–2020–0010–0004; FEMA–2020–0010–0005; and FEMA–2020–0010–0003). FEMA considers one comment non-germane to the information collection because it merely reads ''Docket ID FEMA 2020–0010 OMB 1660–0033''.

In the first germane comment, FEMA–2020–0010–0004, the anonymous commenter recommended that ''[t]he form should be updated/reviewed to reflect/evaluate whether or not all or any of the April 2020 Flood Insurance Manual changes for floodproofing rating credit apply; based on the Flood Insurance Manual the updated guidance appears to be specific to nonresidential.'' FEMA reviewed the April 2020 Flood Insurance Manual (available at *https://go.usa.gov/xwGu2*) and found that it only reflected changes to non-residential floodproofing requirements. This information collection applies only to residential basement floodproofing requirements, so FEMA finds no reason to adjust this information collection based on changes to the April 2020 Flood Insurance Manual.

In the second germane comment, FEMA–2020–0010–0005, the anonymous commenter recommended

that '' 'walls that are impermeable to the passage of water without human intervention' should be 'walls that are substantially impermeable to the passage of water without human intervention.' '' FEMA disagrees with the commenter's recommendation because it deviates from the requirements of 44 CFR 60.6(c)(2)(i). Under applicable regulations, if FEMA allows a community to allow floodproofed residential basements pursuant to 44 CFR 60.6(c), the community must require that new residential construction ''be designed and built so that any basement area, together with attendant utilities and sanitary facilities below the floodproofed design level, is watertight with *walls that are impermeable to the passage of water without human intervention.*'' 44 CFR 60.6(c)(2)(i) (emphasis added). This language is mirrored in the current information collection. FEMA believes that the commenter may be confusing the requirements applicable to basements in non-residential buildings at 44 CFR 60.3(c)(3). This regulation states in part, that buildings ''be designed so that below the base flood level the structure is watertight *with walls substantially impermeable to the passage of water . . .*'' (emphasis added). These requirements do not apply to this information collection.

In the third germane comment, FEMA–2020–0010–0003, a former Executive Director of the Association of State Floodplain Managers (ASFPM) generally commented that ASFPM supports the continuation of the information collection, but he had concerns regarding how the form is used and the applicable regulations. First, the commenter expressed concern that individuals were submitting Residential Basement Floodproofing Certification forms for buildings located in communities not eligible to allow the construction of floodproofed residential basements. The commenter suggested adding a clear statement on FEMA's website to download the form that submission of a Residential Basement Floodproofing Certification form is only appropriate in certain eligible communities. Based on this comment, FEMA will add the recommended statement on the appropriate websites to help individuals avoid unnecessarily completing the form. Second, the commenter suggested enhancing FEMA's oversight of community compliance with the regulations concerning residential basement floodproofing at 44 CFR 60.6(c). FEMA is committed to ensuring the proper oversight of community compliance with the NFIP's floodplain management regulations and will ensure that communities' continued compliance with 44 CFR 60.6(c) is part of that oversight. Third, the commenter suggested that FEMA work with the United States Army Corps of Engineers to provide technical assistance and guidance on floodproofing basements. FEMA will consider providing additional assistance in the future. Fourth, the commenter recommended that if FEMA were to end the Residential Basement Floodproofing program, FEMA should develop a policy to address the status of homes that would no longer comply with floodplain management requirements as a result. FEMA does not plan to end this program at this time, but will take this comment under advisement if FEMA does discontinue the program in the future.

This information collection expired on April 30, 2020. FEMA is requesting a reinstatement, without change, of a previously approved information collection for which approval has expired. This notice is to notify the public that FEMA will submit the information collection abstracted below to OMB for review and clearance.

Collection of Information

Title: Residential Basement Floodproofing Certification.

Type of Information Collection: Reinstatement, without change, of a previously approved collection for which approval has expired.

OMB Number: 1660–0033.

Form Titles and Numbers: FEMA Form 086–0–24, Residential Basement Floodproofing Certification.

Abstract: The Residential Basement Floodproofing Certification, completed by a registered professional surveyor, engineer, or architect, is required to certify that floodproofing of a structure meets at least minimal floodproofing specifications. Residential structures that receive this certification are granted reduced rates on flood insurance premiums.

Affected Public: Businesses or other for profit.

Estimated Number of Respondents: 100.

Estimated Number of Responses: 100.

Estimated Total Annual Burden Hours: 325.

Estimated Total Annual Respondent Cost: $21,525.

Estimated Respondents' Operation and Maintenance Costs: $35,000.

Estimated Respondents' Capital and Start-Up Costs: $0.

Estimated Total Annual Cost to the Federal Government: $3,543.

Comments

Comments may be submitted as indicated in the **ADDRESSES** caption above. Comments are solicited to (a) evaluate whether the proposed data collection is necessary for the proper performance of the agency, including whether the information shall have practical utility; (b) 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; (c) enhance the quality, utility, and clarity of the information to be collected; and (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.

Millicent Brown,

Senior Manager, Records Management Branch, Office of the Chief Administrative Officer, Mission Support, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. 2021–03352 Filed 2–18–21; 8:45 am]

BILLING CODE 9110–52–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. CISA–2020–0020]

Interoperable Communications and Technical Assistance Program (ICTAP) Training Survey

AGENCY: Cybersecurity and Infrastructure Security Agency (CISA), Department of Homeland Security (DHS).

ACTION: 60-Day notice and request for comments; NEW information collection request, 1670–NEW.

SUMMARY: The Emergency Communications Division (ECD) within the Cybersecurity and Infrastructure Security Agency (CISA) will submit the following Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted until April 20, 2021.

ADDRESSES: You may submit comments, identified by docket number CISA–

2020–0020, by one of the following methods:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Please follow the instructions for submitting comments.

• *Email: COMU@cisa.dhs.gov.* Please include docket number CISA–2020–0020 in the subject line of the message.

• *Mail:* Written comments and questions about this Information Collection Request should be forwarded to DHS/CISA/ECD, ATTN: ICTAP—John Peterson, CISA–NGR STOP 0645, Cybersecurity and Infrastructure Security Agency, 1110 N Glebe Rd., Arlington, VA 20598–0645.

Instructions: All submissions received must include the words ''Department of Homeland Security'' and the docket number for this action. Comments received will be posted without alteration at *http://www.regulations.gov,* including any personal information provided.

Comments submitted in response to this notice may be made available to the public through relevant websites. For this reason, please do not include in your comments information of a confidential nature, such as sensitive personal information or proprietary information. If you send an email comment, your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. Please note that responses to this public comment request containing any routine notice about the confidentiality of the communication will be treated as public comments that may be made available to the public notwithstanding the inclusion of the routine notice.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact John Peterson, *COMU@cisa.dhs.gov,* or 202–503–5074.

SUPPLEMENTARY INFORMATION: The National Emergency Communications Plan (NECP) is the Nation's over-arching strategic plan to drive measurable improvements in emergency communications across all levels of government and disciplines. First released in 2008, the plan is periodically updated to reflect the ongoing evolution of emergency communications technologies and processes. In support of the NECP, the Interoperable Communications and Technical Assistance Program (ICTAP) within the Cybersecurity and Infrastructure Security Agency (CISA) Emergency Communications Division (ECD) provides a portfolio of no-cost communications technical assistance (TA) to support the implementation of the NECP, state's and territories' Statewide Communication Interoperability Plans (SCIPs), broadband planning, voice and digital network engineering, training, exercise support, and operational assessment focused on interoperable emergency communications at all levels of government.

The purpose of the ICTAP Training Survey is to obtain anonymous feedback regarding several of the training courses offered by the ICTAP. The feedback and experience given by survey respondents will assist the ICTAP in improving, revising, and updating the course materials for future students. The three courses which the ICTAP would like to obtain feedback are for:

• Communications Unit Leader (COML);

• Communications Unit Technician (COMT); and

• Information Technology Service Unit Leader (ITSL)

COML is designed for all state/territory, tribal, regional, and local emergency response professionals and for support personnel with a communications background. It is designed to familiarize these professionals with the role and responsibilities of a COML under the National Incident Management System (NIMS) Incident Command System (ICS) and to provide hands-on exercises that reinforce the lecture materials. CISA and FEMA Emergency Management Institute (EMI) offer this course jointly as ''L0969, NIMS ICS All-Hazards Communications Unit Leader Course.'' Under the NIMS ICS structure, a COML is the focal point within the Communications Unit. This course provides DHS-approved and NIMS-compliant instruction to ensure that every state/territory has trained personnel capable of coordinating on-scene emergency communications during a multi-jurisdictional response or planned event.

COML is designed for all state/territory, tribal, regional, and local emergency response professionals and for support personnel with a communications background. It is designed to familiarize these professionals with the role and responsibilities of a COML under the National Incident Management System (NIMS) Incident Command System (ICS) and to provide hands-on exercises that reinforce the lecture materials. CISA and FEMA Emergency Management Institute (EMI) offer this course jointly as ''L0969, NIMS ICS All-Hazards Communications Unit Leader Course.'' Under the NIMS ICS structure, a COML is the focal point within the Communications Unit. This course provides DHS-approved and NIMS-compliant instruction to ensure that every state/territory has trained personnel capable of coordinating on-scene emergency communications during a multi-jurisdictional response or planned event.

The COMT course provides introductory and refresher training for the NIMS ICS COMT position. It introduces public safety professionals and support staff to various communications concepts and technologies including interoperable communications solutions, LMR communications, satellite, telephone, data, and computer technologies used in incident response and planned events. It is designed for state/territory, tribal, urban, and local emergency response professionals and support personnel in all disciplines who have a technical communications background. Participants develop the essential core competencies required for performing the duties of the COMT in an all-hazards incident, including responsibilities while operating in a local, regional, or state-level All-Hazards Incident Management Team.

In 2018 and 2019, ICTAP introduced the ITSL course, and SAFECOM/National Counsel of Statewide Interoperability Coordinators (NCSWIC) have coordinated with FEMA National Integration Center (NIC) and other organizations focused on public safety communications to establish the best way to integrate the ITSL into the ICS. The ITSL is needed to provide information management, cybersecurity, and application management for the many critical incident/event related functions to include: Incident/Unified Command Post, Incident Communications Centers, and various tactical operations centers, joint information center (JIC), staging areas, and field locations. The ITSL course targets Federal, state/territory, tribal, urban, local, and emergency response professionals, and support personnel in all disciplines with a communications background and an aptitude for and extensive experience in information technology. Specifically, the training course provides an overview of the ITSL components including Communications/IT Help Desk or Unified Help Desk, IT Infrastructure Manager, Network Manager. It covers their roles and responsibilities and provides an in-depth overview with exercises for the ITSL's major functions, to include ensuring reliable and timely delivery of IT services to participating agencies and officials.

The ICTAP Training Survey will not collect any personal identifiable information (PII) from respondents (emergency communications stakeholders) of the survey. In collecting feedback regarding the ITSL, COML, and COMT courses, the survey will collect what state the respondent lives, where they took the course, did the course provide the information needed, should the course curriculum be updated, and any comments to improve the course material. The survey will encompass 10 questions regarding the former student's experience, anything that they liked, disliked, or something new that they would like to see incorporated into the refreshed class. It is estimated that it will take each participant 10 minutes to complete the training survey. For 300 respondents annually, the burden is 50 hours. To estimate the cost of this collection, CISA uses the mean hourly wage of ''All Occupations'' of $25.72. CISA then applies a load factor of 1.4597 to this average wage to obtain a fully loaded average hourly wage of $37.54. The total respondent cost burden for this collection is $1,877 (50 hours × $37.54).

This is a NEW collection of information.

The Office of Management and Budget is particularly interested in comments which:

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.

Analysis

Agency: Cybersecurity and Infrastructure Security Agency (CISA), Department of Homeland Security (DHS).

Title of Collection: Interoperable Communications and Technical Assistance Program (ICTAP) Training Survey.

OMB Control Number: 1670–NEW.

Frequency: Annually.

Affected Public: State, Local, Tribal, and Territorial Governments.

Number of Annualized Respondents: 300.

Estimated Time per Respondent: 10 Minutes.

Total Annualized Burden Hours: 50 hours.

Total Annualized Respondent Opportunity Cost: $1,877.16.

Total Annualized Respondent Out-of-Pocket: $0.

Total Annualized Government Cost: $4,082.67.

Samuel Vazquez,

Acting Chief Information Officer, Department of Homeland Security, Cybersecurity and Infrastructure Security Agency.

[FR Doc. 2021–03404 Filed 2–18–21; 8:45 am]

BILLING CODE 9110–9P–P

INTERNATIONAL BOUNDARY AND WATER COMMISSION, UNITED STATES AND MEXICO

Notice of Availability of an Amended Draft Environmental Assessment (EA) and Finding of No Significant Impact (FONSI) for Aquatic Habitat Restoration in the Rio Grande Canalization Project

AGENCY: United States Section, International Boundary and Water Commission, United States and Mexico (USIBWC).ACTION: Notice.

SUMMARY: Pursuant to the National Environmental Policy Act (NEPA) of 1969, the Council on Environmental Quality Final Regulations, and USIBWC *Operational Procedures for Implementing Section 102 of NEPA,* published in the **Federal Register** September 2, 1981, the USIBWC hereby gives notice that the amended *Draft Environmental Assessment* (EA) *and Finding of No Significant Impact* (FONSI) *for Aquatic Habitat Restoration in the Rio Grande Canalization Project* is available. The EA seeks to identify, develop, and design aquatic projects to implement aquatic habitat, wetland, and riparian habitat restoration for the Rio Grande Canalization Project (RGCP). An Environmental Impact Statement will not be prepared unless additional information which may affect this decision is brought to our attention within 30 days from the date of this Notice.

DATES: *Public Comments:* USIBWC will consider substantive comments from the public and stakeholders for 30 days after the date of publication of this notice in the **Federal Register**.

Please note all written and email comments received during the comment period will become part of the public record, including any personal information you may provide. 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. All submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public disclosure in their entirety.

ADDRESSES: Comments should be sent to: Elizabeth Verdecchia, Natural Resources Specialist, USIBWC, 4191 N Mesa; El Paso, Texas 79902. Telephone: (915) 832–4701, Fax: (915) 493–2428, email: *Elizabeth.Verdecchia@ibwc.gov.*

FOR FURTHER INFORMATION CONTACT: Elizabeth Verdecchia, Natural Resources Specialist, Telephone: (915) 832–4701, email: *Elizabeth.Verdecchia@ibwc.gov.*

SUPPLEMENTARY INFORMATION: On June 4, 2009, the USIBWC issued a Record of Decision (ROD) on the long-term management of the RGCP in southern New Mexico and western Texas. The ROD committed the USIBWC to the restoration of aquatic and riparian habitat at up to 30 sites over 10 years (through 2019). In May 2019, the USIBWC prepared a Draft EA to analyze the potential impact of seven action alternatives and a No Action Alternative to implement aquatic habitat within the RGCP, and the USIBWC extended the comment period (**Federal Register** July 22, 2019). After public input and subsequent development of preliminary designs, USIBWC re-evaluated alternative sites for aquatic habitat and assessed the feasibility of three additional sites, two of which were added to the EA. The USIBWC has prepared an Amended Draft EA, which evaluates potential impacts of ten alternatives, including the No Action Alternative and the following sites: Yeso Arroyo, Angostura Arroyo, Broad Canyon Arroyo, Selden Point Bar, Las Cruces Effluent, Mesilla Valley Bosque State Park, Downstream of Courchesne Bridge, Trujillo Restoration Site, and Montoya Intercepting Drain.

Restoration actions could include invasive vegetation removal, native vegetation planting, overbank lowering, bank cuts, natural levee breaches, secondary channels, bank

destabilization, channel widening, arroyo mouth management, construction of inset floodplains, construction of wetland depressions, and use of supplemental water for on-site irrigation.

Based on a review of the facts and analyses contained in the Amended Draft EA, the USIBWC has selected five projects as the Preferred Alternatives: Alternative D—Broad Canyon Arroyo, Alternative F—Las Cruces Effluent, Alternative G—Mesilla Valley Bosque State Park (MVBSP), Alternative H—Downstream of Courchesne Bridge, and Alternative J—Trujillo Arroyo. Alternatives Las Cruces Effluent and Downstream of Courchesne Bridge would require engineering designs prior to construction, while Alternatives Broad Canyon Arroyo and Trujillo Restoration Site, which are smaller and less complicated projects, could be constructed from conceptual designs. Downstream of Courchesne Bridge would be implemented as part of compensatory mitigation for future levee improvement projects. All alternatives would require appropriate permits from the United States Army Corps of Engineers for dredge and fill of Waters of the United States, per the Clean Water Act Sections 404 and 401.

Potential impacts on natural, cultural, and other resources were evaluated in the Draft EA. The USIBWC has prepared a FONSI for the Preferred Alternatives, based on a review of the facts and analyses contained in the amended Draft EA.

Availability: The electronic version of the amended Draft EA is available at the USIBWC web page: *https://www.ibwc.gov/EMD/EIS_EA_Public_Comment.html.*

Dated: February 10, 2021.

Jennifer Peña,

Chief Legal Counsel, International Boundary and Water Commission, United States Section.

[FR Doc. 2021–03303 Filed 2–18–21; 8:45 am]

BILLING CODE 7010–01–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1217]

Enforcement Proceeding; Certain Blowers and Components Thereof; Notice of Institution of Formal Enforcement Proceeding

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has instituted a formal enforcement proceeding relating to the Consent Order issued on November 12, 2020, in the above-referenced investigation.

FOR FURTHER INFORMATION CONTACT: Cathy Chen, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone 202–205–2392. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its internet server at *https://www.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 the original investigation on September 8, 2020, based on a complaint filed by Regal Beloit America, Inc (''Regal'') of Beloit, Wisconsin. 85 FR 55491–92 (Sep. 8, 2020). The complaint alleged violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain blowers and components thereof by reason of infringement of one or more of claims 1, 2, 7–10, and 15 of U.S. Patent No. 8,079,834 (''the '834 patent''). *Id.* at 55492. The Commission's notice of investigation named as respondents East West Manufacturing, LLC of Atlanta, Georgia, and East West Industries of Binh Duong, Vietnam (collectively, ''Respondents''). *Id.* at 55492. The Office of Unfair Import Investigations (''OUII'') did not participate as a party in the original investigation. *Id.*

On October 14, 2020, Respondents filed a motion to terminate the investigation with respect to themselves based upon a consent order stipulation. The motion included a consent order stipulation and a proposed consent order.

On October 22, 2020, the presiding administrative law judge (''ALJ'') issued an initial determination (''ID'') granting the motion and terminating the investigation with respect to Respondents based on the entry of a consent order. Order No. 6 at 3 (Oct. 22, 2020). Thereafter, the Commission determined not to review the ID and issued a Consent Order. 85 FR 73511 (Nov. 18, 2020). Respondents were therefore terminated from the original investigation and the investigation was terminated in its entirety. *Id.*

On January 15, 2021, Regal filed a complaint requesting that the Commission institute a formal enforcement proceeding under Commission Rule 210.75 to investigate the alleged violation of the Consent Order by Respondents.

Having examined the enforcement complaint and the supporting documents, the Commission has determined to institute a formal enforcement proceeding, pursuant to 19 CFR 210.75(a), to determine whether a violation of the Consent Order, issued on November 12, 2020, in the original investigation has occurred and to determine what, if any, enforcement measures are appropriate. The named respondents are East West Manufacturing, LLC of Atlanta, Georgia, and East West Industries of Binh Duong, Vietnam. OUII is also named as a party.

The Commission vote for this determination took place on February 16, 2021.

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 p10.

By order of the Commission.

Issued: February 16, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–03409 Filed 2–18–21; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Milad I. Shaker, M.D.; Decision and Order

On October 5, 2020, the Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, Government), signed an Order to Show Cause (hereinafter, OSC) addressed to Milad I. Shaker, M.D. (hereinafter, Registrant). OSC, at 1. The OSC proposed the revocation of Registrant's Certificate of Registration No. FS1471818. *Id.* It alleged that Registrant is without ''authority to handle controlled substances in the State of Pennsylvania, the state in which [Registrant is] registered with DEA.'' OSC, at 2 (citing 21 U.S.C. 824(a)(3)).

I. Background

The OSC alleged that the Pennsylvania State Board of Medicine (hereinafter, Board) issued a Preliminary Order October 29, 2019. *Id.* This Preliminary Order, according to the OSC, indefinitely suspended Registrant's Pennsylvania Medical Physician and Surgeon license following the Board's ''finding of [Registrant's] noncompliance with conditions of probation approved by the Board on December 18, 2018.'' *Id.*

The OSC notified Registrant of the right to request a hearing on the allegations or to submit a written statement, while waiving the right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. *Id.* at 2 (citing 21 CFR 1301.43). The OSC also notified Registrant of the opportunity to submit a corrective action plan. OSC, at 3 (citing 21 U.S.C. 824(c)(2)(C)).

a. Adequacy of Service

According to the declaration of a DEA Diversion Investigator (hereinafter, DI), DEA made arrangements for service of the OSC on Registrant, while he was incarcerated at the United States Penitentiary (USP)—Hazelton correctional facility in Bruceton, West Virginia. Request for Final Agency Action (hereinafter, RFAA) Exhibit (hereinafter, RFAAX) 10 (Declaration of DI), at 1–3. To accomplish service, DEA established a point of contact with Special Investigative Services at USP—Hazelton, and made arrangements to serve the OSC on Registrant by hand delivery. *Id.* at 3; RFAAX 5 (emails to and from Special Investigative Services, dated October 20–21, 2020). According to the emails, the OSC was served on Registrant on October 21, 2020. RFAAX 5, at 1; RFAAX 10, at 3.

In its RFAA, the Government represents that ''more than 30-days have passed since Registrant received the [OSC]'' and that ''Registrant has not submitted to DEA a request for hearing.'' RFAA, at 2; *see also* RFAAX 6 (email, dated December 17, 2020, confirming no correspondence from Registrant). The Government also represents that DEA has not received ''any other written correspondence, telephonic communication, or any other communication from Registrant, or any representative on his behalf in response to the [OSC].'' RFAA, at 4. I find that more than thirty days have now passed since the Government accomplished service of the OSC. Accordingly, I find that Registrant has waived the right to a hearing and the right to submit a written statement and corrective action plan. 21 CFR 1301.43(d) and 21 U.S.C. 824(c)(2)(C). I, therefore, issue this Decision and Order based on the record submitted by the Government, which constitutes the entire record before me. 21 CFR 1301.46.

II. Findings of Fact

a. Registrant's DEA Registration

Registrant is the holder of DEA Certificate of Registration No. FS1471818 at the registered address of 308 Bessemer Road, Suite 100, Mount Pleasant, Pennsylvania 15666. RFAA, at 2; RFAAX 1 (Controlled Substance Registration Certificate); RFAAX 2 (Certification of Registration History). Pursuant to this registration, Registrant is authorized to dispense controlled substances in schedules II through V as a practitioner. *Id.* Registrant's registration expires on February 28, 2021, and is ''in an active pending status.'' RFAAX 2, at 1.

b. The Status of Registrant's State License

On October 2, 2018, Registrant was indicted by a grand jury for fifty-four felony charges, which appear to be related to Registrant's practice of medicine (hereinafter, Indictment).[1] RFAAX 3 (Board's Preliminary Order with Exhibits), at 37–47. As a result of the Indictment, the Board petitioned for immediate temporary suspension of Registrant's license, alleging that Registrant was ''guilty of unprofessional conduct by failing to conform to the quality standard of the profession,'' and an Order of Temporary Suspension was issued on October 9, 2018. *Id.* at 15; *see also* RFAAX 3, at 12. On December 13, 2018, Registrant and the Board entered into a Consent Agreement and Order (hereinafter, Consent Agreement). *Id.* at 11–36.

Pursuant to the Consent Agreement, the Board indefinitely suspended Registrant's state license, but immediately stayed the suspension ''in favor of a period of indefinite probation.'' *Id.* at 16–17 (emphasis omitted). The Board required that Registrant satisfy a number of conditions during his indefinite probation.[2] *Id.* at 17–26. On October 29, 2019, the Board made a probable cause determination that Registrant violated the terms of the Consent Agreement and issued a Preliminary Order. *Id.* at 2. The Preliminary Order stated ''the stay of the suspension of [Registrant's] license is now VACATED, the period of probation is now TERMINATED, and [Registrant's] license to practice as a physician and surgeon, license number MD437512, along with any other licenses . . . are now actively indefinitely SUSPENDED.'' *Id.* (emphasis in original). Registrant was ordered to ''immediately cease practicing the profession.'' *Id.* The Preliminary Order's indefinite suspension of Registrant's state medical license served as the basis for the OSC's allegation that Registrant lacked state authority to handle controlled substances. RFAAX 10, at 2; OSC, at 1.

On April 30, 2020, the Board issued a Notice and Order of Automatic Suspension, which automatically suspended Registrant's license to practice medicine and surgery based on Registrant's ''conviction in Federal court for unlawful distribution of a Schedule II controlled substance'' (hereinafter, second suspension). RFAAX 8 (Final Order dated December 1, 2020[3]), at 5. The second suspension was affirmed by the Board in a Final Order dated December 1, 2020. The Final Order was retroactive to July 28, 2020, and suspended Registrant's license to practice medicine and surgery for at least 10 years.[4] *Id.* at 1, 18. Similar to the Preliminary Order, the Final Order provided that Registrant ''shall immediately CEASE the practice of

[1] The felony charges included allegations that Registrant ''issued prescriptions for controlled substances to [two patients] in return for sexual favors;'' issued thirty-six Schedule II controlled substance prescriptions ''outside of the usual course of professional practice and not for a legitimate medical purpose;'' issued 16 Schedule IV controlled substances ''outside of the usual course of professional practice and not for a legitimate medical purpose;'' and engaged in two ''[f]elony counts of Health Care Fraud.'' RFAAX 3, at 13–14.

[2] One of the conditions required that Registrant ''contract for the services of a Board Approved Practice Monitor,'' ''allow the Practice Monitor access to all aspects of his practice,'' and allow the Practice Monitor a minimum of ''[m]onthly in-person overview[s] . . . to determine that the monitor's directions are being implemented.'' RFAAX 3 22–23. On September 3, 2019, Registrant's practice monitor notified Registrant and the Board that they were ''ceasing all services . . . effective immediately'' based on Registrant's failure to allow two of the required monthly visits and his failure to respond to communications. *Id.* at 50–51. On October 29, 2019, a Petition for Appropriate Relief was filed with the Board seeking suspension of Registrant's license because ''[Registrant's] failure to fully cooperate and successfully comply with the monitoring terms and conditions of the probation [was] a violation of [the Consent Agreement].'' *Id.* at 9.

[3] DEA obtained a copy of the Board's Final Order after the OSC was issued to Registrant. RFAAX 10, at 3. The Final Order is not material as the record is clear that Registrant's license had been suspended since the Preliminary Order issued on October 29, 2019.

[4] The suspension of the license was retroactive to May 20, 2020. It appears that as of May 20, 2020, there were two concurrent suspension applied to Registrant's license. The number of suspensions is not material as the record is clear that Registrant's license had been suspended since October 29, 2019.

medicine and surgery.'' *Id.* at 18 (emphasis in original).

According to DI, on December 17, 2019, DI queried the Pennsylvania Department of State licensing verification website at *https://www.pals.pa.gov/#/page/searchresult* and determined that Registrant's medical physician license was still suspended at that time and that Registrant was without authorization to handle controlled substances or practice medicine in Pennsylvania. RFAAX 10, at 3. According to Pennsylvania's online records, of which I take official notice, Registrant's license is still revoked.[5] Pennsylvania Licensing System Verification, *https://www.pals.pa.gov/#/page/search* (last visited date of signature of this Order).

Accordingly, I find that Registrant currently is neither licensed to engage in the practice of medicine nor registered to dispense controlled substances in Pennsylvania, the state in which Registrant is registered with the DEA.

III. Discussion

Pursuant to 21 U.S.C. 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under section 823 of the Controlled Substances Act (hereinafter, CSA) ''upon a finding that the registrant . . . has had his State license or registration suspended . . . [or] revoked . . . by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances.'' With respect to a practitioner, the DEA has also long held that the possession of authority to dispense controlled substances under the laws of the state in which a practitioner engages in professional practice is a fundamental condition for obtaining and maintaining a practitioner's registration. *See, e.g., James L. Hooper, M.D.,* 76 FR 71,371 (2011), *pet. for rev. denied,* 481 F. App'x 826 (4th Cir. 2012); *Frederick Marsh Blanton, M.D.,* 43 FR 27,616, 27,617 (1978).

This rule derives from the text of two provisions of the CSA. First, Congress defined the term ''practitioner'' to mean ''a physician . . . or other person licensed, registered, or otherwise permitted, by . . . the jurisdiction in which he practices . . . , to distribute, dispense, . . . [or] administer . . . a controlled substance in the course of professional practice.'' 21 U.S.C. 802(21). Second, in setting the requirements for obtaining a practitioner's registration, Congress directed that ''[t]he Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices.'' 21 U.S.C. 823(f). Because Congress has clearly mandated that a practitioner possess state authority in order to be deemed a practitioner under the CSA, the DEA has held repeatedly that revocation of a practitioner's registration is the appropriate sanction whenever he is no longer authorized to dispense controlled substances under the laws of the state in which he practices. *See, e.g., James L. Hooper,* 76 FR at 71,371–72; *Sheran Arden Yeates, M.D.,* 71 FR 39,130, 39,131 (2006); *Dominick A. Ricci, M.D.,* 58 FR 51,104, 51,105 (1993); *Bobby Watts, M.D.,* 53 FR 11,919, 11,920 (1988); *Frederick Marsh Blanton,* 43 FR at 27,617.

Under the Pennsylvania Controlled Substance, Drug, Device and Cosmetic Act, ''no controlled substance in Schedule II shall be dispensed without an electronic prescription of a practitioner.'' 35 PA. Stat. and Const. Stat. Ann. § 780–111(a) (West October 24, 2019). Further, ''no controlled substance in Schedule III, IV or V shall be dispensed without an electronic prescription of a practitioner.'' *Id.* at § 780–111(b). The definition of ''practitioner,'' as used in the state Act, includes a ''physician . . . or other person licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to or to administer a controlled substance . . . in the course of professional practice . . . in the Commonwealth of Pennsylvania.'' *Id.* at 780–102(b).

Here, the undisputed evidence in the record is that Registrant currently lacks authority to practice medicine in Pennsylvania. As already discussed, a physician must be a licensed practitioner to dispense a controlled substance in Pennsylvania. Thus, because Registrant lacks a license to practice medicine in Pennsylvania and, therefore, is not authorized to handle controlled substances in Pennsylvania, Registrant is not eligible to maintain a DEA registration. Accordingly, I will order that Registrant's DEA registration be revoked.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration No. FS1471818 issued to Milad I. Shaker, M.D. Further, pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 823(f), I hereby deny any pending application of Milad I. Shaker, M.D. to renew or modify this registration or for any other registration in Pennsylvania. This Order is effective March 22, 2021.

D. Christopher Evans,

Acting Administrator.

[FR Doc. 2021–03358 Filed 2–18–21; 8:45 am]

BILLING CODE 4410–09–P

[5] Under the Administrative Procedure Act, an agency ''may take official notice of facts at any stage in a proceeding—even in the final decision.'' United States Department of Justice, Attorney General's Manual on the Administrative Procedure Act 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). Pursuant to 5 U.S.C. 556(e), ''[w]hen an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary.'' Accordingly, Registrant may dispute my finding by filing a properly supported motion for reconsideration of finding of fact within fifteen calendar days of the date of this Order. Any such motion shall be filed with the Office of the Administrator and a copy shall be served on the Government. In the event Registrant files a motion, the Government shall have fifteen calendar days to file a response. Any such motion and response shall be filed and served by email to the other party and to Office of the Administrator, Drug Enforcement Administration at *dea.addo.attorneys@dea.usdoj.gov.*

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 17–33]

Michael W. Carlton, M.D.; Decision and Order

On April 18, 2017, a former Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause (hereinafter, OSC) to Michael W. Carlton, M.D. (hereinafter, Respondent). Administrative Law Judge Exhibit (hereinafter, ALJX) 1 (Order to Show Cause), at 1. The OSC proposed the revocation of Respondent's Certificate of Registration No. BC3579969 pursuant to 21 U.S.C. 824(a)(4) ''because [his] continued registration is inconsistent with the public interest . . . .'' *Id.* (citing 21 U.S.C. 823(f)).

I. Procedural History

The OSC alleged that ''between May 8, 2015 and November 21, 2015, on approximately forty-two (42) occasions, [Respondent] unlawfully prescribed controlled substances to thirty-one (31) patients by issuing prescriptions for other than a legitimate medical purpose and outside the usual course of professional practice.'' OSC, at 1–2. The OSC alleged violations of 21 U.S.C. 841(a), 21 CFR 1306.04(a), and Ariz. Rev. Stat. Ann. § 32–1401(27). *Id.* at 2. The OSC stated that ''a medical expert has concluded that [Respondent's] issuance of the [forty-two] prescriptions

listed [in the OSC] violated minimal medical standards applicable to the practice of medicine in the state of Arizona.'' *Id.* For each of the forty-two prescriptions listed in the OSC, the Government alleged that Respondent's deficiencies ''include [his] failure to conduct a physical examination, take an adequate medical history, and assess and discuss functional issues'' prior to their issuance. *Id.* at 2; *see also id.* at 3–10.

The OSC notified Respondent of the right to either request a hearing on the allegations or submit a written statement in lieu of exercising the right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. *Id.* at 10 (citing 21 CFR 1301.43). The OSC also notified Respondent of the opportunity to submit a corrective action plan. *Id.* at 11 (citing 21 U.S.C. 824(c)(2)(C)).

By letter dated May 18, 2017, Respondent timely requested a hearing.[1] ALJX 2 (Request for Hearing), at 1. The matter was placed on the docket of the Office of Administrative Law Judges and was initially assigned to Chief Administrative Law Judge John J. Mulrooney, II (hereinafter, the Chief ALJ). On May 22, 2017, the Chief ALJ established a schedule for the filing of prehearing statements. ALJX 3 (Order for Prehearing Statements), at 1. The Government filed its prehearing statement on May 31, 2017. ALJX 4 (Government's Prehearing Statement), at 1. After twice requesting and receiving additional time, Respondent filed his Prehearing Statement on July 5, 2017. *See* ALJX 5 (Letter from Respondent dated June 9, 2017), ALJX 6 (Government Opposition to Continuance Request), ALJX 7 (Order Granting Respondent's First Extension Request), ALJX 8 (Respondent's Request for Extension to File Prehearing Statement), ALJX 9 (Order Granting Respondent's Second Extension Request), and ALJX 10 (Respondent's Prehearing Statement).

On July 6, 2017, the Chief ALJ issued a Prehearing Ruling that, among other things, set out one agreed upon stipulation and established schedules for the filing of additional joint stipulations and for the hearing. ALJX 11 (Prehearing Ruling), at 1, 4. The Prehearing Ruling stated that ''[n]o later than July 28, 2017, the parties are to serve each other with copies of all identifiable documents listed in their prehearing statements.'' *Id.* at 2 (emphasis omitted). The parties were also directed to file supplemental prehearing statements and exchange ''any additional documents identified in the parties' supplemental prehearing statements'' by no later than August 21, 2017. *Id.* Thereafter, the matter was reassigned to Administrative Law Judge Mark M. Dowd (hereinafter, the ALJ). ALJX 15 (Order Reassigning Case). The Government timely served the exhibits identified in its prehearing statement on Respondent on July 28, 2017. Government's Certificate of Service Regarding Government's Proposed Exhibits 1–34; ALJX 11, at 2. Respondent did not serve the exhibits identified in its prehearing statement on the Government at that time. The Respondent filed a supplemental prehearing statement on July 27, 2017, which identified the same exhibits as were listed in his original prehearing statement. ALJX 16 (Respondent's First Supplemental Prehearing Statement). The Government timely filed a supplemental prehearing statement on August 21, 2017. ALJX 17 (Government's Supplemental Prehearing Statement). The Respondent missed the July 28, 2017 deadline to exchange exhibits, which set off a variety of motions (including additional requests for continuances and a motion *in limine*) and a variety of procedural rulings. See ALJX 18–30. I have reviewed and agree with the procedural rulings of the ALJ during the administration of the hearing.

The hearing in this matter took place in Phoenix, Arizona, and spanned two days. *See generally* Transcript of Proceedings in the Matter of Michael W. Carlton, M.D. (hereinafter, Tr.). Both parties filed posthearing briefs. *See* Government's Proposed Findings of Fact, Conclusions of Law, and Argument (hereinafter, Govt Posthearing), and Respondent's Post-Hearing Brief (hereinafter, Resp Posthearing). Both parties also briefed the issue of whether or not Respondent should receive an adverse inference for failing to provide behavioral health records, which Respondent claimed existed, but were not produced by RIM pursuant to the subpoena[2] or by Respondent on his own behalf. *See* Govt Posthearing, and Respondent's Brief on RIM Medical Records. Then on April 12, 2018, the ALJ issued his Recommended Rulings, Findings of Fact, Conclusions of Law and Decision (hereinafter, RD). The Government filed exceptions to the RD. *See* Government's Exceptions to the Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge (hereinafter, Govt Exceptions).

Having considered the record in its entirety, I find that Respondent issued forty prescriptions beneath the applicable standard of care and outside of the usual course of the professional practice in Arizona in violation of federal law, and I find that Respondent committed violations of state law. I agree with the ALJ that revocation is the appropriate sanction. RD, at 96. I make the following findings of fact.

II. Findings of Fact

A. DEA Registration

The parties stipulated that Respondent is registered with DEA as a data-waived DW/100 practitioner able to handle controlled substances in schedules II through V under DEA Certificate of Registration No. BC3579969, at 15721 North Greenway-Hayden Loop, Suite 205, Scottsdale, Arizona 85260. ALJX 11, at 1; and GX 1 (Controlled Substance Registration Certificate).

B. The Investigation

The Diversion Investigator assigned to this matter (hereinafter, DI) first interacted with Respondent in 2007 for a ''scheduled regulatory investigation.'' Tr. 149. During the scheduled investigation, DI discovered potential violations,[3] resulting in DEA's issuance of an Order to Show Cause, which was dismissed following the execution of a Memorandum of Agreement (hereinafter, MOA) between Respondent and DEA. Tr. 150–52; GX 35 (MOA). The MOA did not require Respondent to admit any wrongdoing, but it did remind Respondent of his obligation to abide by all federal, state, and local laws and regulations pertaining to controlled substances and placed additional obligations and conditions on Respondent that remained in effect until 2013. Tr. 151, 153–54, 213; GX 35. One of those obligations stated that ''[Respondent] must conduct an initial examination validating the necessity to

[1] I find that the Government's service of the OSC was adequate.

[2] The Diversion Investigator testified that the subpoena request was for ''all medical records for any patient who was treated at Recovery in Motion and received a controlled substance prescription from Dr. Carlton.'' Tr. 164. She also testified that ''because of the privacy concerns with opioid patients . . . [DEA] had to apply for a court order that protected, saying that yes, in fact, we can have these, but we'll handle these records in a particular way, and [DEA was] to get that court order.'' Tr. 156–57. Both the subpoena and the court order were served on RIM. Tr. 157, 165. Ultimately, I do not find that the missing behavioral health records, if they existed, are relevant to the standard of care as discussed in *infra* II.E.1 & n.13.

[3] It was alleged that Respondent exceeded the number of patients he was permitted to treat for addiction; he operated an illegal take-back program wherein he took patients' unused controlled substances and redistributed them to other patients; and he failed to maintain required records. Tr. 150–52; GX 35, at 1–2.

prescribe Suboxone or Subutex to each [new] OBOT patient. This paragraph does not preclude initiation of medication in an emergent/urgent detoxification setting, provided Dr. Carlton conducts an examination within twenty-four (24) hours of initiation.'' GX 35, at 3.

DEA opened this investigation into Respondent after DI received a call from a former employee of Recovery in Motion (hereinafter, RIM). Tr. 154–55, 213–14. The former employee, who was a physician, expressed concerns that Respondent's patients ''were receiving drugs but had never received any sort of visit or examination from the doctor first.'' Tr. 155. She told DI that she left RIM because she was concerned about the way the facility operated; more specifically, ''[s]he was very concerned about patient welfare, and she was afraid that somebody was going to die.'' Tr. 213–14. During the investigation, DI interviewed several employees of RIM, and DI stated that ''every one of the employees that [she] spoke with was . . . concerned because the patients were starting drugs without ever having been treated or evaluated by the doctor first.'' Tr. 156. DI also interviewed some of Respondent's patients, none of whom ''said that they saw [Respondent] upon admission,'' and most of whom ''didn't recall anything that would be a physical examination to include vital signs.'' Tr. at 194.

Thereafter, DEA subpoenaed RIM for the medical records of patients for whom Respondent had prescribed controlled substances. Tr. 156–57. RIM promptly responded to the subpoena, and DI reviewed the records that were produced. Tr. 157. DI believed that she had received all of the necessary records from RIM. Tr. 158, 161, 163. Thereafter, DEA retained a medical expert, Dr. Loes, to review the patient files and provide his expert opinion. Tr. 199–200. The Government expert concluded that Respondent's prescribing of controlled substances fell below the standard of care, and the OSC forming the basis of this action was issued. OSC, at 2; GX 36 (Government's Expert Report), at 2.

C. Government's Case

The Government's documentary evidence consisted primarily of patient records for thirty-one [4] individuals prescribed controlled substances by Respondent between May 8, 2015, and November 21, 2015. The Government's evidence also contained prescription records for those same thirty-one patients, the Curriculum Vitae and draft report for its expert witness, and a Memorandum of Agreement between the DEA and Respondent that predates the issues raised in this case. *See* GX 1–36. Additionally, the Government called three witnesses: Respondent (whose testimony is summarized in the Respondent's Case, *see infra* Section II.D.), DI, and the Government's expert Dr. Michael W. Loes.

DI testified regarding her professional background, Tr. 147–49, and about her 2007 interactions with Respondent that resulted in a Memorandum of Agreement between DEA and Respondent. *See supra* Section II.B; Tr. 149–54; RD, at 3–4. She also testified about her investigation-related actions in this matter including her role in requesting and receiving records from RIM in connection with this matter. *See supra* Section II.B & n. 2; Tr. 154–201; RD, at 4–6. Having read and analyzed all of the record evidence, I agree with the ALJ that DI's testimony ''was candid and straightforward.'' RD, at 6. I also agree that DI's testimony was ''sufficiently objective, detailed, plausible, and internally consistent to be considered fully credible.'' *Id.*

Dr. Loes testified regarding his professional and educational background. Tr. 217–28. He obtained a medical doctorate from the University of Minnesota, completed a clinical pharmacology fellowship, and later an internal medicine residency. Tr. 219–21; GX 34 (Curriculum Vitae of Dr. Loes); RD, at 7. Dr. Loes is board certified in internal medicine, addiction medicine, and pain medicine. Tr. 221–22; GX 34; RD, at 7. Dr. Loes first began practicing medicine in Arizona in 1994, when he became the Director of the Maricopa County Pain Program. Tr. 222–23; RD, at 7. He has held a variety of positions since then [5] in private practice, at inpatient treatment facilities, and at outpatient treatment facilities.[6] Tr. 222–25; GX 34; RD, at 7. Dr. Loes is licensed in Arizona and was accepted in this matter ''as an expert in the field of addiction medicine in the State of Arizona.'' Tr. 234; RD, at 7. Dr. Loes' remaining testimony covered the standard of care in Arizona and his professional opinion that Respondent failed to meet the standard of care with regard to all of the prescriptions at issue in this case.[7] *See infra* Section II.F; Tr. 234–424; RD, at 8–28, 70–83. ''Dr. Loes testified that his opinion was based upon both his analysis of the Arizona and federal regulations, as well as his almost 40-years' experience in the field.'' RD, at 80.

With regard to credibility, the ALJ found that ''Dr. Loes demonstrated limited familiarity herein with the relevant Arizona regulatory scheme [which led the ALJ] to discount his opinion somewhat . . . where such opinion [was] contrary or unsupported by the text of the relevant Arizona regulatory scheme.'' *Id.* For example, the ALJ found that the Arizona regulations did not support Dr. Loes' testimony ''that a physician at an outpatient facility can never prescribe a controlled substance before physically examining a patient.'' RD, at 81. *But see infra* II.E.4. The ALJ did not discount Dr. Loes' opinion as to the relevant standard of care on the basis of his experience. *Id.* The ALJ explained ''[he was] convinced that Dr. Loes, by actively working in this field for nearly 40-years, [was] familiar with acceptable standards of care within the relevant medical community in Arizona as [it] related to the general requirements for establishing a doctor-patient relationship, and the permissive 48-hour delay in examining patients admitted to inpatient facilities after [being] prescribed controlled substances.'' [8] *Id.*

As explained below, I find that Dr. Loes' opinions regarding the standard of care as it applied outpatient facilities, such as the one in this case, were supported by Arizona law and regulations and I therefore find Dr. Loes' testimony to be fully credible. *See infra* Section II.E.

D. Respondent's Case

The Respondent's documentary evidence consisted solely of what appears to be a scholarly article: *Louis A. Trevisan et al., Complications of Alcohol Withdrawal: Pathophysiological Insights,* 22 Alcohol Health & Res.

[4] The Government appears to have abandoned the allegations regarding one of the patients, A.A., because the expert testified that these prescriptions were issued within the standard of care; therefore, I am not including findings of fact related to patient A.A. RD, at 83; Tr. 316; *see generally* Gov Posthearing. *See also,* GX 2, at 22–23; GX 20 (Patient Records for A.A.); GX 36, at 18.

[5] Dr. Loes worked with Respondent for approximately six months providing physician coverage at Phoenix Recovery at Ellsworth. Tr. 223, 228, 381–82. Dr. Loes left, on good terms, to focus on private practice. Tr. 224. None of the parties raised any issues about Dr. Loes' previous contact with Respondent.

[6] The majority of Dr. Loes' work since 1994 has been in Arizona, but he briefly relocated to Minnesota in 2012. Tr. 223.

[7] Dr. Loes identified the following controlled substances as being at issue in this case: Buprenorphine (Suboxone, Zubsolv), Category III; diazepam (Valium), Category IV; phenobarbital, Category IV; tramadol (Ultram), Category IV; hydrocodone (Vicodin), Category II; amphetamine salts (Adderall), Category II; pregabalin (Lyrica); Category V. GX 36, at 3.

[8] *But see infra.* II.E.4, which discusses the Arizona regulations' support of Dr. Loes' opinion and addresses the 48-hour delay referenced here.

World, 61 (1998).[9] *See* Respondent's Exhibit (hereinafter, RX) 1. Respondent testified on his own behalf and presented no other testimony in support of his case.

Respondent testified that he completed a combined residency in internal medicine and pediatrics, that he is board certified in addiction medicine, and that he has been treating chemically dependent patients since 1994. Tr. 78, 125–26, 429–31. Respondent testified that he has been the medical director at RIM since its inception in March of 2015. Tr. 23. As the medical director Respondent testified that it was his duty ''[t]o make sure that medical policies [were] established and to see patients.'' Tr. 23. RIM provided partial hospitalization and intensive outpatient therapy. RD, at 41 (citing Tr. 66, 212–13).

Respondent testified that he went to Europe between July 24, 2015, and August 8, 2015. Tr. 60, 260, 290. While in Europe, Respondent testified that he received phone calls and emails from his staff regarding patients, and he continued to treat those patients to include writing prescriptions for controlled substance. Tr. 61–64, 67, 71, 81; RD, at 41. Respondent further testified that he conducted telephone evaluations (audio only) of patients while in Europe,[10] but that he did not have video capabilities. Tr. 72–73. Respondent did not document in his medical records the fact that he was performing evaluations of patients remotely. Tr. 72.

Throughout his testimony, Respondent maintained that he acted within the standard of care for two reasons. First, Respondent argued that the ''trained staff'' at RIM conducted a ''sufficient and appropriate evaluation'' of each patient upon admission to constitute a physical examination. Tr. 112–13. Second, Respondent argued that a physical examination of the patients identified in the OSC was not required because withdrawal is an emergent situation that qualifies as an ''emergency medical situation,'' and therefore allows a physician to prescribe without first conducting an examination. Resp Posthearing, at 2. Respondent testified to an alternative version of the standard of care in Arizona.[11] Tr. 144, 435–36; *infra* Section II.E. Respondent testified that at RIM, as he claimed was common within the industry,[12] new patients would enter treatment and be examined by staff, then the doctor would consult the staff (over phone or email), authorize a prescription if appropriate, and would complete paperwork after the fact. Tr. 108, 144–45. Respondent testified that not all of the staff at RIM held medical licenses, but that they were trained to ''take an appropriate history and physicals.'' Tr. 145–46. Respondent testified that the staff's admission notes, which he claimed justified the issuance of the initial prescriptions, were contained in the behavioral health portion of the medical record.[13] Tr. 26–27, 33, 57–58. Respondent testified that he would see new patients anywhere between 8 hours and 96 hours after intake depending on when the patient entered the facility (as Respondent only saw patients twice a week). Tr. 23, 106. Respondent also testified that patients would typically complete the initial history and physical records on the day that Respondent saw the patient. Tr. 106.

I agree with the ALJ that the ''Respondent overall did not express any sense of wrongdoing.'' RD, at 36. While at times Respondent acknowledged mistakes or deficiencies in recordkeeping (such as an undated record), he stated that it was an ''oversight'' and that he otherwise had followed the standard of care. Tr. 121, 122.

The ALJ found, and I agree, that Respondent's credibility was mixed. RD, at 38. The ALJ found that Respondent's testimony regarding his background and experience was credible. RD, at 38. The ALJ found that Respondent did not testify credibly regarding: (1) His knowledge of RIM's withholding of the behavioral health records, (2) his claim that all of the patients at issue had received physical exams within RIM's protocol time period (ninety-six hours) where the evidence suggested that at least seven patients were not examined within ninety-six hours, (3) his claim that he properly reviewed the admission protocol, personally directed the ordering of medication, and actively monitored patients while he was in Europe. RD, at 38–39. I agree with the ALJ's credibility findings on all of these matters. However, the ALJ found that the Respondent's testimony regarding RIM's policies and protocols was credible and I, as discussed below, find that testimony to not be credible. RD, at 38; *infra* II.E.4.

E. The Standard of Care in the State of Arizona

The crux of this case is the appropriate standard of care in Arizona for prescribing controlled substances as it applies to outpatient treatment centers, such as RIM. In accordance with Dr. Loes' testimony and the record as a whole, I find that the standard of care in Arizona requires that a physician perform a physical examination of a patient or otherwise develop a doctor-patient relationship prior to prescribing controlled substances when a relevant exception does not apply. In finding this standard of care, I note that there was significant confusion at the hearing stage regarding a number of issues: (1) Who can perform the physical examination; (2) when the exceptions apply, such as what constitutes an emergency medical situation or telemedicine appointment; (3) when the physical examination must be performed, such as whether Arizona law provides an exception that allows the examination to be performed later for addiction services. I will address each of these issues in turn.

1. Generally, the Record Evidence Supports a Finding That the Standard of Care in Arizona Requires That a Physician Perform a Physical Examination of a Patient Prior To Prescribing Controlled Substances

Dr. Loes testified that the general standard of care in Arizona requires that a doctor-patient relationship be established through a physical or mental[14] exam prior to a physician

[9] Respondent offered this evidence to support his testimony regarding the potentially deadly side effects of withdrawal, and to support his argument that withdrawal treatment is always an emergency. Tr. 431–38.

[10] Respondent's exact words were ''I evaluated a patient in person telephonically.'' Tr. 72. When asked how he evaluated Patient A.H.'s appearance as being clean and neat with a telephonic evaluation, Respondent stated ''I—I can't answer that.'' Tr. 73.

[11] The Respondent was not offered as an expert witness; however, he was permitted to testify as to his understanding of the Arizona standards of care in order to explain why he believed his actions were in compliance with the Arizona standard of care. *See* 144, 435–37; RD, at 76–77.

[12] Respondent testified that this practice was followed by several well-known outpatient addiction treatment facilities and a prominent physician. Tr. 438–40.

[13] As the ALJ noted, Respondent did not produce any records to support his proposition that the medical justification for the controlled substance prescriptions was contained in the behavioral health portion of the patients' corresponding electronic medical record. RD, at 29, 62–68. However, it is unclear how the behavior health records, if they exist, could have impacted the standard of care as I have found it. *See infra* II.E. Any records documenting what Respondent's staff did to evaluate the patients upon admission are not relevant to determining whether or not a physician or a medical practitioner examined the patients prior to the issuance of the controlled substance prescriptions. *See infra* II.E & n.17.

[14] There is no evidence of, nor has Respondent argued that, any mental exam was performed by Respondent in lieu of a physical exam prior to prescribing. The evidence establishes that Respondent did not see or perform any type of examination on the patients prior to prescribing. *See supra* II.F.

prescribing controlled substances. Tr. 222–23, 234, 422–23. Dr. Loes' opinion is supported by Arizona statute which states that it is ''unprofessional conduct'' to ''[p]rescrib[e], dispens[e] or furnish[ ] a prescription medicine . . . to a person unless the doctor first conducts a physical or mental health status examination of that person or has previously established a doctor-patient relationship.'' Ariz. Rev. Stat. Ann. § 32–1401(27)(ss) (2014).

According to Dr. Loes, a physical examination sufficient to create a doctor-patient relationship for the purposes of prescribing controlled substances, ''requires that (1) the physician sees the patient, (2) examine[s] the patient, (3) assesses and diagnose[s] the condition(s) that establish the need for the controlled substance(s) and then (4) develops and executes an appropriate plan to improve or eliminate the medical condition wherein controlled substance(s) are integral to that plan.'' GX 36, at 2. Similarly, Dr. Loes testified that in order to establish a doctor-patient relationship at an outpatient treatment facility, the physician must take a medical history, take an addiction history, review the patient's symptoms, use the physical examination to determine whether the patient is in withdrawal, and develop a treatment plan—all prior to prescribing. Tr. 232–33.

Respondent argued that in an outpatient treatment center, the standard of care does not require a physician to perform the physical examination, but instead the standard of care ''is to take patients who get admitted in acute withdrawal settings and to treat them based on the history that—the history that's obtained from the staff . . . .'' Tr. 49. Respondent testified that his use of the word ''staff'' referred, not to persons with a medical license, but to people who were trained to ''take an appropriate history and physicals'' Tr. 145–46; *see also* Tr. 112–113.

Dr. Loes opined unequivocally that ''it's not appropriate for a staffer to do a physical exam.'' [15] Tr. 376. Dr. Loes testified that the physical examination had to be performed by a physician, but that the authority to perform the physical examination could be delegated to another physician [16] or a nurse practitioner. Tr. 282, 398. Dr. Loes' testimony appears to be supported by Arizona law and regulations. The plain language of the statute states that a doctor cannot prescribe controlled substances, ''unless *the doctor* first conducts a physical or mental health status examination . . . .'' Ariz. Rev. Stat. Ann. § 32–1401(27)(ss) (emphasis added). Additionally, the Arizona regulations governing outpatient treatment centers provide that, for a patient receiving opioid treatment services, ''a physician, or a medical practitioner under the direction of a physician performs a medical history and physical examination on the patient . . . within 48 hours after admission.'' Ariz. Admin. Code § R9–10–1020(c)(2) (2014). Medical practitioner is defined as ''a physician, physician assistant, or registered nurse practitioner.'' Ariz. Admin. Code § R9–10–101(128). Under Arizona state law, physicians, physician assistants, and registered nurse practitioners are required to be licensed as such. Ariz. Admin. Code § R9–10–101(128), citing to Ariz. Rev. Stat. Ann 32–1601(21)&(22), and 32–2501(12)&(13). Based on Dr. Loes' testimony and the record as a whole, I find that Respondent's ''staff'' could not perform a physical examination to meet the requirements under Arizona law, unless the staff met the definition of a medical practitioner.[17] During cross examination, Government's attorney specifically asked Respondent whether these ''trained staff'' were licensed by ''some type of medical board in the state of Arizona'' to which Respondent answered, ''They were trained by our staff.'' Tr. 112–13.

Based on Dr. Loes' testimony as supported by Arizona law, I find that the applicable standard of care in Arizona requires that a physician perform a physical examination of a patient or otherwise develop a doctor-patient relationship prior to prescribing controlled substances, unless an exception applies.

2. Emergency Medical Situation Exception

Neither the Government nor the Respondent disputed that the requirement that a physician conduct a physical or mental health status examination and develop a doctor-patient relationship before prescribing controlled substances does not apply in a medical emergency; however, the parties disagree over what qualifies as an ''emergency medical situation.'' *See* Govt Posthearing, at 26; Resp Posthearing, at 8–9. Ariz. Rev. Stat. Ann. § 32–1401(27)(ss) provides that a doctor is not required to conduct a physical or mental health status examination before prescribing when there is an ''(ii) [e]mergency medical situation as defined in § 41–1831.'' Ariz. Rev. Stat. Ann. § 32–1401(27)(ss). Section § 41–1831 states that ''[e]mergency medical situation means a condition of emergency in which immediate medical care or hospitalization,[18] or both, is required by a person or persons for the preservation of health, life, or limb.'' Ariz. Rev. Stat. Ann. § 41–1831(9) (2012).

Dr. Loes testified that an emergency occurs when there are ''[u]nstable vital signs, . . . the Clinical Opioid Withdrawal Scale[ ] was done and was very elevated, showing a shaky, vomiting painful type patient that looked like they could seize.'' Tr. 238–39. Respondent, on the other hand, testified that ''the way that the statute defines emergency, it does not say that a patient has to be unstable for there to be an emergency . . . what we do is prevent instability by providing treatment.'' Tr. 443. Respondent implies that treatment meant to prevent a patient from entering a state of medical emergency itself constitutes an ''emergency medical situation.'' [19] Tr. 431–35, 443.

[15] Dr. Loes further testified that it is ''common for a history to be taken by staffers . . . A staff might take vital signs, but that's not a physical exam.'' Tr. 376.

[16] Dr. Loes testified that it is permissible for one doctor to prescribe based on another doctor's (which he called a coverage physician) performance of the physical examination. Tr. 254. This testimony appears consistent with the exception laid out in Ariz. Rev. Stat. Ann. § 32–1401(27)(ss)(i).

[17] As noted throughout, Respondent raised an argument that his staff conducted physical examinations on his behalf and documented those examinations in records which had not been produced by RIM in response to the Government's subpoena. If these records existed, in order for them to even be relevant to whether or not Respondent was acting within the standard of care, the staff would have had to fall within the Arizona state statutory definition of medical practitioner. The record evidence, based on Respondent's own testimony does not indicate that these staff fell within the statutory definition, and therefore, I find that the records, if they existed, could have limited relevance to whether Respondent acted within the standard of care.

[18] The same section defines an ''[e]mergency receiving facility'' as ''a licensed health care institution that offers emergency medical services, that is staffed twenty-four hours a day and that has a physician who is licensed pursuant to title 32, chapter 13 or 17, on call.'' Ariz. Rev. Stat. Ann. § 41–1831(10) (2012). There is no evidence on the record, nor did Respondent make any argument, that RIM is an emergency receiving facility.

[19] Although not specific to the statutory definition, the Arizona Medical Board (hereinafter, Board) discussed the application of a life-threatening emergency in *In the Matter of: Darrell J. Jessop, M.D., Respt.,* 11A–23441–MDX, 2012 WL 432838 (Ariz.Med.Bd. Feb. 6, 2012). Jessop was a practitioner at an urgent care clinic who, pursuant to a consent agreement with the Board, was prohibited from prescribing or administering controlled substances for three years. *Id.* at 2. However, there was an exception in the agreement that allowed the Jessop to administer controlled

Continued

The ALJ found, and I agree, that ''the plain language of the statute in limiting the covered conditions to those requiring 'immediate' medical care would rebut the Respondent's overly broad interpretation of the statute . . . as encompassing potential or even non-medical eventualities.'' RD, at 82 (citing Ariz. Rev. Stat. Ann. § 41–1831).[20] I find that Dr. Loes' description of an emergency is in line with the statutory definition.

Dr. Loes further testified that ''an outpatient program doesn't handle acute emergencies,'' Tr. 226. Dr. Loes' opinion appears to be supported by Arizona law and regulation. It appears that an outpatient treatment center is required to have additional authorization in order to provide emergency room services. *See* Ariz. Admin. Code § 09–10–1019 (An outpatient treatment center authorized to provide emergency room services must have emergency room services available on the premises at all times, and must ensure that both a physician and a registered nurse are present in the area designated for emergency room services). Respondent has not argued that RIM is authorized to provide emergency room treatment services, nor does it appear that RIM would qualify to provide emergency treatment services.

I find that where an emergency medical situation—instability requiring immediate medical care—exists, the applicable standard of care as testified to by Dr. Loes and supported by Arizona law does not require a physician to conduct a physical or mental health status examination and develop a doctor-patient relationship before prescribing controlled substances; however, as explained further herein, Dr. Loes credibly testified that there is no evidence in this case to support that the prescriptions were issued pursuant to an emergency medical situation.

3. Telemedicine Exception

The second exception to the physical examination requirement that is potentially relevant to this case applies when there are ''(viii) [p]rescriptions written by a licensee through a telemedicine program that is covered by the policies and procedures adopted by the administrator of a hospital or outpatient treatment center.'' Ariz. Rev. Stat. Ann. § 32–1401(27)(ss). Arizona law states that ''[t]he physical or mental health status examination may be conducted during a real-time telemedicine encounter with audio and video capability if the telemedicine audio and video capability meets the elements required by the centers for medicare and medicaid services . . . .'' *Id.* Dr. Loes testified to the same, and indicated that telemedicine requires the use of a television portal or other video capability. Tr. 377–78. Dr. Loes testified that, ''a telephonic call with the patient, in [his] opinion, is not sufficient to develop a . . . strategy for treatment and the . . . doctor patient relationship.'' Tr. 233. In other words, ''a phone interview doesn't entail a kind of physical exam,'' and a physician cannot ''start controlled substances without a physical exam.'' Tr. 239.

I find that where a facility has a telemedicine program, and a telemedicine visit has audio and video capability, the applicable standard of care as testified to by Dr. Loes and supported by Arizona law, does not require a physician to conduct an in-person physical or mental health status examination and develop a doctor-patient relationship before prescribing controlled substances; however, as further explained herein, there is no evidence that Respondent conducted physical examinations using telemedicine with audio and video capability in this case. *See supra* II.D & n.10.

4. Respondent's Claimed Regulatory/Policy Exception

Respondent argues that there is an additional exception to the statutory requirement that a physician first conduct a physical examination prior to prescribing controlled substances found in RIM's policies, which were drafted pursuant to Arizona's Health Care regulations.[21] Arizona Regulations require an outpatient treatment facility, such as RIM, to ensure that ''[p]olicies and procedures for services provided at or by an outpatient treatment center are established, documented, and implemented to protect the health and safety of a patient . . . .''[22] Ariz. Admin. Code § R9–10–1003(D)(2) (2015).

Respondent argues that, under RIM's policies, a physician at an outpatient treatment facility can prescribe medication to a patient for a limited period of time prior to the physician performing a physical examination so long as trained staff first evaluated the patient. Tr. 107–08. Respondent testified that RIM's policy[23] was that upon admission, ''trained staff''[24] would evaluate the patient and consult telephonically with the physician, then, if deemed appropriate, the physician would issue a prescription to the patient—the physician would conduct a physical examination of the patient up to seventy-two or ninety-six[25] hours after admission. Tr. 112–13; *see also* Tr. 107–08.

In contrast, Dr. Loes credibly testified that it was his expert opinion that no outpatient facility can prescribe to a patient without first having a physical examination performed by a physician.[26] Tr. 396, 405, 407. Dr. Loes' opinion of the standard of care as it is relevant to this case appears to be consistent with and supported by Arizona's statutes and regulations, the application of which to outpatient

substances in ''life threatening emergencies.'' *Id.* Jessop argued that a life-threatening emergency did not require that death be imminent and that a ''life-threatening emergency'' existed ''anytime that the practitioner . . . determines that the patient's condition might deteriorate if he does not prescribe medication . . . .'' *Id.* at 9; *see also id.* at 2. The Board disagreed and stated, ''[u]nder Respondent's own authorities, an urgent care clinic is not equipped to handle life-threatening emergencies and if such an emergencies [sic.] arise, the urgent care physician must refer the patients to an emergency room.'' *Id.* at 9.

[20] Moreover, the Arizona Supreme Court noted that although there are various definitions of emergency care, ''the need for immediate attention seems to be the common thread.'' *Thompson* v. *Sun City Community Hospital,* 688 P.2d 605, 611 (1984); *see also Callen* v. *Rogers,* 216 Ariz. 499, 509 (2007).

[21] The ALJ stated that ''[t]he Respondent's testimony that RIM had policies and procedures governing aspects of treatment protocol were sufficiently credible to credit, as they appeared to be corroborated by the Arizona Administrative Code.'' RD, at 38. I agree with the ALJ the regulations required RIM to have policies and procedures.

[22] By regulation, these policies are required to, amongst other things: ''a. [c]over patient screening, admission, assessment, . . . discharge plan, and discharge; . . . d. [c]over obtaining, administering, storing, and disposing of medications, including provisions for controlling inventory and preventing diversion of controlled substances; e. [c]over prescribing a controlled substance to minimize substance abuse by a patient; . . . g. [c]over telemedicine, if applicable.'' Ariz. Admin. Code § R9–10–1003(D)(2) (2015).

[23] Respondent's description of RIM's policies was similar to Respondent's version of the standard of care. Respondent testified that, ''the standard of care is to take patients who get admitted in acute withdrawal settings and to treat them based on the history that—the history that's obtained from the staff, and then see [the patient] afterwards. And in some programs, that is within 24 hours, and in some programs it's within five to seven days.'' Tr. at 49.

[24] As already discussed, trained staff would be required to fall within the definition of medical practitioner under the statute. *See supra* II.E.1 & n.17.

[25] Respondent first testified that a physician had 72 hours to evaluate a patient after admission. Tr. 107. He then testified that RIM changed its policies and procedures to say that a physician had 96 hours to evaluate a patient after admission. *Id.* Respondent did not clarify whether RIM's policy was 72 hours or 96 hours at the time relevant to this case. The ALJ applied 96 hours to his standard of care. Ultimately this is irrelevant, because I do not find that RIM's policies provide an exception to the requirement that a physician examine a patient prior to prescribing.

[26] *See also supra* II.E.1.

treatment centers is complex.[27] Article 9, Chapter 10 of Arizona's Administrative Code covers ''Department of Health Services Health Care Institutions: Licensing'' (hereinafter, licensing regulations). Chapter 10 of the licensing regulations sets forth the licensing requirements for, and a number of requirements covering various types of health care institutions. It seems likely that these are the ''licensing regulations'' that Dr. Loes referenced, without citing, in his testimony. *See* Tr. 405, 407. Within the licensing regulations, there are sub-articles for ''Behavioral Health Inpatient Facilities'' (Article 3) (hereinafter, inpatient regulations) and for ''Outpatient Treatment Centers'' (Article 10) (hereinafter, outpatient regulations).

With regard to outpatient facilities,[28] Dr. Loes opined that that no outpatient facility can prescribe to a patient without first having a physical examination performed by a physician. Tr. 396, 405, 407. Pursuant to Arizona's regulations, an outpatient treatment center that provides opioid treatment[29] services:

> . . . shall ensure that for a patient receiving opioid treatment services:
>
> 2. A physician or a medical practitioner[30] under the direction of a physician:
>
> a. Performs a medical history and physical evaluation on the patient within 30 calendar days before admission or within 48 hours after admission, and
>
> b. Documents the medical history and physical examination in the patient's medical record within 48 hours after admission.

Ariz. Admin. Code § R9–10–1020(C) (2014). *See* Ariz. Admin Code § R9–10–1020(C) and § R9–10–1003(D). Although the outpatient regulations permit the physical examination to occur within 48 hours of admission, nowhere do they state that controlled substances can be prescribed before the physical examination is completed.[31] The requirement to conduct a physical examination after admission is separate from the requirement to conduct one prior to prescribing controlled substances and the two should not be conflated. In light of the above, I find Respondent's testimony regarding the substance of RIM's policy, which was not supported by any corroborating evidence, to lack credibility; if I were to credit Respondent's testimony, RIM's policies would appear to be in conflict with the licensing regulations and statute.[32] Tr. 107–08. Instead I credit Dr. Loes' opinion, which appears to be more consistent with the licensing regulations and statute. Accordingly, I find that the standard of care in Arizona as described by Dr. Loes requires that, at an outpatient facility, a physician, not ''trained staff,'' must conduct the physical examination, and that a physical examination is required before a physician can prescribe controlled substances.

Indeed, there are a variety of options available for patients upon admission besides receiving controlled substances. Respondent testified that there are 12-step meetings, group meetings, therapy sessions, and other behavioral health counselings. Tr. 130. There is no evidence to give credence to Respondent's claim that Arizona's statutory requirements should be usurped by a health care facility's policy, even where the existence of the policy is mandated by regulation.

The outpatient regulations do not appear to conflict with, nor be an exception to, the statutory requirement that a physician must conduct a physical examination prior to treating a patient with controlled substances. Therefore, in accordance with Dr. Loes' testimony and the record as a whole, I find that where, as in this case, there is not an emergency medical situation and no appropriate telemedicine examination was conducted, the applicable standard of care in Arizona requires that a physician perform a physical examination of a patient or otherwise develop a doctor-patient relationship prior to prescribing controlled substances.

[27] The ALJ discounted ''[Dr. Loes'] opinion somewhat . . . where such opinion was unsupported by the text of the relevant Arizona regulatory scheme.'' RD, at 80. The ALJ was ''unable to identify any provision in the Arizona Administrative Code, which specifically addressed [whether there could be a ''delay between prescribing a controlled substance and the physician physically examining the patient''] as to any of the various classes and subclasses of health care facilities in Arizona.'' RD, at 78. Additionally, the RD was unable to find support within the regulations for Dr. Loes' opinion that is was permissible for a physician to prescribe controlled substance prior to a physical exam in the inpatient, but not outpatient, context. RD, at 78–79. I find support in Arizona law for Dr. Loes' testimony where there is an emergency, as Dr. Loes' explained was frequent in the inpatient context; however, I agree with the ALJ that there was some confusion in Dr. Loes' testimony about when treatment can be initiated in an inpatient facility when there is no emergency. RD, at 75–76. However, ultimately, based on my examination of Arizona law, I credit and do not discount Dr. Loes' opinion regarding the applicable standard of care for the patients at issue in this case in the outpatient context, which, along with the substantial evidence in this case has led to my finding that prescriptions issued to thirty patients, instead of seven (RD, at 93), were issued outside the standard of care.

[28] With regard to inpatient facilities (unlike RIM), Dr. Loes opined that an emergency patient may be prescribed medication before a physical examination, which must be conducted within forty-eight hours, so long as the patient is examined by a registered nurse in direct communication with a physician. Tr. 405–09; RD, at 72, 74. Dr. Loes' testimony appears to be mostly consistent with the inpatient regulations and with the emergency exception found in Ariz. Rev. Stat. Ann. § 32–1401(27)(ss)(ii) *supra* II.E.2. The inpatient regulations state that a ''medical practitioner must perform a medical history and physical examination on a patient within . . . 72 hours after admission. . . .'' Ariz. Admin Code § R9–10–307(8). The inpatient regulations state that ''[e]xcept when a patient needs crisis services, a behavioral health assessment of a patient is completed before treatment for the patient is initiated.'' Ariz. Admin Code § R9–10–307(10) (emphasis added). The inpatient regulations explicitly allow for a behavioral health technician, registered nurse, or behavioral health paraprofessional to conduct the initial behavioral health assessment necessary to initiate treatment. *Id.* at (11). There was some confusion in Dr. Loes' testimony about when a physician can prescribe in an inpatient facility when there is no emergency. Tr. 407–08; *see supra* n.27. However, Dr. Loes' testimony was clear regarding when a physician can prescribe in an outpatient facility, which according to Dr. Loes is not equipped to handle emergencies (Tr. 226, 230, 407, 410–11) and is bolstered by Arizona law. Tr. 396, 405–06.

[29] Under the regulation, '' '[t]reatment' means a procedure or method to cure, improve, or palliate an individual's medical condition or behavioral health issue.'' Ariz. Admin Code § R9–10–101(236). It appears that ''treatment'' includes, but is not limited to, prescribing medication (*e.g.* '' '[o]pioid treatment' means providing medical services, nursing services, behavioral health services, health-related services, and ancillary services to a patient receiving an opioid agonist treatment medication for opiate addiction opioid-related substance use disorder.''). Ariz. Admin Code § R9–10–101(151). *See also id.* at § R9–10–101(221).

[30] As explained *supra* at II.E.1, the definition of medical practitioner is limited. There is nothing on the record to suggest that Respondent's staff would have qualified as medical practitioners, nor is there any documentation suggesting that a physical examination was conducted.

[31] The Government, in its exceptions, argued that that Respondent's claim that he was permitted to prescribe 72 or 96 hours prior to conducting a physical examination of a patient is not relevant to this litigation because the inpatient licensing regulation ''merely requires taking a medical history and performing a physical examination of a patient within 72 hours of admission. It neither addresses nor governs the prescribing or dispensing of controlled substances.'' Gov Exceptions, at 5 & n.4. This argument is similar to what I have found regarding the outpatient licensing regulations which are applicable here (but within 48 hours).

[32] Portions of RIM's established policies, as required by Arizona regulations, are documented in the public record. According to these records, RIM's policy (for much of the time relevant to this case) states that ''[p]rior to initiation of treatment, all Clients will be assessed by a medical practitioner for a medical assessment which shall include: a. [m]edical history b. [p]hysical examination c. [p]ain screen d. [n]utrition screen.'' Gov Exceptions, Attachment B, at 1. The RIM policy further states that ''[a] Client admitted to Recovery in Motion will see the medical provider within 72 hours for a medical assessment.'' *Id.* As such, the provider must see the client within 72 hours; however, the policy does not permit a provider to initiate treatment prior to the conduct of a physical examination. RIM's established policies appear inconsistent with Respondent's testimony, but appear more consistent with Arizona's statute and regulations and the testimony of Dr. Loes regarding the applicable standard of care in Arizona.

F. Patients

1. Patient L.H.[33]

On May 8, 2015, Respondent prescribed a controlled substance, Suboxone 8 mg., to Patient L.H. GX 2 (Prescription Records), at 1; GX 3 (Patient Record for L.H.), at 38; GX 36, at 7; RD, at 42. Dr. Loes testified that at the time the May 8, 2015 prescription was issued, there was no doctor-patient relationship between Respondent and Patient L.H. Tr. 237–38; *see also* GX 36, at 7. In support of his opinion, Dr. Loes testified that ''there was no physical, . . . no documentation of [an] interview or exam or lab; no assessment . . . about what kind of state of withdrawal that patient was in and then, of course, no comprehensive plan prior to that prescription being started.'' Tr. 238. Dr. Loes further testified that there was no evidence of an emergency medical situation. Tr. 238; RD, at 42. Respondent first examined Patient L.H. on May 9, 2015, and Dr. Loes testified that a doctor-patient relationship was established at that time. GX 36, at 7; GX 3, at 39; RD, at 42.

In accordance with Dr. Loes' testimony and the record as a whole, I find that, because there was no legitimate doctor-patient relationship established between Respondent and Patient L.H. at the time the prescription was issued, the Suboxone prescription that Respondent issued to Patient L.H. on May 8, 2015, was issued outside of the usual course of professional practice and beneath the applicable standard of care in Arizona.

2. Patient D.P.

On May 13, 2015, Respondent prescribed a controlled substance, diazepam (Valium) 5 mg., to Patient D.P. GX 2, at 2; GX 4 (Patient Record for D.P.), at 22–23; GX 36, at 7; RD, at 42; Tr. 41–43, 244–45. Dr. Loes testified that at the time the May 13, 2015 prescription was issued, there was no doctor-patient relationship between Respondent and Patient D.P. Tr. 245, 247; *see also* GX 36, at 7. In support of his opinion, Dr. Loes testified that ''the patient was started on Valium on May 13th and not seen until May 22nd.'' Tr. 245. Dr. Loes further testified that there was no evidence of an emergency medical situation. Tr. 250; RD, at 42. Respondent first examined Patient D.P. on May 22, 2015. GX 36, at 7; Tr. 245; GX 4, at 53; RD, at 42.

In accordance with Dr. Loes' testimony and the record as a whole, I find that, because there was no legitimate doctor-patient relationship established between Respondent and Patient D.P. at the time the prescription was issued, the diazepam prescription that Respondent issued to Patient D.P. on May 13, 2015, was issued outside of the usual course of professional practice and beneath the applicable standard of care in Arizona.

3. Patient N.B.

On June 1, 2015, Respondent prescribed a controlled substance, diazepam (Valium) 10 mg. tablets, to Patient N.B. GX 2, at 3; GX 5 (Patient Records for N.B.), at 84; GX 36, at 8; RD, at 42. Dr. Loes testified that at the time the June 1, 2015 prescription was issued, there was no doctor-patient relationship between Respondent and Patient N.B. Tr. 249; *see also* GX 36, at 8. In support of his opinion, Dr. Loes testified that ''[t]here was no documentation of anything that constituted an interview, physical exam, assessment, lab, urine, vitals, none of that was present that [Dr. Loes] could see to justify a doctor-patient relationship.'' Tr. 249. Dr. Loes further testified that there was no evidence of an emergency medical situation. Tr. 250; RD, at 42. Respondent first examined Patient N.B. on June 3, 2015. GX 36, at 8; GX 5, at 1–4; RD, at 42.

In accordance with Dr. Loes' testimony and the record as a whole, I find that, because there was no legitimate doctor-patient relationship established between Respondent and Patient N.B. at the time the prescription was issued, the diazepam prescription that Respondent issued to Patient N.B. on June 1, 2015, was issued outside of the usual course of professional practice and beneath the applicable standard of care in Arizona.

4. Patient A.J.C.

On June 28, 2015, Respondent prescribed a controlled substance, 20 tablets of phenobarbital 64.8 mg., to Patient L.H. GX 2, at 4; GX 6 (Patient Records for A.J.C.), at 26; GX 36, at 8; RD, at 43. Dr. Loes testified that at the time the June 28, 2015 prescription was issued, there was no doctor-patient relationship between Respondent and Patient A.J.C. Tr. 251; *see also* GX 36, at 8. In support of his opinion, Dr. Loes testified that ''there's no documentation of a telephonic or a physical exam or assessment or treatment plan to justify this particular prescription.'' Tr. 251–52. Dr. Loes further testified that there was no evidence of an emergency medical situation. Tr. 376–77. A.J.C. was first examined by a physician (not by Respondent, but by a collaborating physician Dr. T.J.)[34] on July 2, 2015. GX 36, at 8; GX 6, at 87–116; RD, at 43.

In accordance with Dr. Loes' testimony and the record as a whole, I find that, because there was no legitimate doctor-patient relationship established between Respondent and Patient A.J.C. at the time the prescription was issued, the phenobarbital prescription that Respondent issued to Patient A.J.C. on June 28, 2015, was issued outside of the usual course of professional practice and beneath the applicable standard of care in Arizona.

5. Patient S.S.

On July 4, 2015, Respondent prescribed a controlled substance, 45 tablets of buprenorphine 8 mg., to Patient S.S. GX 2, at 5; GX 7 (Patient Records for S.S.), at 79; GX 36, at 9; RD, at 43. Dr. Loes testified that at the time the July 4, 2015 prescription was issued, there was no doctor-patient relationship between Respondent and Patient S.S. Tr. 255; *see also* GX 36, at 9. In support of his opinion, Dr. Loes testified that ''[t]here's no information that a patient visit, interview, examination, assessment, lab, collaborating lab or urine test was done prior to this [prescription] . . .'' Tr. 255. Dr. Loes further testified that there was no evidence of an emergency medical situation. Tr. 376–77. S.S. was first examined by a physician (not by Respondent, but by collaborating physician T.J.) on July 6, 2015. GX 36, at 9; GX 7, at 25–54; RD, at 43.

In accordance with Dr. Loes' testimony and the record as a whole, I find that, because there was no legitimate doctor-patient relationship established between Respondent and Patient S.S. at the time the prescription was issued, the buprenorphine prescription that Respondent issued to Patient S.S. on July 4, 2015, was issued outside of the usual course of professional practice and beneath the applicable standard of care in Arizona.

6. Patient J.L.

On July 5, 2015, Respondent prescribed a controlled substance, 20 tablets of diazepam (Valium) 10 mg., to

[33] Patient L.H. is referred to by the initials E.H. in the OSC. *See* OSC, at 2.

[34] Dr. Loes testified that where there is an issue of resources in medical coverage, one physician, in this case Dr. T.J., can follow the treatment course established by the physician who issued the controlled substance prescription, in this case Respondent. Tr. 253–54; *see also* Ariz. Rev. Stat. Ann. § 32–1401(27)(ss)(i). However, in this case, this physical examination did not occur until well after the controlled substance prescription was issued by Respondent and therefore, the prescriptions were issued beneath the standard of care and outside of the usual course of the professional practice.

Patient J.L. GX 2, at 6; GX 8 (Patient Records for J.L.), at 39; GX 36, at 9; RD, at 43. Dr. Loes testified that at the time the July 5, 2015 prescription was issued, there was no doctor-patient relationship between Respondent and Patient J.L. Tr. 257, 259; *see also* GX 36, at 10. In support of his opinion, Dr. Loes testified that there was ''no doctor presence interview, physical exam, corroborating lab assessment or plan.'' Tr. 257. Dr. Loes further testified that there was no evidence of an emergency medical situation. Tr. 376–77. J.L. was first examined by a physician (not by Respondent, but by collaborating physician T.J.) on July 6, 2015. GX 36, at 10; GX 8, at 40–69; RD, at 43.

In accordance with Dr. Loes' testimony and the record as a whole, I find that, because there was no legitimate doctor-patient relationship established between Respondent and Patient J.L. at the time the prescription was issued, the diazepam prescription that Respondent issued to Patient J.L. on July 5, 2015, was issued outside of the usual course of professional practice and beneath the applicable standard of care in Arizona.

7. Patient K.R.K.

On July 15, 2015, Respondent prescribed a controlled substance, 23 tablets of buprenorphine 2 mg., to Patient K.R.K. GX 2, at 7; GX 9 (Patient Records for K.R.K.), at 80; GX 36, at 10; RD, at 44. Dr. Loes testified that at the time the July 15, 2015 prescription was issued, there was no doctor-patient relationship between Respondent and Patient K.R.K. Tr. 260–61; *see also* GX 36, at 11. In support of his opinion, Dr. Loes testified that there was ''[n]o face-to-face interview, exam; no corroborating lab, urine, no assessment or plan.'' Tr. 261. Dr. Loes further testified that there was no evidence of an emergency medical situation. Tr. 376–77. Respondent first examined Patient K.R.K. on July 18, 2015. GX 36, at 10; GX 9, at 81–110; RD, at 44.

In accordance with Dr. Loes' testimony and the record as a whole, I find that, because there was no legitimate doctor-patient relationship established between Respondent and Patient K.R.K. at the time the prescription was issued, the buprenorphine prescription that Respondent issued to Patient K.R.K. on July 15, 2015, was issued outside of the usual course of professional practice and beneath the applicable standard of care in Arizona.

8. Patient J.Z.

On July 15, 2015, Respondent prescribed a controlled substance, 23 tablets of buprenorphine 2 mg., to Patient J.Z. GX 2, at 8; GX 10 (Patient Records for J.Z.), at 35; GX 36, at 11; RD, at 44. Dr. Loes testified that at the time the July 15, 2015 prescription was issued, there was no doctor-patient relationship between Respondent and Patient J.Z. Tr. 270; *see also* GX 36, at 11. In support of his opinion, Dr. Loes testified that there was ''no evidence of an interview, a history by the doctor, a physical exam, any lab or diagnosis, comprehensive evaluation of the clinical situation or treatment plan documented.'' Tr. 270–71. Dr. Loes further testified that there was no evidence of an emergency medical situation. Tr. 311. For these reasons, Dr. Loes opined that the treatment provided to J.Z. with regard to the July 15, 2015 prescription was outside of the standard of care in Arizona.[35] Tr. 271–72. Respondent first examined Patient J.Z. on July 18, 2015. GX 36, at 11; GX 10, at 36–65; RD, at 44.

In accordance with Dr. Loes' testimony and the record as a whole, I find that, because there was no legitimate doctor-patient relationship established between Respondent and Patient J.Z. at the time the prescription was issued, the buprenorphine prescription that Respondent issued to Patient J.Z. on July 15, 2015, was issued outside of the usual course of professional practice and beneath the applicable standard of care in Arizona.

9. Patient A.H.

On July 31, 2015, Respondent (while outside of the country) issued two prescriptions for controlled substances, one for 9 tablets of buprenorphine 8 mg. and one for 9 tablets of buprenorphine 2 mg, to Patient A.H. GX 2, at 9–10; GX 11 (Patient Records for A.H.), at 33; GX 36, at 11; RD, at 44. Dr. Loes testified that at the time the July 31, 2015 prescriptions were issued, there was no doctor-patient relationship between Respondent and Patient A.H. Tr. 273; *see also* GX 36, at 12. In support of his opinion, Dr. Loes testified that there was ''no history, physical exam, or diagnosis or treatment plan that was done prior to the prescription.'' Tr. 274. Dr. Loes further testified that there was no evidence of an emergency medical situation. Tr. 279–280, 311. Respondent appears to have first examined Patient A.H. on August 29, 2015.[36] GX 36, at 12; GX 11, at 2–9; RD, at 44.

In accordance with Dr. Loes' testimony and the record as a whole, I find that, because there was no legitimate doctor-patient relationship established between Respondent and Patient A.H. at the time the prescription was issued, the two buprenorphine prescriptions that Respondent issued to Patient A.H. on July 31, 2015, were issued outside of the usual course of professional practice and beneath the applicable standard of care in Arizona.

10. Patient C.S.

On August 2, 2015, Respondent (while outside of the country) prescribed a controlled substance, 20 tablets of diazepam 10 mg., to Patient C.S. GX 2, at 11; GX 12 (Patient Records for C.S.), at 57; GX 36, at 12; RD, at 45. Dr. Loes testified that at the time the August 2, 2015 prescription was issued, there was no doctor-patient relationship between Respondent and Patient C.S. Tr. 286–87; *see also* GX 36, at 13. In support of his opinion, Dr. Loes testified that there was no record of a physical exam, mental exam, medical history, or assessment of the patient's function. Tr. 287–88. Dr. Loes further testified that there was no evidence of an emergency medical situation. Tr. 311. Respondent first examined Patient C.S. on August 18, 2015. GX 36, at 12; GX 12, at 1–8; RD, at 45. Dr. Loes opined that the treatment provided to C.S. was beneath the standard of care in Arizona. Tr. 288.

In accordance with Dr. Loes' testimony and the record as a whole, I find that, because there was no legitimate doctor-patient relationship established between Respondent and Patient C.S. at the time the prescription was issued, the diazepam prescription that Respondent issued to Patient C.S. on August 2, 2015, was issued outside of the usual course of professional practice and beneath the applicable standard of care in Arizona.

11. Patient J.A.

On August 7, 2015, Respondent (while outside of the country) prescribed a controlled substance, namely 64 tablets of buprenorphine 2 mg., to Patient J.A. GX 2, at 12; GX 13 (Patient Records for J.A.), at 23; GX 36,

[35] Dr. Loes later testified that Respondent's treatment of each one of the patients at issue in this case fell below the standard of care because in all the cases the Respondent did not establish a doctor-patient relationship before prescribing. Tr. 404.

[36] Dr. Loes pointed out that the medical records suggest that Respondent evaluated Patient A.H. on July 31, 2015. This is because the ''Comprehensive Physical Evaluation and Examination'' record in the file is dated July 31, 2015, on the first page and is signed by Respondent on the last page (which is undated). Tr. 272–73; GX 36, at 12; GX 11, 34–63. However, Respondent was out of the country on July 31, 2015, and according to Dr. Loes, the RIM staff could not have transmitted sufficient material to Respondent to justify the creation of a doctor-patient relationship on July 31, 2015. Tr. 71–73, 281. I find that the evidence does not support a finding that Respondent or any other physician performed a physical examination of A.H. on July 31, 2015. Tr. 71–73, 272–273, 276, 278–79.

at 13; RD, at 45. Dr. Loes testified that at the time the August 7, 2015 prescription was issued, there was no doctor-patient relationship between Respondent and Patient J.A. Tr. 290; *see also* GX 36, at 13. In support of his opinion, Dr. Loes testified that there was ''no doctor-patient relationship established based on the records, the absence of a history, the physical by the physician, and any associated lab or other documentation wasn't there.'' Tr. 290. Dr. Loes further testified that there was no evidence of an emergency medical situation. Tr. 311. Respondent first examined Patient J.A. on August 27, 2015. GX 36, at 13; GX 13, at 2–8; RD, at 45. Dr. Loes opined that the treatment provided to J.A. was beneath the standard of care in Arizona. Tr. 291.

In accordance with Dr. Loes' testimony and the record as a whole, I find that, because there was no legitimate doctor-patient relationship established between Respondent and Patient J.A. at the time the prescription was issued, the buprenorphine prescription that Respondent issued to Patient J.A. on August 7, 2015, was issued outside of the usual course of professional practice and beneath the applicable standard of care in Arizona.

12. Patient Z.J.

On August 7, 2015, Respondent (while outside of the country) prescribed a controlled substance, namely 45 tablets of buprenorphine 2 mg., to Patient Z.J. GX 2, at 13; GX 14 (Patient Records for Z.J.), at 7; GX 36, at 13; RD, at 45. Dr. Loes testified that at the time the August 7, 2015 prescription was issued, there was no doctor-patient relationship between Respondent and Patient Z.J. Tr. 293–94; *see also* GX 36, at 14. In support of his opinion, Dr. Loes testified that there was a ''lack of history, physical, and diagnosis, treatment plan, and associated lab.'' Tr. 294. Dr. Loes further testified that there was no evidence of an emergency medical situation. Tr. 311. Also, ''[t]here is no documentation that this patient was ever seen by a physician.'' GX 36, at 14; *see also* GX 14; RD, at 45; Tr. 293. Dr. Loes opined that the treatment provided to Z.J. was beneath the standard of care in Arizona. Tr. 294.

In accordance with Dr. Loes' testimony and the record as a whole, I find that, because there was no legitimate doctor-patient relationship established between Respondent and Patient Z.J. at the time the prescription was issued, the buprenorphine prescription that Respondent issued to Patient Z.J. on August 7, 2015, was issued outside of the usual course of professional practice and beneath the applicable standard of care in Arizona.

13. Patient L.O.[37]

On August 12, 2015,[38] Respondent prescribed a controlled substance, 20 tablets of diazepam 10 mg., to Patient L.O. GX 2, at 14; GX 15 (Patient Records for L.O.), at 105; GX 36, at 14; RD, at 46. Dr. Loes testified that at the time the August 12, 2015 prescription was issued, there was no doctor-patient relationship between Respondent and Patient L.O. Tr. 298; *see also* GX 36, at 14. In support of his opinion, Dr. Loes testified that at the time of the prescription there was not an adequate medical history taken, adequate physical exam, or adequate mental exam to establish a doctor-patient relationship. Tr. 298. Dr. Loes further testified that there was no evidence of an emergency medical situation. Tr. 311. Respondent first examined Patient L.O. on August 15, 2015. GX 36, at 14; GX 15, at 1–30; RD, at 46. Accordingly, Dr. Loes opined that Respondent's August 13, 2015 prescription to L.O. ''fell below the standard of care.'' Tr. 298.

In accordance with Dr. Loes' testimony and the record as a whole, I find that, because there was no legitimate doctor-patient relationship established between Respondent and Patient L.O. at the time the prescription was issued, the diazepam prescription that Respondent issued to Patient L.O. on August 13, 2015, was issued outside of the usual course of professional practice and beneath the applicable standard of care in Arizona.

14. Patient T.G.[39]

On, August 21, 2015, Respondent prescribed two controlled substances, ten tablets of buprenorphine 8 mg. and nine tablets of buprenorphine 2 mg., to Patient T.G. GX 2, at 15–16; GX 16 (Patient Records for T.G.), at 113; GX 36, at 15; RD, at 46. Dr. Loes testified that at the time the August 21, 2015 prescription was issued, there was no doctor-patient relationship between Respondent and Patient T.G. Tr. 301; *see also* GX 36, at 15. In support of his opinion, Dr. Loes testified that there was an ''[a]bsence of physical exam and associated labs and assessment and a treatment plan.'' Tr. 301. Dr. Loes further testified that there was no evidence of an emergency medical situation. Tr. 311. Respondent first examined Patient T.G. on August 23, 2015. GX 36, at 15; GX 16, at 1–30; RD, at 46. Accordingly, Dr. Loes opined that Respondent's treatment of T.G. fell beneath the standard of care in Arizona. Tr. 301–02.

In accordance with Dr. Loes' testimony and the record as a whole, I find that, because there was no legitimate doctor-patient relationship established between Respondent and Patient T.G. at the time the prescriptions were issued, the buprenorphine prescriptions that Respondent issued to Patient T.G. on August 13, 2015, were issued outside of the usual course of professional practice and beneath the applicable standard of care in Arizona.

15. Patient A.S.

On August 25, 2015, Respondent issued two prescriptions for controlled substances, 22 tablets of buprenorphine 2 mg. and 30 tablets of phenobarbital 32.4 mg., to Patient A.S. GX 2, at 17–18; GX 17 (Patient Records for A.S.), at 9–10; GX 36, at 16; RD, at 47. Although the prescriptions were dated August 25, 2015, the medical records reflect that Patient A.S. began taking both controlled substances on August 24, 2015. GX 17, at 9–10; GX 36, at 16; RD, at 47. Dr. Loes testified that at the time the August 25, 2015 prescriptions were issued, there was no doctor-patient relationship between Respondent and Patient A.S. Tr. 304–05; *see also* GX 36, at 16. In support of his opinion, Dr. Loes testified that there was not an adequate medical history, physical examination, or mental examination performed prior to August 25, 2015. Tr. 305. Dr. Loes further testified that there was no evidence of an emergency medical situation. Tr. 311. Patient A.S. discontinued her treatment on August 25, 2015, and was never seen by Respondent. GX 36, at 16; GX 17, at 1, 3; RD, at 47. Accordingly, Dr. Loes opined that Respondent's treatment of A.S. fell beneath the standard of care in Arizona. Tr. 305.

In accordance with Dr. Loes' testimony and the record as a whole, I find that, because there was no legitimate doctor-patient relationship established between Respondent and Patient A.S. at the time the prescriptions were issued, the buprenorphine and phenobarbital prescriptions that

[37] Patient L.O. (referencing her nickname) is referred to by the initials E.O. (referencing her legal name) in the OSC. *See* OSC, at 4.

[38] The pharmacy records indicate that the prescription was dated August 12, 2015, but not picked up until August 13, 2015. GX2, at 14. The August 13, 2015 was used in the Recommended Decision and Expert Report. RD, at 46; GX 36, at 14. Regardless of whether the prescription was issued on August 12th or 13th, Respondent did not perform a physical examination until August 15, 2015.

[39] T.G., the initials used in the Recommended Decision, is referred to as R.G. in the OSC, and as R.T.G. in the Expert's Report—all three identify the same patient. *See* RD, at 46; OSC, at 4; GX 36, at 15.

Respondent issued to Patient A.S. on August 25, 2015, were issued outside of the usual course of professional practice and beneath the applicable standard of care in Arizona.

16. Patient J.P.

On September 4, 2015, Respondent prescribed two controlled substances, 40 tablets of phenobarbital 32.4 mg. and 15 tablets of buprenorphine (Zubsolv) 5.7 mg., to Patient J.P. GX 2, at 19–20; GX 18 (Patient Records for J.P.), at 166–68; GX 36, at 17; RD, at 47. Dr. Loes testified that at the time the September 4, 2015 prescription was issued, there was no doctor-patient relationship between Respondent and Patient J.P. Tr. 309; *see also* GX 36, at 17. In support of his opinion, Dr. Loes testified that there was a ''lack of history, physical examination, assessment, [and] associated lab.'' Tr. 310. Dr. Loes further testified that there was no evidence of an emergency medical situation. Tr. 311. Respondent first examined Patient J.P. on September 5, 2015. GX 36, at 17; GX 18, at 97–127; RD, at 47. Accordingly, Dr. Loes opined that Respondent's treatment of A.S. fell beneath the standard of care in Arizona. Tr. 311.

In accordance with Dr. Loes' testimony and the record as a whole, I find that, because there was no legitimate doctor-patient relationship established between Respondent and Patient J.P. at the time the prescriptions were issued, the phenobarbital and buprenorphine prescriptions that Respondent issued to Patient J.P. on September 4, 2015, were issued outside of the usual course of professional practice and beneath the applicable standard of care in Arizona.

17. Patient K.M.

On September 8, 2015, Respondent prescribed a controlled substance, 20 tablets of diazepam (Valium) 10 mg., to Patient K.M. GX 2, at 21; GX 19 (Patient Records for K.M.), at 36; GX 36, at 17; RD, at 47. Dr. Loes testified that at the time the September 8, 2015 prescription was issued, there was no doctor-patient relationship between Respondent and Patient K.M. Tr. 313; *see also* GX 36, at 18. In support of his opinion, Dr. Loes testified that there was not an adequate medical history, physical examination, or mental examination performed, nor any attempt to assess K.M.'s psychological or physical function prior to September 8, 2015. Tr. 313. Dr. Loes further testified that there was no evidence of an emergency medical situation. Tr. 314. Respondent first examined Patient K.M. on September 11, 2015. GX 36, at 17; GX 19, at 37–66; RD, at 47. Accordingly, Dr. Loes opined that Respondent's treatment of K.M. fell beneath the standard of care in Arizona. Tr. 314.

In accordance with Dr. Loes' testimony and the record as a whole, I find that, because there was no legitimate doctor-patient relationship established between Respondent and Patient K.M. at the time the prescription was issued, the diazepam prescription that Respondent issued to Patient K.M. on September 8, 2015, was issued outside of the usual course of professional practice and beneath the applicable standard of care in Arizona.

18. Patient T.K.

On September 11, 2015, Respondent prescribed a controlled substance, 20 tablets of Valium 10 mg., to Patient T.K. GX 2, at 24; GX 21 (Patient Records for T.K.), at 30; GX 36, at 18–19; RD, at 48. Dr. Loes testified that at the time the September 11, 2015 prescription was issued, there was no doctor-patient relationship between Respondent and Patient T.K. Tr. 317; *see also* GX 36, at 19. In support of his opinion, Dr. Loes testified that there was not an adequate medical history, physical examination, or mental examination performed prior to the September 11, 2015 prescription. Tr. 317–18. Dr. Loes further testified that there was no evidence of an emergency medical situation. Tr. 318. Respondent first examined Patient T.K. on September 12, 2015. GX 36, at 19; GX 21, at 141–170; RD, at 48. Accordingly, Dr. Loes opined that Respondent's treatment of T.K. fell beneath the standard of care in Arizona. Tr. 318.

In accordance with Dr. Loes' testimony and the record as a whole, I find that, because there was no legitimate doctor-patient relationship established between Respondent and Patient T.K. at the time the prescription was issued, the Valium prescription Respondent issued to Patient T.K. on September 11, 2015, was issued outside of the usual course of professional practice and beneath the applicable standard of care in Arizona.

19. Patient B.F.[40]

On September 12, 2015, Respondent prescribed a controlled substance, 20 tablets of Valium 10 mg., to Patient B.F. GX 2, at 25; GX 22 (Patient Records for B.F.), at 259; GX 36, at 19; RD, at 48. Dr. Loes testified that at the time the September 12, 2015 prescription was issued, there was no doctor-patient relationship between Respondent and Patient B.F. Tr. 321; *see also* GX 36, at 20. In support of his opinion, Dr. Loes testified that there was ''no history of physical or exam of any sort prior to the prescribing.'' Tr. 321. Dr. Loes further testified that there was no evidence of an emergency medical situation. Tr. 322. Respondent first examined Patient B.F. on September 24, 2015. GX 36, at 19; GX 22, at 261–77; RD, at 48. Accordingly, Dr. Loes opined that Respondent's treatment of B.F. fell beneath the standard of care in Arizona. Tr. 321.

In accordance with Dr. Loes' testimony and the record as a whole, I find that, because there was no legitimate doctor-patient relationship established between Respondent and Patient B.F. at the time the prescription was issued, the Valium prescription Respondent issued to Patient B.F. on September 12, 2015, was issued outside of the usual course of professional practice and beneath the applicable standard of care in Arizona.

20. Patient J.G.

On September 16, 2015, Respondent prescribed three controlled substances, 13 tablets of buprenorphine 8 mg., 10 tablets of Zubsolv 5.7 mg./1.4 mg., and 12 Zubsolv 1.4 mg./.36 mg., to Patient J.G. GX 2, at 26–28; GX 23 (Patient Records for J.G.), at 24–25; GX 36, at 20; RD, at 49. Dr. Loes testified that at the time the September 16, 2015 prescriptions were issued, there was no doctor-patient relationship between Respondent and Patient J.G.[41] Tr. 325; *see also* GX 36, at 20. In support of his opinion, Dr. Loes testified that there was not an adequate medical history, physical examination, mental examination, or attempt to assess psychological and physical function prior to the September 16, 2015 prescriptions. Tr. 325. Dr. Loes further testified that there was no evidence of an emergency medical situation. Tr. 325–26. Respondent first examined Patient J.G. on October 3, 2015. GX 36, at 20; GX 23, at 27–58; RD, at 49. Accordingly, Dr. Loes opined that Respondent's treatment of J.G. fell beneath the standard of care in Arizona. Tr. 325.

In accordance with Dr. Loes' testimony and the record as a whole, I find that, because there was no legitimate doctor-patient relationship

[40] Patient B.F. (referencing her nickname) is referred to by the initials E.F. (referencing her legal name) in the OSC. *See* OSC, at 6.

[41] I note that the record is unclear as to whether the patient took Zubsolv; however, the pharmacy records indicate that the Zubsolv prescriptions were issued and dispensed and, therefore, Dr. Loes testified that they were issued outside the standard of care. *See* GX 2, at 26–28; GX 23; GX 36, at 20; Tr. 325. The record clearly indicates that the patient took buprenorphine. GX 23, at 24.

established between Respondent and Patient J.G. at the time the prescriptions for buprenorphine and Zubsolv were issued, the buprenorphine and two Zubsolv prescriptions that Respondent issued to Patient J.G. on September 16, 2015, were issued outside of the usual course of professional practice and beneath the applicable standard of care in Arizona.

21. Patient N.R.

On September 26, 2015, Respondent prescribed a controlled substance, 12 tablets of buprenorphine 2 mg., to Patient N.R. GX 2, at 29; GX 24 (Patient Records for N.R.), at 53; GX 36, at 21; RD, at 49. The pharmacy records show that the prescription was picked up on September 28, 2015; however, the patient records show that Patient N.R. began receiving buprenorphine on September 24, 2015, prior to the prescription being picked up. GX 2, at 29; GX 24, at 53; GX 36, at 21; RD, at 49. Dr. Loes testified that at the time the September 26, 2015 prescription was issued, there was no doctor-patient relationship between Respondent and Patient N.R. Tr. 327; *see also* GX 36, at 21. In support of his opinion, Dr. Loes testified that there was no documentation in the patient record to indicate that there was any kind of examination of N.R. prior to September 28, 2015. Tr. 328. Dr. Loes further testified that there was no evidence of an emergency medical situation. Tr. 333. The date Respondent first examined N.R. is unknown as the corresponding medical records were undated—the first dated examination of N.R. was October 3, 2015.[42] GX 36, at 21; GX 24, at 61–91; 92; RD, at 49. Accordingly, Dr. Loes opined that Respondent's treatment of N.R. fell beneath the standard of care in Arizona. Tr. 330.

In accordance with Dr. Loes' testimony and the record as a whole, I find that, because there is no evidence of a legitimate doctor-patient relationship established between Respondent and Patient N.R. at the time the prescription was issued, the buprenorphine prescription that Respondent issued to Patient N.R. on September 26, 2015, was issued outside of the usual course of professional practice and beneath the applicable standard of care in Arizona.

[42] Even if the patient records are incorrect and N.R. did not begin receiving the controlled substance until September 28, 2015, the delay in conducting the physical exam on October 3, 2015, was still outside the standard of care.

22. Patient A.C.F.[43]

On October 17, 2015, Respondent prescribed a controlled substance, 15 tablets of buprenorphine (Zubsolv) 5.7/1.4 mg., to Patient A.C.F. GX 2, at 30; GX 25 (Patient Records for A.C.F.), at 46; GX 36, at 21; RD, at 49. Dr. Loes testified that at the time the October 17, 2015 prescription was issued, there was no doctor-patient relationship between Respondent and Patient A.C.F. Tr. 334; *see also* GX 36, at 22. In support of his opinion, Dr. Loes testified that at the time of the prescription, there was not an adequate medical history taken, adequate physical or mental examination performed, nor attempt to assess A.C.F.'s physical or psychological function. Tr. 334–35. Dr. Loes further testified that there was no evidence of an emergency medical situation. Tr. 335. Respondent first examined Patient A.C.F. on October 20, 2015. GX 36, at 20; GX 25, at 62–80; RD, at 49. Accordingly, Dr. Loes opined that Respondent's treatment of A.C.F. fell beneath the standard of care in Arizona. Tr. 335.

In accordance with Dr. Loes' testimony and the record as a whole, I find that, because there was no legitimate doctor-patient relationship established between Respondent and Patient A.C.F. at the time the prescription was issued, the buprenorphine prescription that Respondent issued to Patient A.C.F. on October 17, 2015, was issued outside of the usual course of professional practice and beneath the applicable standard of care in Arizona.

23. Patient L.R.

On October 23, 2015, Respondent issued prescriptions for two controlled substances, 12 tablets of buprenorphine 8 mg. and 12 tablets of buprenorphine 2 mg., to Patient L.R. GX 2, at 31–32; GX 26 (Patient Records for L.R.), at 64; GX 36, at 22; RD, at 50. Dr. Loes testified that at the time the October 23, 2015 prescriptions were issued, there was no doctor-patient relationship between Respondent and Patient L.R. Tr. 337; *see also* GX 36, at 22. In support of his opinion, Dr. Loes testified that there was ''no doctor-patient relationship documented to [have been] established.'' Tr. 337. Dr. Loes further testified that there was no evidence of an emergency medical situation. Tr. 340. Respondent first examined Patient L.R. on October 24, 2015. GX 36, at 22; GX 26, at 74–103; RD, at 50.

In accordance with Dr. Loes' testimony and the record as a whole, I find that, because there was no legitimate doctor-patient relationship established between Respondent and Patient L.R. at the time the two prescriptions were issued, the buprenorphine prescriptions that Respondent issued to Patient L.R. on October 23, 2015, were issued outside of the usual course of professional practice and beneath the applicable standard of care in Arizona.

[43] Patient A.C.F. is referred to by the initials A.F. in the OSC. *See* OSC, at 7.

24. Patient F.H.

On October 24, 2015, Respondent issued prescriptions for two controlled substances, 12 tablets of buprenorphine 8 mg. and 12 tablets of buprenorphine 2 mg., to Patient F.H. GX 2, at 33–34; GX 27 (Patient Records for F.H.), at 33; GX 36, at 22; RD, at 50. Dr. Loes testified that at the time the October 24, 2015 prescriptions were issued, there was no doctor-patient relationship between Respondent and Patient F.H. Tr. 343; *see also* GX 36, at 23. In support of his opinion, Dr. Loes testified that there was ''[a] lack of documentation for physical[,] interview, assessment, [and] plan'' and there was no evidence that any examination was performed. Tr. 343. Dr. Loes further testified that there was no evidence of an emergency medical situation. Tr. 343–44. Respondent first examined Patient F.H. on October 27, 2015. GX 36, at 22; GX 27, at 40–73; RD, at 50.

In accordance with Dr. Loes' testimony and the record as a whole, I find that, because there was no legitimate doctor-patient relationship established between Respondent and Patient F.H. at the time the prescriptions were issued, the buprenorphine prescriptions that Respondent issued to Patient F.H. on October 24, 2015, were issued outside of the usual course of professional practice and beneath the applicable standard of care in Arizona.

25. Patient A.J.

On October 24, 2015, Respondent prescribed a controlled substance, 20 tablets of Valium 10 mg., to Patient A.J. GX 2, at 35; GX 28 (Patient Records for A.J.), at 46; GX 36, at 23; RD, at 50. On October 25, 2015, Respondent prescribed another controlled substance, 12 tablets of Zubsolv .36/1.4 mg., to Patient A.J. GX 2, at 35; GX 28, at 42; GX 36, at 23; RD, at 50. Dr. Loes testified that at the time the October 24 and 25, 2015 prescriptions were issued, there was no doctor-patient relationship between Respondent and Patient A.J. Tr. 346; *see also* GX 36, at 23. In support of his opinion, Dr. Loes testified that ''[t]he first medical visit [was] October 27th, so there is no evidence that a doctor-patient relationship was

established prior to those prescriptions.'' Tr. 346. *See also* GX 36, at 23; GX 28, at 102–107, 110–113, 127–148; RD, at 50. Dr. Loes further testified that there was no evidence of an emergency medical situation. Tr. 347. Accordingly, Dr. Loes opined that Respondent's treatment of A.J. fell beneath the standard of care in Arizona. Tr. 347.

In accordance with Dr. Loes' testimony and the record as a whole, I find that, because there was no legitimate doctor-patient relationship established between Respondent and Patient A.J. at the time the prescriptions were issued, the Valium and Zubsolv prescriptions that Respondent issued to Patient A.J. on October 24 and 25, 2015, respectively, were issued outside of the usual course of professional practice and beneath the applicable standard of care in Arizona.

26. Patient J.A.2 [44]

On October 27, 2015, Respondent prescribed a controlled substance, 9 tablets of buprenorphine 8 mg., to Patient J.A.2. GX 2, at 37; GX 29 (Patient Records for J.A.2), at 86; GX 36, at 23; RD, at 51. Dr. Loes testified that at the time the October 27, 2015 prescription was issued, there was no doctor-patient relationship between Respondent and Patient J.A.2. Tr. 349; *see also* GX 36, at 24. In support of his opinion, Dr. Loes testified that ''[t]here was no doctor-patient relationship prior to prescribing or the initiation of that medication.'' Tr. 349. Dr. Loes further testified that there was no evidence of an emergency medical situation. Tr. 351–52. Respondent first examined Patient J.A.2 on October 31, 2015. GX 36, at 22; GX 29, at 2–39; RD, at 51.

In accordance with Dr. Loes' testimony and the record as a whole, I find that, because there was no legitimate doctor-patient relationship established between Respondent and Patient J.A.2 at the time the prescription was issued, the buprenorphine prescription that Respondent issued to Patient J.A.2 on October 27, 2015, was issued outside of the usual course of professional practice and beneath the applicable standard of care in Arizona.

27. Patient H.S.

On October 28, 2015, Respondent prescribed a controlled substance, 12 tablets of buprenorphine (Zubsolv) 5.7/1.4 mg., to Patient H.S. GX 2, at 38; GX 30 (Patient Records for H.S.), at 43; GX 36, at 24; RD, at 51. Although there is no record that H.S. ever received the Zubsolv tablets (*see* GX 30, at 111 and 113), Dr. Loes testified that at the time the October 28, 2015 prescription was issued, there was no doctor-patient relationship between Respondent and Patient H.S.[45] Tr. 354; *see also* GX 36, at 24. In support of his opinion, Dr. Loes testified that as of October 28, 2015, there was no documentation of a medical history, physical or mental examination, or assessment of physical or psychological function. Tr. 354. Dr. Loes further testified that there was no evidence of an emergency medical situation. Tr. 354–55. Respondent first examined Patient H.S. on October 31, 2015. GX 36, at 24; GX 30, at 114–143; RD, at 51. Accordingly, Dr. Loes opined that Respondent's treatment of H.S. fell beneath the standard of care in Arizona. Tr. 355.

In accordance with Dr. Loes' testimony and the record as a whole, I find that, because there was no legitimate doctor-patient relationship established between Respondent and Patient H.S. at the time the prescription was issued, the Zubsolv prescription that Respondent issued to Patient H.S. on October 28, 2015, was issued outside of the usual course of professional practice and beneath the applicable standard of care in Arizona.

28. Patient J.K.

On November 5, 2015, Respondent prescribed two controlled substances, 15 tablets of Zubsolv 5.7/1.4 mg. and 15 tablets of Zubsolv 1.4/.36 mg., to Patient J.K. GX 2, at 39–40; GX 32 (Patient Records for J.K.), at 27; GX 36, at 25; RD, at 51. Dr. Loes testified that at the time the November 5, 2015 prescriptions were issued, there was no doctor-patient relationship between Respondent and Patient J.K. Tr. 358; *see also* GX 36, at 25. In support of his opinion, Dr. Loes testified that there was ''no documentation of the history, physical, no associated labs, and no associated interaction.'' Tr. 358. Dr. Loes further testified that there was no evidence of an emergency medical situation. Tr. 359. Respondent first examined Patient J.K. on November 7, 2015. GX 36, at 25; GX 32, at 36–69; RD, at 51. Accordingly, Dr. Loes opined that Respondent's treatment of J.K. fell beneath the standard of care in Arizona. Tr. 359.

In accordance with Dr. Loes' testimony and the record as a whole, I find that, because there was no legitimate doctor-patient relationship established between Respondent and Patient J.K. at the time the prescriptions were issued, the Zubsolv prescriptions that Respondent issued to Patient J.K. on November 5, 2015, were issued outside of the usual course of professional practice and beneath the applicable standard of care in Arizona.

29. Patient J.W.

On November 21, 2015, Respondent prescribed a controlled substance,[46] 20 tablets of diazepam 10 mg., to Patient J.W. GX 2, at 41; GX 31 (Patient Records for J.W.), at 6; GX 36, at 25; RD, at 52. Dr. Loes testified that at the time the November 21, 2015 prescription was issued, there was no doctor-patient relationship between Respondent and Patient J.W. Tr. 360–61; *see also* GX 36, at 25. In support of his opinion, Dr. Loes testified that there was ''no documentation for the history, physical, evaluation, [or] treatment initiation.'' Tr. 361. Dr. Loes further testified that there was no evidence of an emergency medical situation. Tr. 363. Respondent was discharged on November 24, 2015, and there is no record of him ever being seen by a physician between his November 21, 2015 admission and November 24, 2015 discharge. GX 36, at 25; GX 31; RD, at 52. Accordingly, Dr. Loes opined that Respondent's treatment of J.W. fell beneath the standard of care in Arizona. Tr. 364–65.

In accordance with Dr. Loes' testimony and the record as a whole, I find that, because there was no legitimate doctor-patient relationship established between Respondent and Patient J.W. at the time the prescription was issued, the diazepam prescription that Respondent issued to Patient J.W. on November 21, 2015, was issued outside of the usual course of professional practice and beneath the applicable standard of care in Arizona.

30. Patient K.C.

On November 21, 2015, Respondent prescribed a controlled substance, 15 tablets of Zubsolv 5.7/1.4 mg., to Patient K.C. GX 2, at 42; GX 33 (Patient Records for K.C.), at 15; GX 36, at 26; RD, at 52. Dr. Loes testified that at the time the November 21, 2015 prescription was issued, there was no doctor-patient relationship between Respondent and Patient K.C. Tr. 366; *see also* GX 36, at

[44] Patient J.A.2 is referred to by the initials J.A. in the OSC. *See* OSC, at 9.

[45] Dr. Loes testified that, regardless of whether or not H.S. received the controlled substance, the prescription ''was ordered prior to a doctor-patient relationship being established. So, therefore, it fell below the standard of care because of the actual ordering of the prescription.'' Tr. 355. Here the pharmacy records indicate that the Zubsolv prescription was issued and dispensed. GX 2, at 38.

[46] The record indicates that there may have been other controlled substances issued by Respondent to Patient J.W. prior to him being evaluated by a physician; however, they were not included in the OSC or prehearing filings and I have not considered them as part of my analysis. *See* GX 36, at 25; OSC, at 9.

26. In support of his opinion, Dr. Loes testified that there was ''no evidence in the chart that this patient was ever seen by a physician.'' Tr. 366. Dr. Loes further testified that there was no evidence of an emergency medical situation. Tr. 368. Respondent was discharged on November 23, 2015, and there is no record of her ever being seen by a physician between her November 21, 2015 admission and November 23, 2015 discharge. GX 36, at 26; GX 33; RD, at 52. Accordingly, Dr. Loes opined that Respondent's treatment of K.C. fell beneath the standard of care in Arizona. Tr. 367.

In accordance with Dr. Loes' testimony and the record as a whole, I find that, because there was no legitimate doctor-patient relationship established between Respondent and Patient K.C. at the time the prescription was issued, the Zubsolv prescription that Respondent issued to Patient K.C. on November 21, 2015, was issued outside of the usual course of professional practice and beneath the applicable standard of care in Arizona.

31. Summary of Fact Findings Relevant to All Patients

I find that forty prescriptions were issued by Respondent to thirty patients without Respondent having first performed a physical or mental examination. I find that forty prescriptions were issued by Respondent to patients without first developing a doctor-patient relationship. I credit Dr. Loes' opinion ''that none of the cases that [he] reviewed would have qualified [as emergency medical situations].'' Tr. 401, *see also* Tr. 376–77, 402. Accordingly, I find that none of the thirty patients at issue in this case were suffering from an emergency medical situation at the time that Respondent prescribed the controlled substances at issue in this case. Ultimately, I find that there is substantial evidence that Respondent issued forty prescriptions without a legitimate medical purpose and outside the usual course of professional practice and beneath the applicable standard of care in Arizona.

III. Discussion

A. Allegation That Respondent's Registration Is Inconsistent With the Public Interest

Under Section 304 of the CSA, ''[a] registration . . . to . . . dispense a controlled substance . . . may be suspended or revoked by the Attorney General upon a finding that the registrant . . . has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined by such section.'' 21 U.S.C. 824(a)(4). In the case of a ''practitioner,'' defined in 21 U.S.C. 802(21) to include a ''physician,'' Congress directed the Attorney General to consider the following factors in making the public interest determination:

> (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
> (2) The applicant's experience in dispensing . . . controlled substances.
> (3) The applicant's conviction record under Federal or State laws relating to the . . . distribution[ ] or dispensing of controlled substances.
> (4) Compliance with applicable State, Federal, or local laws relating to controlled substances.
> (5) Such other conduct which may threaten the public health and safety.

21 U.S.C. 823(f). These factors are considered in the disjunctive. *Robert A. Leslie, M.D.,* 68 FR 15227, 15230 (2003).

According to Agency decisions, I ''may rely on any one or a combination of factors and may give each factor the weight [I] deem[ ] appropriate in determining whether'' to revoke a registration. *Id.; see also Jones Total Health Care Pharmacy, LLC* v. *Drug Enf't Admin.,* 881 F.3d 823, 830 (11th Cir. 2018) (citing *Akhtar-Zaidi* v. *Drug Enf't Admin.,* 841 F.3d 707, 711 (6th Cir. 2016); *MacKay* v. *Drug Enf't Admin.,* 664 F.3d 808, 816 (10th Cir. 2011); *Volkman* v. *U.S. Drug Enf't Admin.,* 567 F.3d 215, 222 (6th Cir. 2009); *Hoxie* v. *Drug Enf't Admin.,* 419 F.3d 477, 482 (6th Cir. 2005). Moreover, while I am required to consider each of the factors, I ''need not make explicit findings as to each one.'' *MacKay,* 664 F.3d at 816 (quoting *Volkman,* 567 F.3d at 222); *see also Hoxie,* 419 F.3d at 482. ''In short, . . . the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest; what matters is the seriousness of the registrant's misconduct.'' *Jayam Krishna-Iyer,* M.D., 74 FR 459, 462 (2009). Accordingly, as the Tenth Circuit has recognized, findings under a single factor can support the revocation of a registration. *MacKay,* 664 F.3d at 821.

Respondent has argued broadly that he has not committed acts that render his Registration inconsistent with the public interest. Resp Posthearing, at 16. Rather, Respondent argued, the evidence in the record was that the patients identified in the OSC suffered from addiction and were medically benefitted by the treatment provided by Respondent. *Id.* at 6–7, 16. The CSA requires me to consider Respondent's controlled substance dispensing experience, among other things, not whether Respondent's practice of medicine as a whole was beneficial to the community. 21 U.S.C. 823(f)(2); *see Frank Joseph Stirlacci, M.D.,* 85 FR 45229, 45239 (2020) (declining to accept community impact arguments); *see also Richard J. Settles, D.O.,* 81 FR 64940, n.16 (2016).

DEA regulations state, ''[a]t any hearing for the revocation . . . of a registration, the . . . [Government] shall have the burden of proving that the requirements for such revocation . . . pursuant to . . . 21 U.S.C. [§] 824(a) . . . are satisfied.'' 21 CFR 1301.44(e). In this matter, while I have considered all of the factors,[47] the relevant evidence is confined to Factors Two and Four. I find that the evidence satisfies the Government's *prima facie* burden of showing that Respondent's continued registration would be ''inconsistent with the public interest.'' 21 U.S.C. 824(a)(4). I further find that Respondent failed to produce sufficient evidence to rebut the Government's *prima facie* case.

1. Factors Two and Four—the Respondent's Experience in Dispensing Controlled Substances and Compliance With Applicable Laws Related to Controlled Substances

(a) Allegation That Respondent Issued Prescriptions for Controlled Substances Outside the Usual Course of the Professional Practice

According to the Controlled Substances Act's (hereinafter, CSA) implementing regulations, a lawful

[47] As to Factor One, the evidence in the record is that Respondent has an Arizona medical license, Tr. 431, and there is no evidence in the record of any recommendation from Respondent's state licensing board or professional disciplinary authority. 21 U.S.C. 823(f)(1). State authority to practice medicine is ''a necessary, but not a sufficient condition for registration . . . .'' *Robert A. Leslie, M.D.,* 68 FR at 15230. Therefore, ''[t]he fact that the record contains no evidence of a recommendation by a state licensing board does not weigh for or against a determination as to whether continuation of Respondent's DEA certification is consistent with the public interest.'' *Roni Dreszer, M.D.,* 76 FR 19434, 19444 (2011).

As to Factor Three, there is no evidence in the record that Respondent has a ''conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.'' 21 U.S.C. 823(f)(3). However, as Agency cases have noted, there are a number of reasons why a person who has engaged in criminal misconduct may never have been convicted of an offense under this factor, let alone prosecuted for one. *Dewey C. MacKay, M.D.,* 75 FR 49956, 49973 (2010). Agency cases have therefore held that ''the absence of such a conviction is of considerably less consequence in the public interest inquiry'' and is therefore not dispositive. *Id.*

controlled substance order or prescription is one that is ''issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.'' 21 CFR 1306.04(a).[48] [49] Under the CSA, it is fundamental that a practitioner must establish and maintain a bona fide doctor-patient relationship in order to act ''in the usual course of . . . professional practice'' and to issue a prescription for a ''legitimate medical purpose.'' *Laurence T. McKinney,* 73 FR 43260, 43365 n. 22 (2008); *see also United States* v. *Moore,* 423 U.S. 122, 142–43 (1975). The CSA generally looks to state law to determine whether a doctor and patient have established a doctor-patient relationship. *See Kamir Garces-Mejias,* 72 FR 54931, 54935 (2007); *United Prescription Services, Inc.,* 72 FR 50397, 50407 (2007).

I found above that the Government's expert credibly testified as supported by Arizona law that the standard of care in Arizona is that a physician must perform a physical examination of a patient or otherwise develop a doctor-patient relationship prior to prescribing controlled substances unless one of the statutory exceptions applies. *See supra* II.E. I also found above that Respondent issued forty prescriptions to thirty patients without first performing a physical examination or otherwise establishing a doctor-patient relationship. *See supra* II.F.31. Accordingly, I found that Respondent dispensed controlled substances beneath the applicable standard of care and outside of the usual course of the professional practice in Arizona. *See supra* II.F.31. I find that in issuing forty prescriptions beneath the applicable standard of care and outside the usual course of professional practice in Arizona, Respondent violated 21 CFR 1306.04(a).

Respondent's arguments otherwise are without merit. Respondent testified that he believed that it was proper ''to take patients who get admitted in acute withdrawal settings and to treat them based on the history . . . that [is] obtained from the staff, and then see [the patient] afterwards.'' Tr. 49. Respondent testified that his practice was followed by several well-known outpatient addiction treatment facilities and a prominent physician, but he provided no corroborating evidence of this assertion. Tr. 438–40. Even if Respondent believed his dispensing was within the usual course of professional practice, DEA has found that ''just because misconduct is unintentional, innocent, or devoid of improper motive, [it] does not preclude revocation or denial. Careless or negligent handling of controlled substances creates the opportunity for diversion and [can] justify the revocation of an existing registration . . .'' *Bobby D. Reynolds, N.P., Tina L. Killebrew, N.P., & David R. Stout, N.P.,* 80 FR 28643, 28662 (2015) (quoting *Paul J. Caragine, Jr.* 63 FR 51592, 51601 (1998). And in fact, four of the thirty patients (Patients Z.J, A.S., J.W., and K.C.) were issued controlled substances by Respondent and left treatment without ever being physically examined by or developing a doctor-patient relationship with Respondent. *See supra* II.F.

The Respondent asserted that ''[t]he government provided no testimony or evidence that any patient suffered harm or even potential harm from [Respondent's] practice of medicine[,] . . . [and that] [w]ithout this, the government cannot prove that [Respondent's] practice is inconsistent with the public interest.'' Resp Posthearing, at 16 (internal quotations omitted). Respondent does not, however, cite legal authority for the proposition that I must find harm before I may suspend or revoke a registration. Agency decisions have found that ''diversion occurs whenever controlled substances leave 'the closed system of distribution established by the CSA . . . .' '' *Id.* (citing *Roy S. Schwartz,* 79 FR 34360, 34363 (2014)). In this case, I have found that Respondent issued prescriptions without complying with his obligations under the CSA and Arizona law. *See George Mathew, M.D.,* 75 FR 66138, 66148 (2010)). I therefore find that Factors Two and Four weigh in favor of revocation.

(b) Violation of State Law

In addition to finding a violation of 21 CFR 1306.04(a), I also find that the Government has proven by substantial evidence that Respondent's failure to physically examine or otherwise establish a doctor-patient relationship prior to prescribing controlled substances violated Ariz. Rev. Stat. Ann. § 32–1401(27). Arizona law states that it is ''unprofessional conduct'' to ''[p]rescrib[e], dispens[e] or furnish[] a prescription medicine . . . to a person unless the doctor first conducts a physical or mental health status examination of that person or has previously established a doctor-patient relationship.'' Ariz. Rev. Stat. Ann. § 32–1401(27)(ss) (2014). Respondent argues that in spite of this Arizona statute, Arizona law allows a doctor to ''take patients who get admitted in acute withdrawal settings and to treat them based on the history . . . that [is] obtained from the staff, and then see [the patient] afterwards . . . within 24 hours . . . [or] within five to seven days.'' Tr. 49.

Respondent's argument would necessitate a finding that the statutory term in Ariz. Rev. Stat. Ann. § 32–1401(27) ''the doctor'' includes what Respondent described as ''staff who had training at taking a history and physical from a patient.'' Tr. 113. Further, in this case, Respondent's staff did not appear to take a full physical examination of the patients; therefore, his interpretation would require that the statutory phrase ''physical or mental health status examination'' must be able to be satisfied by trained staff taking an ''appropriate evaluation,'' which, according to Respondent, could include vital signs and soliciting a medical history from the patient. Tr. 112. Respondent made an alternative argument that RIM's purported policies permitted treatment of patients followed by an examination within a certain timeframe. Such an interpretation of the Arizona statute would necessitate a reading of the statutory phrases ''first'' and ''previously'' to be replaced with whatever timeline may be established by the facility's individual policies. Respondent's interpretation conflicts with the plain language of Ariz. Rev. Stat. Ann. § 32–1401(27)(ss).

Arizona interprets Ariz. Rev. Stat. Ann. § 32–1401(27)(ss), in *Golob* v. *Arizona Medical Bd. of State,* 217 Ariz. 505 (2008). In *Golob,* the Arizona Court of Appeals evaluated the establishment of the doctor-patient relationship in the context of a physician who was prescribing medication over the internet. *Id.* at 508. After conceding that she performed no physical examinations, Dr. Golob argued that she fulfilled the requirements of Ariz. Rev. Stat. Ann. § 32–1401(27)(ss) because she created ''a previously established . . . doctor-patient relationship'' in each case by accepting a consultation fee and reviewing the individual's responses to

[48] Respondent suggested that the only ground for revocation was Ariz. Rev. Stat. Ann. § 32–1401(27). Tr. 191; Resp Posthearing, at 4. The ALJ thoroughly analyzed the notice allegation and found that there were multiple instances where the Respondent was placed on notice of the factual and legal basis upon which the government relied in proposing to revoke Respondent's Registration including, amongst other things, 21 CFR 1306.04. RD, at 56–62. Respondent's Posthearing Brief alone makes clear that Respondent understood the basis of the allegations against him, had the opportunity to litigate those allegations, and did, in fact, litigate those allegations. *See* Resp Posthearing, at 2–4. Like the ALJ, I am not persuaded by Respondent's notice argument.

[49] Similarly, the law in Arizona states that it is ''unprofessional conduct'' to ''[p]rescrib[e], dispens[e], or administer [ ], any controlled substance or prescription-only drug for other than accepted therapeutic purposes.'' Ariz. Rev. Stat. Ann. § 32–1401(27)(j) (year).

the questionnaire, occasionally directing an operator to ask the person additional questions before she prescribed. *Id.* at 510. The court wholly rejected her argument and upheld the state board's finding that Dr. Golob deviated from the standard of care because she prescribed medication over the internet without establishing an appropriate physician-patient relationship. *Id.* at 508–09. The court found that the state board's interpretation of Ariz. Rev. Stat. Ann. § 32–1401(27)(ss), was aligned with the *American Medical Association's Guidance for Physicians on internet Prescribing* stating that a ''valid patient-physician relationship'' is formed when the physician, among other things, ''obtain[s] a reliable medical history and perform[s] a physical examination of the patient'' and has ''sufficient dialogue with the patient regarding treatment options.'' *Id.* at 511 (*citing American Medical Association's Guidance for Physicians on Internet Prescribing,* H–120.949 (June 2003)). Although not directly applicable to the facts here, the finding in *Golob* is consistent with my finding that the standard of care in Arizona requires that a physician perform a physical examination of a patient or otherwise develop a doctor-patient relationship prior to prescribing controlled substances.

I have found that Respondent did not personally examine any of the thirty patients at issue in this case nor otherwise establish a doctor-patient relationship with those patients prior to prescribing.[50] Next I must consider whether or not an exception to Ariz. Rev. Stat. Ann. § 32–1401(27)(ss) applies.

While there are several statutory exceptions to Ariz. Rev. Stat. Ann. § 32–1401(27)(ss), one that could arguably be relevant to these facts is that a doctor is not required to conduct a physical or mental health status examination before prescribing when there is an ''(ii) [e]mergency medical situation as defined in § 41–1831.'' Ariz. Rev. Stat. Ann. § 32–1401(27)(ss). Section § 41–1831 states that ''[e]mergency medical situation means a condition of emergency in which immediate medical care or hospitalization, or both, is required by a person or persons for the preservation of health, life, or limb.'' Ariz. Rev. Stat. Ann. § 41–1831(9) (2012). As I discussed above, Respondent argued that an ''emergency medical situation'' should be interpreted to include preventing a patient from entering a state of medical emergency itself. *See supra* II.E.2. To adopt Respondent's definition of medical emergency, I would have to ignore the statutory requirement of ''immediate medical care or hospitalization.'' Again, Respondent's interpretation is irreconcilable with the plain language of Ariz. Rev. Stat. Ann. § 32–1401(27)(ss) (*incorporating* Ariz. Rev. Stat. Ann. § 41–1831(9)). Moreover, based on the credible opinion of Dr. Loes, I found above that there is no evidence in the patient records or otherwise that any of the thirty patients at issue in this case were suffering from an emergency medical situation at the time that the prescriptions at issue in this case were issued. *See supra* II.F.31.

For all these reasons, I find that the Government has proven by substantial evidence that Respondent violated Ariz. Rev. Stat. Ann. § 32–1401(27)(ss).

In conclusion, I find that the Government has proven by substantial evidence that Respondent issued forty controlled substance prescriptions without a legitimate medical purpose and outside of the usual course of professional practice and beneath the applicable standard of care in the State of Arizona in violation of 21 CFR 1306.04(a) and Ariz. Rev. Stat. Ann. § 32–1401(27)(ss). Overall, I find that the Government has established a *prima facie* case that Respondent's continued registration is inconsistent with the public interest.

IV. Sanction

Where, as here, the Government has met its *prima facie* burden of showing that Respondent's continued registration is inconsistent with the public interest, the burden shifts to the Respondent to show why he can be entrusted with a registration. *Garrett Howard Smith, M.D.,* 83 FR 18882, 18910 (2018) (collecting cases). Respondent has made no effort to establish that he can be trusted with a registration.

The CSA authorizes the Attorney General to ''promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this subchapter.'' 21 U.S.C. 871(b). This authority specifically relates ''to 'registration' and 'control,' and 'for the efficient execution of his functions' under the statute.'' *Gonzales* v. *Oregon,* 546 U.S. 243, 259 (2006). A clear purpose of this authority is to ''bar[ ] doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking.'' *Id.* at 270.

In efficiently executing the revocation and suspension authority delegated to me under the CSA for the aforementioned purposes, I review the evidence and arguments Respondent submitted to determine whether or not he has presented ''sufficient mitigating evidence to assure the Administrator that he can be trusted with the responsibility carried by such a registration.'' *Samuel S. Jackson, D.D.S.,* 72 FR 23848, 23853 (2007) (quoting *Leo R. Miller, M.D.,* 53 FR 21931, 21932 (1988)). '' 'Moreover, because ''past performance is the best predictor of future performance,'' *ALRA Labs, Inc.* v. *DEA,* 54 F.3d 450, 452 (7th Cir. 1995), [the Agency] has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for [the registrant's] actions and demonstrate that [registrant] will not engage in future misconduct.' '' *Jayam Krishna-Iyer,* 74 FR 459, 463 (2009) (quoting *Medicine Shoppe,* 73 FR 364, 387 (2008)); *see also Jackson,* 72 FR at 23853; *John H. Kennnedy, M.D.,* 71 FR 35705, 35709 (2006); *Prince George Daniels, D.D.S.,* 60 FR 62884, 62887 (1995).

The issue of trust is necessarily a fact-dependent determination based on the circumstances presented by the individual respondent; therefore, the Agency looks at factors, such as the acceptance of responsibility and the credibility of that acceptance as it relates to the probability of repeat violations or behavior and the nature of the misconduct that forms the basis for sanction, while also considering the Agency's interest in deterring similar acts. *See Arvinder Singh, M.D.,* 81 FR 8247, 8248 (2016).

Here, I agree with the ALJs's finding that ''[t]he Respondent overall did not express any sense of wrongdoing.'' RD, at 36. Even if I had accepted Respondent's version of the standard of care in Arizona that, pursuant to RIM policies, trained staff can perform an initial assessment of a patient to support the issuance of a controlled substance prescription and the physician can perform the physical examination up to ninety-six hours later, his actions on many occasions fell outside of his version of the standard. Tr. 144; *supra* II.D–E; *see* RD, at 93 (ALJ finding that Respondent failed to physically examine seven patients within ninety-six hours of prescribing controlled substances.) Despite the fact that the prescriptions he issued to these patients clearly did not fall within even his own characterization of the standard of care,

[50] When asked whether a valid doctor patient relationship existed with these patients prior to Respondent's prescriptions, Respondent did not directly answer the question and replied: ''I believe that when you walk into a treatment program and you begin getting evaluated by the treatment staff, that that is the first step—that, that, that is—that that is the initial process that has—that is the initial step that evaluates, that determines the doctor-patient relationship.'' Tr. 112.

Respondent did not accept any responsibility for his failure to physically examine those seven patients within ninety-six hours of admission. The ALJ also found that four of the seven patients were admitted for treatment at RIM and received controlled substance prescriptions while the Respondent was out of the country and there was no other physician coverage provided. RD, at 94; *see also supra* II.F. Respondent not only failed to accept responsibility for his failures here, he seemed to pass blame for his lack of coverage onto another physician who left the practice shortly before Respondent's trip abroad. Tr. 74; RD, at 94. Additionally, the ALJ found, and I agree, that Respondent's testimony regarding the work he did perform while in Europe lacked credibility.[51] RD, at 38, 95.

In all, Respondent failed to explain why, in spite of his misconduct, he can be entrusted with a registration. ''The degree of acceptance of responsibility that is required does not hinge on the respondent uttering ''magic words'' of repentance, but rather on whether the respondent has credibly and candidly demonstrated that he will not repeat the same behavior and endanger the public in a manner that instills confidence in the Administrator.'' *Jeffrey Stein, M.D.,* 84 FR 46,968, 49,973.

The Agency also looks to the egregiousness and extent of the misconduct which are significant factors in determining the appropriate sanction. *Garrett Howard Smith, M.D.,* 83 FR at 18910 (collecting cases). Here, the ALJ found, and I agree, that the evidence suggests that Respondent's ''offending practices had been ongoing and patterned behavior.'' RD, at 89. The ALJ found that Respondent's care for four patients while he was in Europe was a ''particularly aggravating circumstance.'' RD, at 94. I agree with the ALJ that Respondent's conduct was egregious, particularly in the prescriptions issued while in Europe and those where he delayed seeing the patients for long periods of time. Additionally, I have found many more instances of misconduct than the ALJ, who nonetheless recommended revocation.

The Government argued that the Respondent was on notice, by virtue of the 2010 MOA, that he could not prescribe controlled substances prior to personally examining his patients. Tr. 12; RD, at 69. The MOA stated that ''Respondent must conduct an initial examination validating the necessity to prescribe Suboxone or Subatex to each [new] OBOT patient.'' I agree with the ALJ that the MOA does not clearly indicate that the examination was required by existing law and that Respondent could have read it to be merely an enhanced requirement placed on Respondent only for the length of the agreement. RD, at 69–70. As such, I will agree with the ALJ and find that the MOA, in and of itself, does not put Respondent on notice that his conduct was illegal per se, even though state law on this matter certainly should have. However, I find the fact that DEA previously gave Respondent an opportunity to correct his behavior and Respondent reverted back to his prior practices upon the expiration of the MOA to be relevant to whether I can entrust the Respondent with a registration. As Respondent did not seem to learn from his prior experience and, as discussed, made no efforts to accept responsibility, I do not trust that a sanction less than revocation will deter Respondent from engaging in this behavior again in the future.

In sanction determinations, the Agency has historically considered its interest in deterring similar acts, both with respect to the respondent in a particular case and the community of registrants. *See Joseph Gaudio, M.D.,* 74 FR 10083, 10095 (2009); *Singh,* 81 FR at 8248. I find that considerations of both specific and general deterrence weigh in favor of revocation in this case. There is simply no evidence that Respondent's egregious behavior is not likely to recur in the future such that I can entrust him with a CSA registration; in other words, the factors weigh in favor of revocation as a sanction.

I will therefore order that Respondent's registration be revoked as contained in the Order below.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration No. BC3579969 issued to Michael W. Carlton, M.D. This Order is effective March 22, 2021.

D. Christopher Evans,

Acting Administrator.

[FR Doc. 2021–03359 Filed 2–18–21; 8:45 am]

BILLING CODE 4410–09–P

[51] Generally, Respondent described his failures as being an ''[o]versight.'' Tr. 122; *see also* Tr. 123; RD, at 36.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–788]

Bulk Manufacturer of Controlled Substances Application: Patheon API Manufacturing, Inc.

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Patheon API Manufacturing, Inc., has applied to be registered as a bulk manufacturer of basic class(es) of controlled substance(s). Refer to Supplemental Information listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before April 20, 2021. Such persons may also file a written request for a hearing on the application on or before April 20, 2021.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on November 12, 2020, Patheon API Manufacturing, Inc., 309 Delaware Street, Greenville, South Carolina 29605, applied to be registered as an bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Tetrahydrocannabinols	7370	I
5-Methoxy-N-N-Dimethyltryptamine.	7431	I
Psilocybin	7437	I
Oxymorphone	9652	II

The company plans to bulk manufacture the listed controlled substances as an Active Pharmaceutical Ingredient (API) for distribution to its customers. In reference to dug code 7370 (Tetrahydrocannabinols), the company plans to bulk manufacture these drugs as synthetic. No other activities for these drug codes are authorized for this registration.

William T. McDermott,

Assistant Administrator.

[FR Doc. 2021–03363 Filed 2–18–21; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Ibrahim Al-Qawaqneh, D.D.S.; Decision and Order

On November 20, 2018, the Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (hereinafter, DEA or Government), issued an Order to Show Cause to Ibrahim Al-Qawaqneh, D.D.S. (hereinafter, Respondent), of Anaheim, California. Administrative Law Judge Exhibit (ALJX) 1 (Order to Show Cause (hereinafter, OSC)), at 1. The OSC proposes the revocation of Respondent's Certificate of Registration No. BA6641472 and denial of any pending application to renew [1] such registration pursuant to 21 U.S.C. 824(a)(5).

I. Procedural History

The OSC alleged that on July 2, 2014, Respondent ''entered a plea of *nolo contendere* in the Superior Court of California, County of Orange, to a charge of Offering Unlawful Medi-Cal Remuneration, a felony. . . .'' OSC, at 1. The OSC further alleged that as a result of Respondent's conviction, on September 30, 2015, the United States Department of Health and Human Services, Office of Inspector General (hereinafter, HHS/OIG), notified Respondent ''of [his] mandatory exclusion from participation in all Federal health care programs for a minimum period of five years pursuant to 42 U.S.C. 1320a–7(a)'' (hereinafter, Exclusion Letter); and that ''[m]andatory exclusion from Medicare is an independent ground for revoking a DEA registration pursuant to 21 U.S.C. 824(a)(5).'' OSC, at 2.

The OSC notified Respondent of the right to either request a hearing on the allegations or submit a written statement in lieu of exercising the right to a hearing, the procedures for electing each option, and the consequences for failing to elect either option. *Id.* at 2 (citing 21 CFR 1301.43). The OSC also notified Respondent of the opportunity to submit a corrective action plan. OSC, at 3 (citing 21 U.S.C. 824(c)(2)(C)).

By letter dated December 21, 2018, Respondent timely requested a hearing.[2] ALJX 2 (Request for Hearing), at 1. The matter was placed on the docket of the Office of Administrative Law Judges and was assigned to Administrative Law Judge Charles Wm. Dorman (hereinafter, the ALJ). On December 28, 2018, the ALJ established a schedule for the filing of prehearing statements. ALJX 3 (Order for Prehearing Statements), at 1. The Government filed its prehearing statement timely on January 14, 2019. ALJX 5 (Government's Prehearing Statement), at 1. Respondent twice missed the deadline for filing his prehearing statement and was granted two extensions. ALJX 6 (Order Rescheduling Prehearing Conference and Order to Respondent to File Prehearing Statement and to Show Good Cause Why Case should not be Terminated); ALJX 7 (Prehearing Ruling). Respondent filed his prehearing statement within the extended deadline on February 26, 2019, and supplemented the prehearing statement on March 7, 2019. ALJX 8 (Resp Prehearing), ALJX 10 (Resp Supp Prehearing).

On February 28, 2019, the ALJ issued a prehearing ruling that, among other things, set out four agreed upon stipulations and established schedules for the remaining prehearing activities and for the hearing. ALJX 9 (Second Prehearing Ruling). The hearing in this matter took place in Los Angeles, California, and spanned two days. *See* ALJX 11 (Ruling Regarding Hearing Location); ALJX 12 (Notice of Hearing); and Transcript of Proceedings in the Matter of Ibrahim Al-Qawaqneh, D.D.S. (hereinafter, Tr.). The Government filed a posthearing brief, but Respondent did not. ALJX 16 (Government's Proposed Findings of Fact, Conclusions of Law and Argument (hereinafter, Govt Posthearing)). The ALJ's Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision (hereinafter, RD) is dated June 21, 2019. *See* RD. According to the ALJ, neither party filed exceptions to the RD and the deadline for doing so has passed. *See* Transmittal Letter from the ALJ, dated July 15, 2019. I have reviewed and agree with the procedural rulings of the ALJ during the administration of the hearing.

Having considered the record in its entirety, I agree with the ALJ and find that the Government established ''that HHS mandatorily excluded [Respondent] from Federal health care programs based on a program-related conviction.'' RD, at 17. I also agree with the ALJ that the Respondent failed to accept responsibility for his misconduct, and that revocation is the appropriate sanction. *See* RD, at 28. I make the following findings of fact.

II. Findings of Fact

A. Respondent's DEA Registration

The parties stipulated that Respondent is registered with the DEA ''as a dentist practitioner in Schedules II–V [3] under DEA registration number BA6641472 at 1719 W. Romneya Drive, Anaheim, California 92801.'' ALJX 9, at 1; Government Exhibit (hereinafter, GX) 1 (Controlled Substance Registration Certificate); and GX 2 (Certified Registration History of Respondent). According to Agency records, Respondent did not submit a renewal application and his registration expired on June 30, 2020.[4] *See also* GX 1, GX 2.

B. Government's Case

The Government's documentary evidence consisted primarily of records from the Superior Court of California, County of Orange, regarding Respondent's conviction; documents regarding the Dental Board of California's accusation against and settlement with Respondent; and the HHS/OIG exclusion letter notifying Respondent of his Medicare and Medicaid exclusion. *See* GX 1–6. Additionally, the Government called the Diversion Investigator (hereinafter DI) as a witness both in the Government's case-in-chief and in rebuttal. Tr. 15–20, 82–86.

DI testified regarding his professional background and about his involvement in the investigation into Respondent. Tr. 17–18. DI testified that he obtained the HHS/OIG exclusion letter regarding Respondent's five-year minimum exclusion from Medicare and Medicaid as part of his investigation. *Id.* at 18. He also testified that DEA has not received any information that the five-year minimum exclusion HHS/OIG imposed on Respondent has been modified, lifted, or otherwise rescinded. *Id.* at 18–19. On rebuttal, DI testified that he searched the Controlled Substance Utilization Review and Evaluation System for the 18 months prior to his testimony (approximately November 2017 to May 7, 2019) and found just one controlled substance prescription issued by Respondent. *Id.* at 84–85. Having read and analyzed all of the record

[1] The OSC also proposed denial of any pending application to modify a DEA registration. Because there is no evidence in the record of a pending application to modify a DEA registration, and because the Government made no arguments regarding the factors in 21 U.S.C. 823(f), I will not address this proposal herein.

[2] I find that service of the OSC was proper. *See* ALJX 4 (Government's Notice Regarding Service of Order to Show Cause and Position on Motion for Termination of Proceedings), Attachment 2 (Form DEA–12 (8–02) ''Receipt for Cash or Other Items,'' dated November 27, 2018).

[3] As the ALJ noted in his decision, the Respondent is actually only registered in Schedules II–III. RD, at 6; GX 1; GX 2.

[4] The fact that a respondent allows his registration to expire during the pendency of an OSC does not impact my jurisdiction or prerogative under the Controlled Substances Act (hereinafter, CSA) to adjudicate the OSC to finality. *Jeffrey D. Olsen, M.D.,* 84 FR 68474 (2019).

evidence, I agree with the ALJ that DI's testimony was straightforward and professional, and I likewise ''give his testimony full credit.'' RD, at 3.

C. Respondent's Case

Respondent's documentary evidence consisted of Respondent's resume and a list of continuing dental education courses that Respondent has recently taken. Respondent's Exhibits (hereinafter RX), 1–2. Respondent testified on his own behalf and presented no other testimony in support of his case. Respondent testified regarding his professional background, experience, and education; and regarding his dental practice. Tr. 22–28, 38, 52–54. Respondent testified that he has had his dental practice for over twenty years, and that he has never had any malpractice claims filed against him, DEA has not expressed any concerns regarding his prescribing practices, and that the matters at issue in this case resulted in the only time the Respondent was ever called before the Dental Board of California (hereinafter, Board).[5] *Id.* at 22–23, 37–38, 42. Respondent also testified that, although he does not often prescribe controlled substances, he needs his DEA registration to be able to provide quality care to his patients.[6] *Id.* at 24–26. Respondent testified that he might prescribe controlled substances three or four times a month,[7] but that 95 percent of his prescriptions are for non-controlled substances. *Id.* at 52–53.

Respondent also testified regarding the event that led to his criminal conviction. *See infra* II.D. He testified that in December 2013, an undercover agent from the Medi-Cal fraud department going by the name of Mr. Gonzales came to Respondent's dental office to talk to him. Tr. 28–29; RD, at 9, GX 5, at 5. According to Respondent, Mr. Gonzales informed Respondent that he did ''marketing'' and that he could bring Respondent a lot of medical patients for $90–$120 per patient. Tr. 29; RD, at 9. Respondent stated, ''I told [Mr. Gonzales], that's a lot. I wouldn't do that. And I won't pay more than $80.''[8] Tr. 29. Respondent stated, ''I did tell [Mr. Gonzales] that is illegal . . . like paying per patient. And I was telling him . . . it's legal to do marketing if you get paid like, an hourly or salary but not per patient. That's the law.'' *Id.* at 29. Respondent testified that his conversation with Mr. Gonzales lasted approximately fifteen minutes. *Id.* at 30; RD, at 9. Respondent admitted that during the conversation he offered Mr. Gonzales: $20 for patients who had their teeth cleaned; $40 for patients who had sealants put on their teeth; $50 for patients for who received three to four fillings; and $100 for patients who received six or more fillings. Tr. 75–78; GX 5, at 5; RD, at 9. In addition, Respondent warned Mr. Gonzales not to tell anyone about getting paid for bringing patients. Tr. at 75–78.

At times, Respondent appeared to accept responsibility for his actions and acknowledge that what he did was wrong.[9] *Id.* at 33, 39, 67–68, 79, 80–81.[10] However, more frequently, Respondent clearly denied doing anything wrong. *See id.* at 29, 31, 68–69, 76–78.

> I did not do anything. It's just like talking to this person. But I—I felt bad because, you know, this happened to me. And I feel like, sorry, and it's really, like, you know, the—the judgment on [sic] the Court with the final decision will affect my life and my practice and my family, you know. But I never gave him any money. I never gave any checks. He brought no patients to me at all.

Id. at 31. Respondent also testified that he was unfairly charged, that he is innocent, and that the judgment was unfair. *Id.* at 56, 68. I agree with the ALJ that ''it is obvious that during [Respondent's] testimony on direct examination, he was downplaying his criminal conduct.'' RD, at 5.

Respondent testified that because of his conversation with the undercover agent he entered a *nolo contendere* plea in state court to a misdemeanor charge of offering to pay for patients. Tr. 33, 35; RD, at 9–10. Respondent testified that he was sentenced to informal probation, to perform 40 hours of community service, and to pay some minimal fees. Tr. 33, 36–37; RD, at 10. He testified that he has satisfied the terms of his probation. Tr. 37, 74; RD, at 10.

The ALJ found that Respondent generally presented his testimony in a clear, candid, and convincing manner, but found that Respondent's testimony lacked credibility on two points (*see supra* n.7 and n.8), and was concerning or evasive on four other points.[11] RD, at 4–5. I agree with the ALJ and adopt all of his credibility findings in this matter.

D. Respondent's Exclusion

The evidence in the record demonstrates that on July 2, 2014, Respondent signed a Superior Court of California, County of Orange, General Misdemeanor[12] Guilty Plea Form

[5] Due to the conviction, on January 13, 2017, the Dental Board of California (hereinafter, Board) filed an accusation against Respondent. GX 5 (Accusation from the Board, dated January 13, 2017), at 1. The parties stipulated that Respondent and the Board agreed, ''*inter alia,* that Respondent's dental license would be revoked; however, the revocation was stayed, and Respondent's dental license was placed on probation for three years subject to several terms and conditions.'' ALJX 9, at 2; RD, at 6; *see also* GX 6 (Board Decision and Stipulated Settlement and Disciplinary Order). In the settlement, Respondent ''admit[ted] the truth of each and every charge and allegation in [the Board's] Accusation.'' GX 6, at 3.

[6] The Government argued that Respondent's registration should be revoked because he ''has not demonstrated a need for a DEA [registration] in order to continue his practice of dentistry.'' ALJX 16, at 19; RD, at 26. The ALJ assessed and rejected this argument, and I agree. RD, at 26–27. Respondent's need for a registration is not relevant to my determination of whether or not Respondent can be entrusted with a registration. *See infra* IV.

[7] The ALJ found that this testimony was rebutted by DI's testimony that Respondent had issued only one controlled substance prescription in the year and a half prior to the hearing. RD, at 4; and *see supra* II.B. Thus, the ALJ did not find Respondent's testimony on this issue to be credible. RD, at 4.

[8] Respondent repeatedly testified that Mr. Gonzales misunderstood what he had said. He testified that ''[t]he conversation was in general about just marketing'' and that Mr. Gonzales put his words together in a way that made it seem like Respondent was offering to pay for patients. Tr. 78–79. Respondent testified that what he really meant was: ''when I say I spent $80 on a patient, like if you put an ad in the newspaper . . . let's say you spent $1,000, and you got, like, maybe 10 patients or 12 patients, roughly, you're spending about $80 per patient.'' Tr. 30. At one point, Respondent testified, Mr. Gonzales was ''talking to me and—and trying to trick my tongue in saying things like, wrong.'' Tr. 69. I agree with the ALJ that ''[i]n comparing [Respondent's] testimony on direct examination about his conversation with the undercover agent with the detailed facts contained in Government Exhibit 5, I do not find it credible that the agent misunderstood what [Respondent] had said.'' RD, at 5. Ultimately, whether Respondent intended to get patients from Mr. Gonzales for a fee or the conversation was in fact a misunderstanding is irrelevant to determining whether or not Respondent was excluded from participation in Medicare, Medicaid, or other Federal health care program. However, the mitigation of his crime is relevant to his acceptance of responsibility. *See infra* IV.

[9] Respondent's testimony where he accepted responsibility most often was in response to a leading question from his attorney. *See* Tr. 33, 67–68, 79, 80–81.

[10] When asked by his attorney what caused his conviction, Respondent answered ''. . . that talking about—offering someone money to refer you patients, that's considered a crime.'' Tr. 80.

[11] (1) Respondent neglected to mention in his testimony that the Board had revoked his dental license and then stayed the revocation, but Respondent had stipulated to that fact prior to the hearing. RD, at 4. (2) Respondent's testimony regarding his continuing education courses was evasive. RD, at 4–5. (3) Respondent was reluctant to acknowledge that his agreement with the Board stated that he was convicted of a felony. RD, at 5. (4) Respondent claimed to not understand the ALJ's question when the ALJ asked him why he pled *nolo contendere* instead of guilty. *Id.*

[12] There is evidence in the record that Respondent plead *nolo contendere* to and was convicted of a felony, not a misdemeanor. *See* GX 5, at 5; Resp Prehearing, at 2; Resp Supp Prehearing, at 2. The testimony at the hearing, however, clarified that Respondent was originally charged with a felony violation, but ultimately plead *nolo contendere* to and was convicted of a misdemeanor. Tr. 19, 35. Ultimately whether he was convicted of a felony or a misdemeanor is irrelevant to determining whether or not Respondent was excluded from participation in Medicare, Medicaid, or other Federal health care program, which is the

Continued

(hereinafter, Plea Agreement). GX 3, at 1. In the Plea Agreement, Respondent plead *nolo contendere* to the charge of violating Welfare and Institution Code 14107.2(b) offering unlawful Medi-Cal remuneration. GX 3, at 1; Tr. 33; GX 5, at 5. Upon his conviction, Respondent's sentencing terms stated: ''imposition . . . of sentence is suspended 3 years''; ''[i]nformal PROBATION as to Count(s) 1''; and ''[p]robation to termination . . . upon 18 months no violation.'' GX 3, at 4–5.

The parties stipulated that on September 30, 2015, Respondent was notified by HHS/OIG of his mandatory exclusion from participation in all federal health care programs for a minimum period of five years pursuant to 42 U.S.C. 1320a–7(a). ALJX 9, at 2; GX 4 (hereinafter, Exclusion Letter), at 1. The Exclusion Letter stated, ''[t]his exclusion is due to your conviction . . . in the Superior Court of California, County of Orange, of a criminal offense related to the delivery of an item or service under the Medicare or a State health care program, including the performance of management or administrative services relating to the delivery of items or services, under any such program.'' GX 4, at 1. The Exclusion Letter stated that the exclusion would become effective twenty days from the date of the letter, and notified Respondent of his appeal rights. *Id.*

Accordingly, I find that the HHS/OIG excluded Respondent from Medicare, Medicaid, and all federal health care programs under 42 U.S.C. 1320a–7(a) for a minimum of five years effective twenty days after September 30, 2015, based on Respondent's conviction.

III. Discussion

Under Section 824(a) of the Controlled Substances Act (hereinafter, CSA), a registration ''may be suspended or revoked'' upon a finding of one or more of five grounds. 21 U.S.C. 824. The ground in 21 U.S.C. 824(a)(5) requires that the registrant ''has been excluded (or directed to be excluded) from participation in a program pursuant to section 1320a–7(a) of Title 42.'' *Id.* 42 U.S.C. 1320a–7(a) provides a list of four predicate offenses for which exclusion from Medicare, Medicaid, and federal health care programs is mandatory and sets out mandatory timeframes for such exclusion. *Id.* The undisputed record evidence demonstrates that HHS/OIG mandatorily excluded Respondent. GX 4, ALJX 9, at 2; RD, at 6.

Each subsection of Section 824(a) provides an independent and adequate ground to impose a sanction on a registrant. *Arnold E. Feldman, M.D.,* 82 FR 39614, 39617 (2017)); *see also Gilbert L. Franklin, D.D.S.,* 57 FR 3441 (1992) (''[M]andatory exclusion from participation in the Medicare program constitutes an independent ground for revocation pursuant to 21 U.S.C. [§] 824(a)(5).'').

Further, this Agency has concluded repeatedly that the underlying crime requiring exclusion from federal health care programs under Section 1320a–7(a) of Title 42 does not require a nexus to controlled substances in order to be used as a ground for revocation or suspension of a registration. *Narciso Reyes, M.D.,* 83 FR 61678, 61681 (2018); *KK Pharmacy,* 64 FR at 49510 (collecting cases); *Melvin N. Seglin, M.D.,* 63 FR 70431, 70433 (1998); *Stanley Dubin, D.D.S.,* 61 FR 60727, 60728 (1996). In this case, HHS/OIG excluded Respondent due to his conviction in state court related to the delivery of an item or service under a state health care program, including the performance of management or administrative services relating to the delivery of items or services such as offering unlawful Medi-Cal remuneration. GX 4, at 1. ''There does not need to be a nexus to controlled substances to make a connection between the activity that caused the mandatory exclusion and the potential for abuse of a DEA registration.'' *Jeffrey Stein, M.D.,* 84 FR 46968, 46972 (2019). Here, the crime of illegal remuneration does not have a nexus to controlled substances; however the crime occurred in the context of Respondent's medical practice, and Respondent knew that paying per patient was illegal. Respondent's knowing deceit and failure to credibly accept responsibility, as discussed below, weigh against my ability to entrust Respondent with a registration and in favor of revocation.

IV. Sanction

There is no dispute in the record that Respondent is mandatorily excluded pursuant to Section 1320a–7(a) of Title 42 and, therefore, the Government has met its *prima facie* burden of showing that a ground for the revocation or suspension of Respondent's registration exists. GX 4, ALJX 9, at 2; RD, at 6. Now, the burden shifts to the Respondent to show why he can be entrusted with a registration. *Garrett Howard Smith, M.D.,* 83 FR 18882, 18910 (2018) (collecting cases).

The CSA authorizes the Attorney General to ''promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under this subchapter.'' 21 U.S.C. 871(b). This authority specifically relates ''to 'registration' and 'control,' and 'for the efficient execution of his functions' under the statute.'' *Gonzales* v. *Oregon,* 546 U.S. 243, 259 (2006). A clear purpose of this authority is to ''bar[ ] doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking.'' *Id.* at 270.

In efficiently executing the revocation and suspension authority delegated to me under the CSA for the aforementioned purposes, I review the evidence and arguments Respondent submitted to determine whether or not he has presented ''sufficient mitigating evidence to assure the Administrator that he can be trusted with the responsibility carried by such a registration.'' *Samuel S. Jackson, D.D.S.,* 72 FR 23848, 23853 (2007) (quoting *Leo R. Miller, M.D.,* 53 FR 21931, 21932 (1988)). '' 'Moreover, because ''past performance is the best predictor of future performance,'' *ALRA Labs, Inc.* v. *DEA,* 54 F.3d 450, 452 (7th Cir. 1995), [the Agency] has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for [the registrant's] actions and demonstrate that [registrant] will not engage in future misconduct.' '' *Jayam Krishna-Iyer,* 74 FR 459, 463 (2009) (quoting *Medicine Shoppe,* 73 FR 364, 387 (2008)); *see also Jackson,* 72 FR at 23853; *John H. Kennnedy, M.D.,* 71 FR 35705, 35709 (2006); *Prince George Daniels, D.D.S.,* 60 FR 62884, 62887 (1995).

While there are places in Respondent's testimony where he claims to accept responsibility,[13] I agree with the ALJ's statement that ''[Respondent's] acceptance of responsibility was, at best, equivocal.'' RD, at 23. Ultimately I agree with the ALJ's finding ''that [Respondent] has not accepted responsibility for offering to pay for patients.'' *Id.* Respondent testified repeatedly that he believed that he did not do anything wrong—he was just talking to a person. Tr. 29, 31, 68–69, 76–78. Respondent also testified that he was unfairly charged, that he is innocent, and that the judgment was unfair. Tr. 56, 68. Moreover, Respondent made statements that minimized his misconduct, which weighs against finding that Respondent accepted

grounds for revocation under the Controlled Substances Act, and the record evidence clearly demonstrates that he was so excluded.

[13] Respondent, in the opening statement, argued that ''he certainly has done everything he could try to take responsibility for this. . . .'' Tr. 14. I disagree.

responsibility. *See supra* II.C; RD, at 21 (citing *Arvinder Singh, M.D.,* 81 FR 8247, 8249–51 (2016)); *Stein,* 84 FR 46973. Additionally, Respondent plead *nolo contendere* instead of guilty to the charge of offering unlawful Medi-Cal remuneration. GX 3. ''In general, however, a plea of *nolo contendere* is inconsistent with the acceptance of responsibility.'' RD, at 21 (citing *United States* v. *Gordon,* 979 F. Supp. 337, 342 (E.D. Pa. 1997) (internal citations omitted)). Finding that a respondent has failed to accept responsibility is warranted where, as here, the respondent pled *nolo contendere* and minimized his role in the crime. *See Jeffery M. Freesemann, M.D.,* 76 FR 60873, 60888 (2011); *see also* RD, at 22.

Respondent must convince the Administrator that his acceptance of responsibility and remorse are sufficiently credible to demonstrate that the misconduct will not recur. Respondent, in his opening statement, argued that his testimony would show ''his genuine remorse . . . .'' Tr. 14. But the record indicates that Respondent was not remorseful for what he did; instead that he regretted the consequences that flowed from his conviction.[14] *Id.* at 31, 39, 68. This lack of remorse goes hand-in-hand with Respondent's failure to accept responsibility and further supports the revocation of his registration.

In sanction determinations, the Agency has historically considered its interest in deterring similar acts, both with respect to the respondent in a particular case and the community of registrants. *See Joseph Gaudio, M.D.,* 74 FR 10083, 10095 (2009); *Singh,* 81 FR at 8248. In this case, the Respondent knew at the time that he committed the crime that his actions were illegal—he even told Mr. Gonzales that the actions were illegal and advised him not to tell anyone. Deterring such deceit and knowing criminal behavior both in Respondent and the general registrant community is relevant to ensuring compliance with the CSA. Although I would not characterize Respondent's underlying crime as particularly egregious, Respondent has not convinced me that he will not repeat such deceitful behavior in using his CSA registration.

Respondent has argued, among other things, that he can be entrusted with a registration because he has seen over 15,000 patients in twenty years and has never had any issues with prescribing, he has never had a malpractice complaint, he is very mindful of the opioid crisis, and he has satisfied the terms of his probation. Tr. 13–14, 37, 74. Even assuming, *arguendo,* all of this to be true, Respondent needed to present evidence of a credible and persuasive acceptance of responsibility. Respondent has not.

Based on Respondent's failure to accept responsibility for his criminal misconduct and lack of demonstrated remorse, I cannot find that Respondent can be entrusted with a DEA registration; and therefore, I find that revocation is the appropriate sanction

I will therefore order that Respondent's registration be revoked as contained in the Order below.

Order

Pursuant to 28 CFR 0.100(b) and the authority vested in me by 21 U.S.C. 824(a), I hereby revoke DEA Certificate of Registration No. BA6641472 issued to Ibrahim Al-Qawaqneh, D.D.S. This Order is effective March 22, 2021.

D. Christopher Evans,

Acting Administrator.

[FR Doc. 2021–03360 Filed 2–18–21; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–793]

Importer of Controlled Substances Application: VHG Labs DBA LGC Standards

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: VHG Labs DBA LGC Standards has applied to be registered as an importer of basic class(es) of controlled substance(s). Refer to Supplemental Information listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before March 22, 2021. Such persons may also file a written request for a hearing on the application on or before March 22, 2021.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on February 2, 2021, VHG Labs DBA LGC Standards, 3 Perimeter Road, Manchester, New Hampshire 03103, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Cathinone	1235	I
Methcathinone	1237	I
Naphyrone	1258	I
N-Ethylamphetamine	1475	I
JWH-250 (1-Pentyl-3-(2-methoxyphenylacetyl) indole)	6250	I
SR-18 (Also known as RCS-–8) (1-Cyclohexylethyl-3-(2-methoxyphenylacetyl) indole)	7008	I
APINACA and AKB48 N-(1-Adamantyl)-1-pentyl-1H-indazole-3-carboxamide	7048	I
JWH-081 (1-Pentyl-3-(1-(4-methoxynaphthoyl) indole)	7081	I
SR-19 (Also known as RCS-4) (1-Pentyl-3-[(4-methoxy)-benzoyl] indole	7104	I

[14] For example, Respondent testified ''I really suffered going through these things—something I didn't do . . . [I] lost most—most of my patients, lost a lot of PPO insurances. I have to pay a lot of employees, and so many things for something that happened—someone faking like, you know, accusing you of doing something, but there's no 100 percent proof.'' Tr. 68.

Controlled substance	Drug code	Schedule
JWH-018 (also known as AM678) (1-Pentyl-3-(1-naphthoyl)indole)	7118	I
JWH-122 (1-Pentyl-3-(4-methyl-1-naphthoyl) indole)	7122	I
UR-144 (1-Pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone	7144	I
JWH-203 (1-Pentyl-3-(2-chlorophenylacetyl) indole)	7203	I
Ibogaine	7260	I
Lysergic acid diethylamide	7315	I
Marihuana Extract	7350	I
Marihuana	7360	I
Tetrahydrocannabinols	7370	I
Mescaline	7381	I
JWH-398 (1-Pentyl-3-(4-chloro-1-naphthoyl) indole)	7398	I
3,4-Methylenedioxymethamphetamine	7405	I
5-Methoxy-N–N-dimethyltryptamine	7431	I
Psilocyn	7438	I
4-Methyl-alphapyrrolidinopropiophenone (4-MePPP)	7498	I
MDPV (3,4-Methylenedioxypyrovalerone)	7535	I
Methylone (3,4-Methylenedioxy-N-methylcathinone)	7540	I
Butylone	7541	I
Pentylone	7542	I
Codeine-N-oxide	9053	I
Desomorphine	9055	I
Dihydromorphine	9145	I
Heroin	9200	I
Morphine-N-oxide	9307	I
Normorphine	9313	I
Tilidine	9750	I
Alpha-methylfentanyl	9814	I
Acetyl Fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide)	9821	I
Methamphetamine	1105	II
Phenmetrazine	1631	II
Methylphenidate	1724	II
Amobarbital	2125	II
Pentobarbital	2270	II
Secobarbital	2315	II
Glutethimide	2550	II
Phencyclidine	7471	II
4-Anilino-N-phenethyl-4-piperidine (ANPP)	8333	II
Norfentanyl	8366	II
Phenylacetone	8501	II
Codeine	9050	II
Dihydrocodeine	9120	II
Diphenoxylate	9170	II
Ecgonine	9180	II
Ethylmorphine	9190	II
Hydrocodone	9193	II
Levorphanol	9220	II
Meperidine	9230	II
Meperidine intermediate-B	9233	II
Meperidine intermediate-C	9234	II
Methadone intermediate	9254	II
Dextropropoxyphene, bulk (non-dosage forms)	9273	II
Morphine	9300	II
Thebaine	9333	II
14-Hydroxmorphone	9665	II
Noroxymorphone	9668	II
Sufentanil	9740	II
Fentanyl	9801	II

The company plans to import the listed controlled substances for sale to research facilities for drug testing and analysis. In reference to drug codes 7360 (Marihuana) and 7370 (Tetrahydrocannabinols) the company plans to import a synthetic cannabidiol and a synthetic tetrahydrocannabinol. No other activities for these drug codes are authorized for this registration.

Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of Food and Drug Administration-approved or non-approved finished dosage forms for commercial sale.

William T. McDermott,

Assistant Administrator.

[FR Doc. 2021–03381 Filed 2–18–21; 8:45 am]

BILLING CODE 4410–09–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice: (21–009)]

NASA Astrophysics Advisory Committee; Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Public

Law 92–463, as amended, the National Aeronautics and Space Administration (NASA) announces a meeting of the Astrophysics Advisory Committee. This Committee reports to the Director, Astrophysics Division, Science Mission Directorate, NASA Headquarters. The meeting will be held for the purpose of soliciting, from the scientific community and other persons, scientific and technical information relevant to program planning.

DATES: Monday, March 15, 2021, 11:00 a.m.–5:00 p.m.; Tuesday, March 16, 2021, 11:00 a.m.–5:00 p.m.; and Wednesday, March 17, 2021, 11:00 a.m.–5:00 p.m.; Eastern Time.

FOR FURTHER INFORMATION CONTACT: Ms. KarShelia Henderson, Science Mission Directorate, NASA Headquarters, Washington, DC 20546, (202) 358–2355, or *khenderson@nasa.gov.*

SUPPLEMENTARY INFORMATION: The meeting will be available to the public by WebEx.

On Monday, March 15, the event address for attendees is: *https://nasaenterprise.webex.com/nasaenterprise/j.php?MTID=md56c2364ad7f625bf9121430ef9d85f9,* the meeting number is 199 340 9228, and meeting password is MJh8JVDV89@.

On Tuesday, March 16, the event address for attendees is: *https://nasaenterprise.webex.com/nasaenterprise/j.php?MTID=m1ce0a71960e457179b7e85dcc41de62b,* the meeting number is 199 888 1998, and meeting password is csAvpYM2@78.

On Wednesday, March 17, the event address for attendees is: *https://nasaenterprise.webex.com/nasaenterprise/j.php?MTID=m26744d6e150f086b3cf3ed99bd6649fa,* the meeting number is 199 029 2743, and meeting password is 9skWYje8P@3.

To join by telephone, the numbers are: 1–929–251–9612 or 1–415–527–5035, for each day.

The agenda for the meeting includes the following topics:

—Astrophysics Division Update
—Updates on Specific Astrophysics Missions
—Reports from the Program Analysis Groups
—Reports from Specific Research and Analysis Programs

The agenda will be posted on the Astrophysics Advisory Committee web page: *https://science.nasa.gov/researchers/nac/science-advisory-committees/apac.*

The public may submit and upvote comments/questions ahead of the meeting through the website *https://arc.cnf.io/sessions/mkky/#!/dashboard* that will be opened for input on March 1, 2021.

It is imperative that the meeting be held on this date to accommodate the scheduling priorities of the key participants.

Patricia Rausch,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 2021–03372 Filed 2–18–21; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL SCIENCE FOUNDATION

Advisory Committee for International Science and Engineering; 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 International Science and Engineering Meeting (AC–ISE) (#25104).

Date and Time: Friday, March 19, 2021, 10:00 a.m. to 5:00 p.m. (Eastern Time).

Place: NSF, 2415 Eisenhower Avenue, Alexandria, VA 22314 | Virtual Zoom.

This AC–ISE meeting is fully virtual. All public participants are required to process the meeting registration via Zoom.

Connect to The Virtual Meeting: Register in advance for the meeting at the Zoom attendee registration link: *https://nsf.zoomgov.com/webinar/register/WN_IRrGAhXcRO2DvpdH7jAVjA.* After registering, you will receive a confirmation email with a unique link to join the meeting.

If you have any login questions, please contact Kirk Grabowski, OISE IT Specialist: *kgrabows@associates.nsf.gov*.

Type of Meeting: Open.

Contact Person: Christopher Street, National Science Foundation, 2415 Eisenhower Avenue, Room W–17220, Alexandria, Virginia 22314; Telephone: (703) 292–8568/Email: *cstreet@nsf.gov*.

Purpose of Meeting: To provide advice, recommendations and counsel on major goals and policies pertaining to international programs and activities.

Agenda

- Updates on OISE activities
- Discussion on Global Leadership in Science, Engineering, and Education
- Innovative Partnerships
- Meet with NSF leadership

Dated: February 16, 2021.

Crystal Robinson,

Committee Management Officer.

[FR Doc. 2021–03389 Filed 2–18–21; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Sunshine Act Meetings

The National Science Board (NSB) hereby gives notice of the scheduling of meetings for the transaction of NSB business as follows:

TIME AND DATE: Tuesday, February 23, 2021, from 11:00 a.m. to 6:45 p.m., and Wednesday, February 24, 2021, from 11:00 a.m. to 6:40 p.m. EST.

PLACE: These meetings will be held by videoconference. There will be no in-person meetings. The public may observe the public meetings, which will be streamed to the NSF You Tube channel. For meetings on Tuesday, February 23, go to: *https://youtu.be/6JjWhwMhIKM.* For meetings on Wednesday, February 24, go to: *https://youtu.be/tmiQwe7o_Y0.*

STATUS: Parts of these meetings will be open to the public. The rest of the meetings will be closed to the public. See full description below.

MATTERS TO BE CONSIDERED:

Tuesday, February 23, 2021

Plenary Board Meeting

Open Session: 11:00 a.m.–1:05 p.m.

- NSB Chair's Remarks
- New Member Swearing-in
  Matthew Malkan
  Scott Stanley
- NSF Director's Remarks
- NSB Chair Activity Summary
- Racial Equity Task Force and NSF Harassment Policy Update
- Vision 2030 Implementation Working Group Update

Committee on Oversight (CO)

Open Session: 1:15 p.m.–2:25 p.m.

- Committee Chair's Opening Remarks
- Approval of Committee Meeting Minutes
- Broader Impacts—Update on Activities
  Discussion and action on statement and resolution re: Reviewer Training
  Discussion and action on statement and resolution re: Broader Impacts Expert on Committees of Visitors
- Inspector General's Update
- Chief Financial Officer's Update

Committee on National Science and Engineering Policy (SEP)

Open Session: 2:35 p.m.–3:25 p.m.

- Committee Chair's Opening Remarks

- Approval of Prior Minutes
- Update on *Indicators 2022*
- Indicators 2020 Impact Report
- Update and Discussion of SEP Policy Products

Committee on Awards and Facilities (A&F)

Closed Session: 4:10 p.m.–6:00 p.m.

- Committee Chair's Opening Remarks
- Approval of Prior Minutes
- Context Item: National Ecological Observatory Network (NEON)
- Action Item: Mid-scale Research Infrastructure Track-2
- Action Item: Authorization of Management Reserve for Daniel D. Inouye Solar Telescope
- Context Item: Gemini Spending Cap Increase
- Arecibo Observatory Update

Committee on Strategy (CS)

Closed Session: 6:10 p.m.–6:45 p.m.

- Committee Chair's Remarks
- Approval of Prior Minutes
- Update on FY 2022 Budget Request Development

Wednesday, February 24, 2021

Plenary Board Meeting

Open Session: 11:00 a.m.–11:45 a.m.

- Panel Discussion: Roadblocks to STEM Graduate Student Retention

Committee on Strategy (CS)

Open Session: 11:45 a.m.–2:15 p.m.

- Committee Chair's Remarks
- Approval of Prior Minutes
- FY 2021 Budget Update
- Presentation and discussion: Strengthening Foundational Research
- Presentation and discussion: NSF Translation and Innovation Activities
- Presentation and discussion: NSF's Missing Millions Efforts
- NSF Strategic Plan 2022–2026

Committee on Awards and Facilities (A&F)

Open Session: 3:25 p.m.–3:45 p.m.

- Committee Chair's Opening Remarks
- Approval of Prior Minutes
- Rolling Calendar Year 2020–2021 Schedule of Planned Action and Context Items
- COVID–19 Impacts on U.S. Antarctic Program

Committee on External Engagement (EE)

Open Session: 3:45 p.m.–4:05 p.m.

- Committee Chair's Opening Remarks
- Approval of Prior Minutes
- Update on Engagement Initiatives
- UT-Knoxville *Vision* Listening Session

Plenary Board

Closed Session: 4:15 p.m.–5:10 p.m.

- NSB Chair's Opening Remarks
- Approval of Prior Minutes
- Director's Remarks
- NSF COVID–19 Recovery Update
- Closed Committee Reports
- Vote: Mid-scale Research Infrastructure-2 Awards
- Vote: DKIST Management Reserve

Plenary Board

Executive Closed Session: 5:10 p.m.–6:05 p.m.

- NSB Chair's Opening Remarks
- Approval of Prior Minutes
- NSF Director's Discussion
  - Personnel updates
- Future Directions in Translation, Innovation and Partnerships
- Ad Hoc Nominations Committee
- Election of Replacement Executive Committee Member

Plenary Board

Open Session: 6:15 p.m.–6:40 p.m.

- NSB Chair's Opening Remarks
- Approval of Prior Minutes
- NSF Director's Remarks
  Senior Staff Updates
  Office of Legislative and Public Affairs Update
- Open Committee Reports
- Votes:
  Statement and Resolution re: Reviewer Training
  Statement and Resolution re: Broader Impacts Expert on Committees of Visitors

Meeting Adjourns: 6:40 p.m.

MEETINGS THAT ARE OPEN TO THE PUBLIC:

Tuesday, February 23, 2021

11:00 a.m.–1:05 p.m. Plenary NSB
1:15 p.m.–2:25 p.m. CO
2:35 p.m.–3:25 p.m. SEP

Wednesday, February 24, 2021

11:00 a.m.–11:45 a.m. Plenary NSB
11:45 a.m.–2:15 p.m. CS
3:25 p.m.–3:45 p.m. A&F
3:45 p.m.–4:05 p.m. EE
6:15 p.m.–6:40 p.m. Plenary

MEETINGS THAT ARE CLOSED TO THE PUBLIC:

Tuesday, February 23, 2021

4:10 p.m.–6:00 p.m. A&F
6:10 p.m.–6:45 p.m. CS

Wednesday, February 24, 2021

4:15 p.m.–5:10 p.m. Plenary
5:10 p.m.–6:05 p.m. Plenary Executive

CONTACT PERSONS FOR MORE INFORMATION: The NSB Office contact is Chris Blair, *cblair@nsf.gov,* 703–292–7000. The NSB Public Affairs contact is Nadine Lymn, *nlymn@nsf.gov,* 703–292–2490. The following persons will be available to provide technical support in accessing the YouTube video: Angel Ntumy (*antumy@associates.nsf.gov*); Phillip Moulden (*pmoulden@associates.nsf.gov*).

SUPPLEMENTAL INFORMATION: All open sessions of the meeting will be webcast live. The Zoom feed will be broadcast on the NSB YouTube channel at: Please feel free to share this link with your colleagues:

Tuesday, February 23—*https://youtu.be/6JjWhwMhIKM*
Wednesday, February 24—*https://youtu.be/tmiQwe7o_Y0*

Please refer to the NSB website for additional information. You will find any updated meeting information and schedule updates (time, place, subject matter, or status of meeting) at *https://www.nsf.gov/nsb/meetings/notices.jsp#sunshine.*

Members of the public are advised that the NSB provides some flexibility around meeting times. A meeting may be allowed to run over by as much as 15 minutes if the Chair decides the extra time is warranted. The next meeting will start no later than 15 minutes after the noticed start time. If a meeting ends early, the next meeting may start up to 15 minutes earlier than the noticed start time. At no point will NSB or committee meetings vary from noticed times by more than 15 minutes. Open meetings can also be watched in their entirety later through the YouTube link.

Chris Blair,

Executive Assistant to the National Science Board Office.

[FR Doc. 2021–03463 Filed 2–17–21; 11:15 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2020–0204]

Information Collection: Domestic Licensing of Production and Utilization Facilities

AGENCY: Nuclear Regulatory Commission.

ACTION: Renewal of existing information collection; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) invites public comment on the renewal of Office of Management and Budget (OMB) approval for an existing collection of information. The information collection

is entitled ''Domestic Licensing of Production and Utilization Facilities.''

DATES: Submit comments by April 20, 2021. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

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

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID: NRC–2020–0204. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* David Cullison, Office of the Chief Information Officer, Mail Stop: T–6 A10M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID: NRC–2020–0204 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods; however, the NRC encourages electronic comment submission through the Federal Website:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2020–0204. A copy of the collection of information and related instructions may be obtained without charge by accessing Docket ID NRC–2020–0204 on this website.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''ADAMS Public Documents'' and then select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* A copy of the collection of information and related instructions may be obtained without charge by accessing ADAMS Accession No. ML20244A279. The seven supporting statements associated with the part 50 information collections and the burden table are available in ADAMS under Accession Nos. ML20264E681, ML20264E682, ML20264E683, ML20264E684, ML20264E685, ML20264E686, ML20264E687 and ML20264E688, respectively.
- *Attention:* The PDR, where you may examine and order copies of public documents is currently closed. You may submit your request to the PDR via email at *PDR.Resource@nrc.gov* or call 1–800–397–4209 between 8:00 a.m. and 4:00 p.m. (EST), Monday through Friday, except Federal holidays.
- *NRC's Clearance Officer:* A copy of the collection of information and related instructions may be obtained without charge by contacting NRC's Clearance Officer, David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal Rulemaking website (*https://www.regulations.gov*). Please include Docket ID NRC–2020–0204 in your comment submission.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *https://www.regulations.gov* as well as enter the comment submissions into ADAMS, and the NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the NRC is requesting public comment on its intention to request the OMB's approval for the information collection summarized.

1. *The title of the information collection:* Domestic Licensing of Production and Utilization Facilities.
2. *OMB approval number:* 3150–0011.
3. *Type of submission:* Extension.
4. *The form number, if applicable:* Not Applicable.
5. *How often the collection is required or requested:* As necessary in order for the NRC to meet its responsibilities to conduct a detailed review of applications for licenses and amendments thereto to construct and operate nuclear power plants, preliminary or final design approvals, design certifications, research and test facilities, reprocessing plants and other utilization and production facilities, licensed pursuant to the Atomic Energy Act of 1954, as amended (the Act) and to monitor their activities. Reports are submitted daily, monthly, quarterly, annually, semi-annually, and on occasion.
6. *Who will be required or asked to respond:* Licensees and applicants for or holder of an operating license or construction permit, applicant for a standard design certification under part 52 of this chapter or an applicant for or holder of a standard design approval, a combined license and research and test facilities.
7. *The estimated number of annual responses:* 41,950 (41,789 reporting responses + 159 recordkeepers + 2 third-party disclosure response).
8. *The estimated number of annual respondents:* 159.
9. *The estimated number of hours needed annually to comply with the information collection requirement or request:* 3.6M hours (1.2M hours reporting + 2.4M hours recordkeeping + 200 hours third-party disclosure).
10. *Abstract:* Part 50 of title 10 of the *Code of Federal Regulations* (10 CFR), ''Domestic Licensing of Production and Utilization Facilities,'' specifies technical information and data to be provided to the NRC or maintained by applicants and licensees so that the NRC may take determinations necessary to protect the health and safety of the public, in accordance with the Atomic Energy Act of 1954, as amended. The reporting and recordkeeping

requirements contained in 10 CFR part 50 are mandatory for the affected licensees and applicants.

III. Specific Requests for Comments

The NRC is seeking comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?
2. Is the estimate of the burden of the information collection accurate?
3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?
4. How can the burden of the information collection on respondents be minimized, including the use of automated collection techniques or other forms of information technology?

Dated: February 16, 2021.

For the Nuclear Regulatory Commission.

David C. Cullison,

NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2021–03357 Filed 2–18–21; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2021–68 and CP2021–71]

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 a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* February 23, 2021.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction
II. Docketed Proceeding(s)

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the market dominant or the competitive product list, or the modification of an existing product currently appearing on the market dominant or the competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3011.301.[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 3030, and 39 CFR part 3040, 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 3035, and 39 CFR part 3040, subpart B. Comment deadline(s) for each request appear in section II.

1. Docket No(s).: MC2021–68 and CP2021–71; *Filing Title:* USPS Request to Add Priority Mail Express & Priority Mail Contract 123 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* February 12, 2021; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; Public Representative: Christopher C. Mohr; *Comments Due:* February 23, 2021.

This Notice will be published in the **Federal Register**.

Erica A. Barker,

Secretary.

[FR Doc. 2021–03411 Filed 2–18–21; 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. 34–91126; File No. SR–NYSE–2020–85]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change To Amend the NYSE Listed Company Manual To Revise the Shareholder Approval Requirements in Sections 312.03 and 312.04 and the Requirements for Related Party Transactions in Section 314.00

February 12, 2021.

On December 16, 2020, New York Stock Exchange LLC filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend Sections 312.03, 312.04 and 314.00 of the NYSE Listed Company Manual. The Commission published notice of the proposed rule change in the **Federal Register** on January 4, 2021.[3] The Commission has received no comments on the proposal.

Section 19(b)(2) of the Act[4] 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 February 18, 2021. The Commission is extending this 45-day time period.

The Commission finds that it is appropriate to designate a longer period within which to take action on the proposed rule change so that it has

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 90803 (December 28, 2020), 86 FR 0148.

[4] 15 U.S.C. 78s(b)(2).

sufficient time to consider the proposed rule change. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[5] designates April 4, 2021, 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 Number SR–NYSE–2020–85).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[6]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2021–03343 Filed 2–18–21; 8:45 am]

BILLING CODE 8011–01–P

[5] *Id.*

[6] 17 CFR 200.30–3(a)(31).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–91124; File No. SR–BX–2020–033]

Self-Regulatory Organizations; Nasdaq BX, Inc.; Order Granting Approval of a Proposed Rule Change To Utilize the FIX Protocol To Submit Orders to BX's Price Improvement Auction Mechanism

February 12, 2021.

I. Introduction

On October 27, 2020, Nasdaq BX, Inc. (''BX'' or ''Exchange'') 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 utilize the ''Financial Information eXchange'' (''FIX'')[3] protocol for BX Participants[4] seeking to submit orders into the Price Improvement Auction (''PRISM'') mechanism. The proposed rule change was published for comment in the **Federal Register** on November 16, 2020.[5] On December 29, 2020, the Commission extended the time period within which to approve, disapprove, or institute proceedings to determine whether to approve or disapprove the proposed rule changes.[6] The Commission received no comments on the proposed rule change. The Commission is approving the proposed rule change.

II. Description of the Proposed Rule Change

Pursuant to BX Options 3, Section 13, a BX Participant may electronically submit for execution an order it represents as agent on behalf of a Public Customer,[7] broker dealer, or any other entity (''PRISM Order'') against principal interest or against any other order[8] it represents as agent (an ''Initiating Order''), provided it submits the PRISM Order for electronic execution into the Auction. According to the Exchange, BX Participants currently solicit contra-side Initiating Orders to pair with their PRISM Orders using methods such as telephone, electronically using an external order management system, or utilizing instant message.[9] BX proposes to provide BX Participants (''sender'') the option to use the FIX protocol to send a message, which includes a PRISM Order, to one or more BX Participants (''recipient'') requesting that they provide a contra-side Initiating Order in response, which would result in the start of a PRISM auction (''Request for PRISM''). BX Participants must opt-in in order to receive Requests for PRISM. A Request for PRISM would be sent simultaneously to all BX Participants who opted in to receive Requests for PRISM,[10] and a BX Participant who opts-in would receive all Requests for PRISM from all senders.[11]

The Exchange proposes to establish a certain time period up to one second[12] within which a recipient, if it chooses to respond to the Request for PRISM, may utilize FIX to submit the sender's PRISM Order, along with its Initiating Order, into the System for execution into PRISM pursuant to Options 3, Section 13 (''response'').[13] The System would enter the PRISM Order and the Initiation Order of the first recipient to respond into the PRISM through FIX to start a PRISM auction and would send a reject message to subsequent responders.[14] Any Initiating Order must match the PRISM Order and is not permitted to improve the price, or else it would be rejected.[15] However, the Initiating Order may be configured to improve the PRISM Order stop price pursuant to Options 3, Section 13(ii)(A)(1)(c);[16] the configuration would apply only if the System initiated a PRISM auction.[17] If there are no responses to the Request for PRISM, the PRISM Order would be placed on the Order Book as a Limit Order or cancelled, consistent with the sending BX Participant's instruction.[18]

Once a recipient of a Request for PRISM has responded to the Request for PRISM by adding the Initiating Order, the PRISM may not be cancelled.[19] The sender may not cancel a Request for PRISM once that Request for PRISM has

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* BX Options 3, Section 7(e)(1). ''FIX'' is an interface that allows BX Participants and their Sponsored Customers to connect, send, and receive messages related to orders and auction orders and responses to and from the Exchange. Features include the following: (1) Execution messages; (2) order messages; and (3) risk protection triggers and cancel notifications.

[4] BX Options 1, Section 1(a)(40) defines ''Participant'' to mean a firm, or organization that is registered with the Exchange pursuant to Options 2A of BX Rules for purposes of participating in options trading on the BX options market as a ''BX Options Order Entry Firm,'' as defined in BX Options 1, Section 1(a)(11), or ''BX Options Market Maker,'' as defined in BX Options 1, Section 1(a)(10).

[5] *See* Securities Exchange Act Release No. 90383 (November 9, 2020), 85 FR 73095 (''Notice'').

[6] *See* Securities Exchange Act Release Nos. 90815, 86 FR 353 (January 5, 2021), in which the Commission designated February 14, 2021 as the date by which it should approve, disapprove, or institute proceedings to determine whether to disapprove these proposed rule changes

[7] A ''Public Customer'' means a person that is not a broker or dealer in securities and is not a Professional as defined within BX Options 1, Section 1(a)(48). *See* BX Options 1, Section 1(a)(49). A ''Professional'' means any person or entity that (i) is not a broker or dealer in securities, and (ii) 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 Participants. *See* BX Options 1, Section 1(a)(48).

[8] PRISM Orders submitted during the final two seconds of the trading session in the affected series are not eligible to initiate an Auction and will be immediately cancelled. *See* BX Options 3, Section 13(i)(F).

[9] *See* Notice, *supra* note 5, at 73095 n.7.

[10] Proposed BX Options 3, Section 7(d)(1)(A)(1)(c).

[11] Proposed BX Options 3, Section 7(d)(1)(A)(1)(a).

[12] The Exchange will initially set the time period to 100 milliseconds to respond to the Request for PRISM or otherwise not respond before the Request for PRISM would become unavailable. The Exchange will post the time period on its System settings page. *See* Notice, *supra* note 5, at 73096 n.8.

[13] Proposed BX Options 3, Section 7(d)(1)(A)(1)(b).

[14] *Id.*

[15] *Id.*

[16] *Id.* BX Options 3, Section 13(ii)(A)(1) provides three options to submit a PRISM Order and initiate the PRISM Auction. Specifically, the Initiating Participant must mark the PRISM Order for Auction processing, and specify either: (a) A single price at which it seeks to execute the PRISM Order (a ''stop price''); (b) that it is willing to automatically match as principal or as agent on behalf of an Initiating Order the price and size of all PAN responses, and trading interest (''auto-match'') in which case the PRISM Order will be stopped at the NBBO on the Initiating Order side; or (c) that it is willing to either: (i) Stop the entire order at a single stop price and auto-match PAN responses and trading interest at a price or prices that improve the stop price to a specified price (a ''No Worse Than'' or ''NWT'' price); (ii) stop the entire order at a single stop price and auto-match all PAN responses and trading interest at or better than the stop price; or (iii) stop the entire order at the NBBO on the Initiating Order side, and auto-match PAN responses and trading interest at a price or prices that improve the stop price up to the NWT price.

[17] Proposed BX Options 3, Section 7(d)(1)(A)(1)(b).

[18] *Id.*

[19] Proposed BX Options 3, Section 7(d)(1)(A)(1)(d).

been sent.[20] The identity of the sender and recipients will not be known to any party,[21] and the Exchange will not disclose a list of BX Participants that have opted-in to receive Requests for PRISM.[22]

It would be deemed conduct inconsistent with just and equitable principles of trade and a violation of Options 9, Section 1, and other Exchange Rules, to utilize non-public information in connection with a Request for PRISM to a BX Participant's economic advantage.[23] The Exchange intends to begin implementation of the proposed rule change by June 30, 2021. The Exchange will issue an Options Trader Alert to BX Participants with the date of implementation.[24]

III. Discussion and Commission Findings

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.[25] In particular, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,[26] which requires that the rules of an exchange be designed, among other things, 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 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, and not be designed to permit unfair discrimination between customers, issuers, brokers or dealers. The Commission also finds that the proposed rule change is consistent with Section 6(b)(8) of the Act,[27] which requires that the rules of a national securities exchange not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

The proposed rule change appears reasonably designed to offer Participants an efficient process to solicit an Initiating Order among other BX Participants for entry into the PRISM auction.[28] The Commission believes that by permitting BX Participants to use FIX to send a Request for PRISM (with a PRISM Order) simultaneously to all BX Participants that have opted-in, the proposed Request for PRISM process would provide BX Participants with another means of soliciting interest for a PRISM auction from a potentially broader group of market participants, potentially providing price improvement to the PRISM Order. The Commission further notes that the proposal would not amend the manner in which PRISM auction operates. Any paired order entered into PRISM must comply with the eligibility requirements of BX Options 3, Section 13(i) to commence the auction and the auction process will operate as it does today.

The Commission also believes that the proposal appears to be designed to provide an objective process for the selection of the contra-side to the PRISM Order. Any BX Participant may choose to opt-in, and those who opt-in would receive any Request for PRISM sent from BX Participants.[29] Further, any BX Participant that chooses to opt-in may subsequently opt-out.[30] In addition, the Exchange has proposed that the identity of the sender and recipients would not be known to any party and that it would not disclose a list of the BX Participants that opted-in to receive a Request for PRISM.[31] Thus, the decision of which Participant is chosen to provide the Initiating Order will be based solely on which recipient responded first to the Request for PRISM.

The Commission also believes that the proposed rule change appears designed to prevent the misuse of information related to the proposed Request for PRISM and create an audit trail for surveilling Requests for PRISM. The Exchange represents that it will employ surveillances to prevent misuse of non-public information related to a Request for PRISM similar to how it employs surveillances today to ensure that information available in auctions is not misused.[32] The Exchange also represents that the communications that would occur, through FIX, would be available to and maintained by the Exchange, and that it would be able to monitor entries into both the order book and the PRISM auction.[33] Further, the Exchange proposes in Options 3, Section 13 that it would be deemed conduct inconsistent with just and equitable principles of trade and a violation of Options 9, Section 1, and other Exchange Rules for BX Participants receiving Requests for PRISM to utilize the information to a BX Participant's economic advantage.[34] In addition, a Request for PRISM would be subject to the restrictions set forth in BX Options 3, Section 22 (Limitations on Order Entry), and any paired order resulting from a Request for PRISM would be subject to the PRISM auction requirements in BX Options 3, Section 13.[35]

For the reasons set forth above, the Commission believes that the proposed rule changes are consistent with the requirements of the Act.

V. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[36] that the proposed rule change (SR–BX–2020–033) hereby is approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[37]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2021–03341 Filed 2–18–21; 8:45 am]

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[20] Proposed BX Options 3, Section 7(d)(1)(A)(1)(e).

[21] Proposed BX Options 3, Section 7(d)(1)(A)(1)(f).

[22] *Id.*

[23] Proposed BX Options 3, Section 7(d)(1)(A)(1)(g).

[24] *See* Notice, *supra* note 5, at 73097.

[25] 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).

[26] 15 U.S.C. 78f(b)(5).

[27] 15 U.S.C. 78f(b)(8).

[28] *See* Notice, *supra* note 5, at 73095–96 (describing the current methods Participants use to find a paired order).

[29] Proposed BX Options 3, Section 7(d)(1)(A)(1)(c).

[30] Notice, *supra* note 5, at 73097.

[31] Proposed BX Options 3, Section 7(d)(1)(A)(1)(f).

[32] Notice, *supra* note 5, at 73097.

[33] Notice, *supra* note 5, at 73098.

[34] Proposed BX Options 3, Section 7(d)(1)(A)(1)(f).

[35] Notice, *supra* note 5, at 73098.

[36] *See id.*

[37] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–91122; File No. SR–CBOE–2020–052]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Order Approving a Proposed Rule Change, as Modified by Amendment No. 1, To Amend Rules 5.37, 5.38, and 5.73 Related to Auction Notification Messages and Index Combo Orders in SPX in the Automated Improvement Mechanism, Complex Automated Improvement Mechanism, and FLEX Automated Improvement Mechanism

February 12, 2021.

I. Introduction

On June 3, 2020, Cboe Exchange, Inc. (''Exchange'' or ''Cboe'') filed with the Securities and Exchange Commission

(''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend Rules 5.37, 5.38, and 5.73 to (1) allow the Exchange to determine to disseminate the stop price in auction notification messages for Automated Improvement Mechanism (''AIM''), Complex Automated Improvement Mechanism (''C–AIM''), and FLEX AIM auctions in S&P 500® Index options (''SPX''); and (2) modify the minimum increment for C–AIM and FLEX AIM auction responses for Index Combo Orders in SPX. The proposed rule change was published for comment in the **Federal Register** on June 18, 2020.[3] On July 22, 2020, the Exchange submitted Amendment No. 1 to the proposed rule change, which replaced and superseded the proposed rule change in its entirety.[4] On July 27, 2020, pursuant to Section 19(b)(2) of the Act,[5] the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.[6] On August 21, 2020, the Commission published notice of Amendment No. 1 and instituted proceedings under Section 19(b)(2)(B) of the Act[7] to determine whether to approve or disapprove the proposed rule change, as modified by Amendment No. 1.[8] On December 8, 2020, pursuant to Section 19(b)(2) of the Act,[9] the Commission designated a longer period within which to approve or disapprove the proposed rule change, as modified by Amendment No. 1.[10] This order approves the proposed rule change, as modified by Amendment No. 1.

II. Description of the Proposal, as Modified by Amendment No. 1

A. Background

The AIM, C–AIM, and FLEX AIM are electronic auctions intended to provide an agency order with the opportunity to receive price improvement (over the National Best Bid or Offer in AIM, or the synthetic best bid or offer on the Exchange in C–AIM).[11] Upon submitting an agency order into one of these auctions, the initiating Trading Permit Holder must also submit a contra-side second order for the same size as the agency order. The contra-side order guarantees that the agency order will receive an execution. Upon commencement of an auction, market participants submit responses to trade against the agency order. At the conclusion of the auction, depending on the contra-side interest available, the contra-side order may be allocated a certain percentage of the agency order.[12]

On March 16, Cboe activated the AIM and C–AIM in SPX options, so that trading in SPX could continue while the trading floor was closed.[13] Once the trading floor re-opened on June 15, 2020, the Exchange disengaged AIM and C–AIM for SPX. Prior to the trading floor closure, the Exchange had not activated C–AIM (or AIM) in SPX and thus all non-FLEX crossing transactions in SPX were previously only able to occur on the trading floor.

B. Minimum Increment for Index Combo Orders in SPX

The Exchange proposes to amend Rules 5.38 and 5.73 to modify the minimum increment for C–AIM and FLEX AIM auction responses, respectively, in which the agency order complex strategy is comprised of an Index Combo Order (as defined in Rule 5.33(b)) in SPX.[14] When submitting an agency order into a C–AIM auction, the initiating member must also submit principal or solicited contra-side complex order(s) for the same size as the agency order, which guarantees that the agency order will receive an execution.[15] Upon commencement of a C–AIM auction, market participants submit responses to trade against the agency order and at the conclusion of an auction, depending on the contra-side interest available, the contra order may be allocated a certain percentage of the agency order.[16]

Rules 5.38(c)(5)(A) and 5.38(a)(4) currently provide that the minimum price increment for C–AIM responses and agency and initiating orders, respectively, must be in an increment the Exchange determines on a class basis, which is $0.05 in SPX options.[17] The corresponding FLEX AIM Rules 5.73(c)(5)(A) and 5.73(a)(4) provide the same treatment for FLEX AIM auctions. Thus, under current rules market participant responses in the C–AIM and FLEX AIM auctions must improve the net package price (*i.e.,* each strategy unit) based on then-current leg markets by at least the minimum increment of $0.05.[18] Because of the differences between the quoting practices on floor and the quoting practices in the C–AIM and FLEX AIM auctions with respect to Index Combo Orders in SPX,[19] however,

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 89063 (June 12, 2020), 85 FR 36923 (''Notice''). Comments received on the proposed rule change are available on the Commission's website at: *https://www.sec.gov/comments/sr-cboe-2020-052/srcboe2020052.htm.*

[4] In Amendment No. 1, the Exchange amended the proposal to: (1) To add that, when the proposed stop price dissemination in auction notification messages is enabled for AIM, C–AIM, or FLEX AIM auctions in SPX, it would apply to all such AIM, C–AIM, or FLEX AIM auctions; (2) specify that the proposed minimum increment modification would apply to Index Combo Orders in SPX, and to correct an internal cross-reference in the proposed rules; (3) provide additional detail to the description and examples of the proposed modification to the minimum increment for Index Combo Orders in SPX; and (4) provide additional justification and support for the proposed rule change. The full text of Amendment No. 1 is available on the Commission's website at: *https://www.sec.gov/comments/sr-cboe-2020-052/srcboe2020052-7464403-221166.pdf.*

[5] 15 U.S.C. 78s(b)(2).

[6] *See* Securities Exchange Act Release No. 89400, 85 FR 46202 (July 31, 2020). The Commission designated September 16, 2020 as the date by which the Commission shall approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change.

[7] 15 U.S.C. 78s(b)(2)(B).

[8] *See* Securities Exchange Act Release No. 89638, 85 FR 53045 (August 27, 2020).

[9] 15 U.S.C. 78s(b)(2).

[10] *See* Securities Exchange Act Release No. 90592, 85 FR 80863 (December 14, 2020). The Commission designated February 13, 2021 as the date by which the Commission shall approve or disapprove the proposed rule change, as modified by Amendment No. 1.

[11] *See* Rules 5.38 (AIM), 5.38 (C–AIM), and 5.73 (FLEX AIM).

[12] *See* Rules 5.37(e), 5.38(e), and 5.73(e).

[13] The Exchange had activated C–AIM and AIM in SPX for the first time as a result of the March 16, 2020 trading floor suspension to help prevent the spread of COVID–19. According to the Exchange, FLEX AIM in SPX had been activated prior to March 16, 2020.

[14] An Index Combo Order is an order to purchase or sell one or more index option series and the offsetting number of Index Combinations defined by the delta. For purposes of an Index Combo order, the following terms have the following meanings: (1) An ''Index Combination'' is a purchase (sale) of an index option call and sale (purchase) of an index option put with the same underlying index, expiration date, and strike price; (2) A ''delta'' is the positive (negative) number of Index Combinations that must be sold (purchased) to establish a market neutral hedge with one or more series of the same index option; and (3) An Index Combo order may not have a ratio greater than eight options to one Index Combination (8.00), and will be subject to all provisions applicable to complex orders (excluding the one-to-three/three-to-one ratio) in the Rules. *See* Rule 5.33(b).

[15] *See* Rule 5.38.

[16] *See generally* Rule 5.38(e). The same process applies to the FLEX AIM auction pursuant to the FLEX Rules. *See generally* Rule 5.73(e).

[17] The System rejects a C–AIM response or agency or initiating order that is not in the applicable minimum increment.

[18] Although members of the trading crowd on the trading floor are permitted to improve the net package price (based on then-current leg markets) by the minimum increment of $0.05, the Exchange states that this is not the common practice. *See* Amendment No. 1, *supra* note 4, at 9.

[19] An Index Combo Order in SPX is a complex order that includes one or more SPX legs, hedged by an SPX combo, or synthetic future, defined by the delta. The Exchange states that Index Combo Orders in SPX comprise a significant portion of crosses in SPX and that a significant amount of SPX volume was executed through C–AIM when the

Continued

applying the $0.05 minimum increment to auction responses in both floor trading and the electronic C–AIM and FLEX AIM auctions could result in a significant difference in the price improvement that an order receives depending on whether the Index Combo Order in SPX is traded in the electronic auctions or on the trading floor.[20] A floor broker seeking to cross SPX complex orders on the trading floor generally identifies the legs of the complex order and their relative sizes to each other with a net package price.[21] The trading crowd then generally provides a market based on the strategy's theoretical value, rather than on the value of the net package (which equals the strategy times the ratio), particularly when the complex order represented is a delta neutral order that includes a combo.[22] In open outcry trading, the trading crowd generally prices the combo hedge portion separately from the non-combo portion of the order.[23] If the crowd improves the price of the non-combo leg of the order by a minimum increment, or greater, that price is given on each contract.[24] The proposed changes are intended to provide for substantially the same price improvement opportunities at meaningful increments for Index Combo Orders in SPX, whether they are submitted to the C–AIM or FLEX AIM electronic auctions or executed on the trading floor.[25]

Accordingly, to better align the C–AIM and FLEX AIM electronic auction crossing processes and the open outcry crossing process for Index Combo Orders in SPX, the Exchange proposes to amend Rule 5.38(c)(5)(A) to provide that the minimum price increment for a C–AIM response in which the agency order complex strategy is comprised of an Index Combo Order in SPX will be the ratio of the non-combo portion of the strategy to the number of combos, multiplied by the minimum price increment the Exchange determines for options on SPX agency orders pursuant to Rule 5.38(a)(4).[26] The Exchange also proposes to amend Rule 5.73(c)(5)(A) to revise the FLEX AIM process for Index Combo Orders in SPX in the same manner.[27]

C. Auction Stop Price Dissemination in SPX

Current Rules 5.37(c)(2), 5.38(c)(2), and 5.73(c)(2) provide that the system initiates the AIM, C–AIM, and FLEX AIM auction processes, respectively, by sending an auction notification message detailing the side, size, auction ID, and options series (and, for C–AIM auctions, complex strategy, or, for FLEX AIM auctions, length of the auction period and options series or complex strategy, as applicable) of the agency order to all users that elect to receive AIM, C–AIM, or FLEX AIM auction notification messages. Because AIM, C–AIM, and FLEX AIM auction notification messages are not included in the disseminated BBO (in connection with AIM auctions) or OPRA, the Exchange does not currently include the stop price of an agency order in auction notification messages.[28] To better align the AIM and C–AIM pricing process in SPX with the open outcry process, the Exchange proposes to amend Rules 5.37(c)(2) and 5.38(c)(2) to provide that the Exchange may also determine to include the stop price in SPX AIM and C–AIM auction notification messages.[29] As with all other information disseminated in an AIM and C–AIM auction notification message, the disseminated stop price for SPX auctions will be available to all users that elect to receive auction notification messages.[30] Because the FLEX AIM rules are similar to the AIM and C–AIM rules, the Exchange also proposes to maintain this consistency by amending Rule 5.73(c)(2) to similarly provide that the Exchange may determine to include the stop price in FLEX AIM auction notification messages for all FLEX AIM auctions in SPX.[31]

III. Discussion and Commission Findings

The Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[32] In particular, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with Section 6(b)(5) of the Act,[33] which requires, among other things, that the rules of a national securities exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest. The Commission also finds that the proposed rule change, as modified by Amendment No. 1, is consistent with Section 6(b)(8) of the Act,[34] which requires that the rules of a national securities exchange do not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

As discussed above, the Exchange proposes to publish the stop price of SPX AIM auctions. As previously noted, according to the Exchange, orders in SPX generally take on greater risk, have a higher notional value, trade in much larger size, and effect increasingly more complex strategies than options in other classes.[35] Therefore, the Exchange believes that this proposed change may address any uncertainties market participants may have when pricing SPX responses.[36] The Exchange further states that, for SPX orders crossed on the trading floor in open outcry, market makers generally have more confidence in the pricing of their responses as the crosses start with a request for market and the trading crowd then provides a ''ballpark'' of the prices at which they are willing to trade, which the market maker may then use to more confidently price its responses.[37] The Exchange believes that its proposal, therefore, has been designed to incentivize continued, competitive responses to SPX electronic auctions in substantially the same manner in which responses may be

Exchange activated C–AIM for SPX options. *See id.* at 7 and n.10 (stating that in April 2020, Index Combo Orders in SPX comprised 60.5% of crossed volume executed in SPX via AIM while the trading floor was inoperable).

[20] See *id.* at 9–11, for examples of these pricing distinctions in practice.

[21] *See id.* at 7.

[22] *See id.*

[23] The price of the combo and the rest of the order are ultimately packaged and appear as a net package price for the entire order on the customer fill report. *See id.* at 8.

[24] *See id.*

[25] *See id.* at 13.

[26] For example, if a market participant buys 800 November 3650 SPX Calls tied to 100 September 3210 Combos, using a delta of 12.5, the System would calculate the minimum increment by multiplying the ratio of the non-combo leg of the order (800) to the number of combos (100) by the minimum increment of $0.05. Therefore, (800/100) × 0.05 = $0.40 as the starting point for price improvement during the C–AIM or FLEX C–AIM auction. *See id.*

[27] *See id.* at 12–13.

[28] *See id.* at 11.

[29] The Exchange represents that it will notify its trading permit holders of a determination to include the stop price in auction notification messages, pursuant to Rule 1.5, via a specification, notice, or regulatory circular with appropriate advanced notice, which will be posted on the Exchange's website, electronic message, or other communication method as provided in the Rules. *See id.* at 12 n.18.

[30] *See* proposed Rules 5.37(c)(2) and 5.38(c)(2).

[31] *See* Amendment No. 1, *supra* note 4, at 12–13.

[32] 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).

[33] 15 U.S.C. 78f(b)(5).

[34] 15 U.S.C. 78f(b)(8).

[35] *See* Amendment No. 1, *supra* note 4, at 16.

[36] *See id.*

[37] *See id.* at 6.

priced on the trading floor, thereby providing for potentially improved liquidity and price improvement opportunities for orders being executed through those auctions, as the dissemination of the stop price may facilitate market participants' confidence in pricing meaningful, competitive responses during electronic auctions in SPX in a manner substantially similar to that which occurs on the trading floor.[38]

The Exchange also proposes to revise the minimum increment for auction responses for Index Combo Orders in SPX that trade in electronic auctions. For these orders, the Exchange proposes to base the minimum auction response increment on the ratio of the non-combo portion of the strategy to the number of combos, multiplied by the minimum price increment the Exchange determines for options on SPX agency orders pursuant to Rule 5.38(a)(4). The Exchange believes that without the proposed change, responders to C–AIM and FLEX AIM auctions of Index Combo Orders in SPX could ''step ahead'' of market participants who are willing to trade with customer orders at the auction price by providing only a trivial amount of price improvement.[39] The Exchange believes that this could discourage market participants from providing contra-side interest at the best prices and liquidity providers from joining or improving at meaningful increments, resulting in fewer price improvement opportunities for customers.[40] By tying the minimum auction response increment to the legs of the order, as opposed to the package price inclusive of the combos, the Exchange believes the proposed rule will require market participants to respond to the C–AIM or FLEX AIM auctions for Index Combo Orders in SPX at prices more aligned with the prices at which responses for these orders generally occur in open outcry.[41] One commenter agreed with Cboe stating that the proposed rule change should provide investors in SPX with enhanced execution and price improvement opportunities for agency orders submitted into the AIM auctions.[42]

According to the Exchange, orders in SPX generally take on greater risk than in other option classes, as SPX options tend to have a higher notional value than options in other classes, trade much larger size than in other options classes, and effect increasingly more complex strategies than executed in other classes.[43] The proposed change to the minimum auction response increment for Index Combo Orders in SPX could help to ensure that market participants seeking to trade with an agency order at a price better than the auction price will be required to provide meaningful price improvement. Because liquidity providers responding to a C–AIM or FLEX AIM auction for an Index Combo Order in SPX will not be able to gain allocation priority over solicited contra side interest by providing only minimal price improvement over the auction price, the proposal could help to ensure that market participants solicited to participate as the contra side to an Index Combo Order in SPX will continue to provide liquidity for these orders. The proposed auction response increment also could help to ensure that an Index Combo Order in SPX that is executed in a C–AIM or FLEX AIM auction receives an amount of price improvement comparable to the amount of price improvement that the order might receive if it traded in open outcry. The proposed change to the minimum auction response increment for Index Combo Orders in SPX is also consistent with Section 6(b)(8) of the Act because it may promote competition on the Exchange by more closely aligning the electronic crossing process with the open outcry crossing process, and thus provide similar execution and price improvement opportunities to customers whether their orders are submitted for electronic or open outcry execution.

The Commission further believes that the Exchange's proposal to allow for the dissemination of the stop price in auction notification messages for AIM, C–AIM, and FLEX AIM auctions in SPX is consistent with the Act.[44] As described above, providing potential auction responders with more information about an upcoming SPX AIM auction may encourage market participants to submit more competitive responses, particularly given the large and complex nature of orders in SPX. Accordingly, the Commission believes the Exchange's proposal may result in increased liquidity in AIM auctions and therefore increased price improvement opportunities for SPX agency orders in the AIM auctions.

The Commission is also aware that other options exchanges currently disseminate the stop price of an agency order in similar auction mechanisms and does not believe this aspect of the proposed rule change raises any novel regulatory issues.[45] The Commission believes that providing similar additional information in its electronic price improvement auction notification messages should make the Cboe electronic price improvement auctions competitive with other options exchanges and encourage the submission of more responses to these auctions. For this reason, the Commission believes that the proposed rule change is also consistent with Section 6(b)(8) of the Act.

Accordingly, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with the requirements of the Act.

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[46] that the proposed rule change, as modified by Amendment No. 1 (SR–CBOE–2020–052), be, and hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[47]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2021–03339 Filed 2–18–21; 8:45 am]

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[38] *See id.* at 16. The Exchange also states that its affiliated options exchange, Cboe EDGX Exchange, Inc. (''EDGX Options'') currently includes the price, along with the other fields the Exchange currently disseminates, in the auction notification messages disseminated at the initiation of its AIM and C–AIM auctions. *See* EDGX Options Rules 21.19(c)(2) and 21.22(c)(2).

[39] *See* Amendment No. 1, *supra* note 4, at 15.

[40] *See id.* at 13–14 (providing an additional example to illustrate the Exchange's arguments).

[41] *See id.* The Exchange states that the proposal will not alter the manner in which the system caps responses pursuant to Rule 5.38(c)(5)(B). Under Rule 5.38(c)(5)(B), C–AIM buy (sell) responses are capped at the following prices that exist at the conclusion of the C–AIM Auction: (i) The better of the synthetic best offer (''SBO'') (synthetic best bid (''SBB'')) or the offer (bid) of a resting complex order at the top of the complex order book (''COB''); or (ii) one minimum increment lower (higher) than the better of the SBO (SBB) or the offer (bid) of a resting complex order at the top of the COB if the BBO of any component of the complex strategy or the resting complex order, respectively, is a Priority Customer order. *See id.* at 14–15.

[42] *See* letter to Vanessa Countryman, Secretary, Commission, from Ellen Greene, Managing Director, Equities & Options Market Structure, The Securities Industry and Financial Markets Association, dated July 9, 2020.

[43] *See* Notice, *supra* note 3, at 36923.

[44] One commenter supported the proposal, highlighting specifically the stop price dissemination aspect of the proposal and stating that it would better align the AIM and C–AIM pricing processes for responses with the open outcry process. *See* letter to Vanessa Countryman, Secretary, Commission, from Ellen Greene, Managing Director, Equities & Options Market Structure, The Securities Industry and Financial Markets Association, dated July 9, 2020, at 3.

[45] *See, e.g.,* BOX Exchange LLC Rule 7150(f); EDGX Options Rules 21.19(c)(2) and 21.22(c)(2); MIAX International Securities Exchange, LLC Rule 515A(a)(2)(i)(B); and Nasdaq ISE, LLC Options 3, Section 13(c).

[46] 15 U.S.C. 78s(b)(2).

[47] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–91123; File No. SR–NYSE–2021–11]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Its Price List

February 12, 2021.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on February 1, 2021, New York Stock Exchange LLC (''NYSE'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its Price List to (1) introduce a new Step Up Adding Tier 5, and (2) modify the incremental step up tier for Supplemental Liquidity Providers (''SLPs'') (''Incremental SLP Step Up Tier''). The Exchange proposes to implement the fee changes effective February 1, 2021. The proposed rule 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.

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.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Price List to (1) introduce a new Step Up Adding Tier 5, and (2) modify the Incremental SLP Step Up Tier.

The proposed changes respond to the current competitive environment where order flow providers have a choice of where to direct liquidity-providing orders by offering further incentives for member organizations to send additional displayed liquidity to the Exchange.

The Exchange proposes to implement the fee changes effective February 1, 2021.

Background

Current Market and Competitive Environment

The Exchange operates in a highly competitive market. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [4]

While Regulation NMS has enhanced competition, it has also fostered a ''fragmented'' market structure where trading in a single stock can occur across multiple trading centers. When multiple trading centers compete for order flow in the same stock, the Commission has recognized that ''such competition can lead to the fragmentation of order flow in that stock.'' [5] Indeed, equity trading is currently dispersed across 16 exchanges,[6] 31 alternative trading systems,[7] and numerous broker-dealer internalizers and wholesalers, all competing for order flow. Based on publicly-available information, no single exchange has more than 16% market share.[8] Therefore, no exchange possesses significant pricing power in the execution of equity order flow. More specifically, the Exchange's market share of trading in Tape A, B and C securities combined is less than 10%.

The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can move order flow, or discontinue or reduce use of certain categories of products, in response to fee changes. With respect to non-marketable order flow that would provide displayed liquidity on an Exchange, member organizations can choose from any one of the 16 currently operating registered exchanges to route such order flow. Accordingly, competitive forces constrain exchange transaction fees that relate to orders that would provide liquidity on an exchange.

In response to the competitive environment described above, the Exchange has established incentives for its member organizations who submit orders that provide liquidity on the Exchange. The proposed fee change is designed to attract additional order flow to the Exchange by incentivizing member organizations to submit additional displayed liquidity to, and quote aggressively in support of the price discovery process on, the Exchange.

Proposed Rule Change

New Step Up Tier 5 Adding Credit

The Exchange proposes to adopt a new ''Step Up Tier 5 Adding Credit'' that would offer incremental credits for providing displayed liquidity to the Exchange in Tape A securities.

As proposed, the Exchange would provide incremental credits in Tape A securities for all orders, other than MPL and Non-Displayed Limit Orders, from a qualifying member organization's market participant identifier (''MPID'') or mnemonic if the member organization has Adding ADV, excluding any liquidity added by a Designated Market Maker (''DMM''), that is at least 1.00% of Tape A CADV,[9] and if the MPID or mnemonic has an Adding ADV as a percentage of Tape A

[4] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37495, 37499 (June 29, 2005) (S7–10–04) (Final Rule) (''Regulation NMS'').

[5] *See* Securities Exchange Act Release No. 61358, 75 FR 3594, 3597 (January 21, 2010) (File No. S7–02–10) (Concept Release on Equity Market Structure).

[6] *See* Cboe Global Markets, U.S. Equities Market Volume Summary, available at *http://markets.cboe.com/us/equities/market_share/. See generally https://www.sec.gov/fast-answers/divisionsmarketregmrexchangesshtml.html.*

[7] *See* FINRA ATS Transparency Data, available at *https://otctransparency.finra.org/otctransparency/AtsIssueData.* A list of alternative trading systems registered with the Commission is *available at https://www.sec.gov/foia/docs/atslist.htm.*

[8] *See* Cboe Global Markets U.S. Equities Market Volume Summary, available at *http://markets.cboe.com/us/equities/market_share/.*

[9] The terms ''ADV'' and ''CADV'' are defined in footnote * of the Price List.

CADV, excluding any liquidity added by a DMM, that is:

• At least two times more than that MPID's or mnemonic's Adding ADV in January 2021 (''Baseline Month'') as a percentage of Tape A CADV, and

• at least 0.10% of Tape A CADV over that MPID's or mnemonic's Adding ADV in in the Baseline Month as a percentage of Tape A CADV.

A member organizations that meets the above requirements would receive a $0.0001 incremental credit for an increase of at least 0.10% and less than 0.175% of Tape A CADV over the Baseline Month. Member organizations would receive a $0.0002 incremental credit for an increase of at least 0.175% of Tape A CADV over the Baseline Month.

For example, assume a member organization has an Adding ADV as a percentage of Tape A CADV of 1.10% in the billing month, and qualified for an Adding Tier 2 credit of $0.0020 per share. Further assume that one of the member organization's MPIDs, MPID1, had an Adding ADV of 0.25% of Tape A CADV. Further assume that MPID1 has an Adding ADV of 0.10% in the Baseline Month. Because that MPID1's Adding ADV was 2.5 times its Baseline Month with a step up of 0.15%, MPID1 would qualify for an incremental credit of $0.0001, for a combined credit of $0.0021, based on the member organization's Adding Tier 2 credit.

If in the following billing month the member organization again had an Adding ADV as a percentage of Tape A CADV of 1.10%, and MPID1 had an Adding ADV of 0.30% of Tape A CADV, for step up in Adding ADV of 0.20% of Tape A CADV, MPID 1 would qualify for an incremental credit of $0.0002, for a combined credit of $0.0022 based on the member organization's Adding Tier 2 credit. If in the third billing month, the member organization had an Adding ADV as a percentage of Tape A CADV of 0.95%, MPID1would not qualify for the Adding Step Up 5 as the member organization's Adding ADV was below the 1.0% requirement.

The purpose of this proposed change is to incentivize member organizations to increase the liquidity-providing orders in the Tape A securities they send to the Exchange, which would support the quality of price discovery on the Exchange and provide additional liquidity for incoming orders. As noted above, the Exchange operates in a competitive environment, particularly as it relates to attracting non-marketable orders, which add liquidity to the Exchange. Because the proposed tier requires a member organization's MPID or mnemonic to increase the volume of its trades in orders that add liquidity over that MPID or mnemonic's January 2021 Adding ADV baseline, the Exchange believes that the proposed credits would provide an incentive for all member organizations to send additional liquidity to the Exchange in order to qualify for them. The Exchange does not know how much order flow member organizations choose to route to other exchanges or to off-exchange venues. Based on the profile of liquidity-adding firms generally, the Exchange believes that additional member organizations could qualify for the tiered rate under the new qualification criteria if they choose to direct order flow to, and increase quoting on, the Exchange. However, without having a view of member organization's activity on other exchanges and off-exchange venues, the Exchange has no way of knowing whether this proposed rule change would result in any member organization directing orders to the Exchange in order to qualify for the new tier.

Incremental SLP Step Up Tier

Pursuant to the Incremental SLP Step Up Tier, the Exchange currently provides an incremental credit to a SLP in addition to the SLP's tiered or non-tiered credit for adding displayed liquidity if the SLP (1) meets the 10% average or more quoting requirement in an assigned security pursuant to Rule 107B (quotes of an SLP-Prop and an SLMM of the same member organization shall not be aggregated) (the ''Quoting Requirement''), and (2) adds liquidity for all assigned SLP securities in the aggregate (including shares of both an SLP-Prop and an SLMM of the same or an affiliated member organization) in the billing month over the SLP's adding liquidity for all assigned SLP securities in the aggregate (including shares of both an SLP-Prop and an SLMM of the same or an affiliated member organization) as a percent of NYSE CADV in the second quarter of 2018 or the third quarter of 2018, whichever is lower, as follows:

• SLPs that (1) meet the Quoting Requirement, and (2) add liquidity for all assigned SLP securities in the aggregate (including shares of both an SLP- Prop and an SLMM of the same or an affiliated member organization) of an ADV of more than 0.10% of NYSE CADV in the billing month over the SLP's adding liquidity for all assigned SLP securities in the aggregate (including shares of both an SLP-Prop and an SLMM of the same or an affiliated member organization) as a percent of NYSE CADV in the second quarter of 2018 or the third quarter of 2018, whichever is lower, receive an incremental credit of $0.0001 per share.

• SLPs that (1) meet the Quoting Requirement, and (2) add liquidity for all assigned SLP securities in the aggregate (including shares of both an SLP-Prop and an SLMM of the same or an affiliated member organization) of an ADV of more than 0.15% of NYSE CADV in the billing month over the SLP's adding liquidity for all assigned SLP securities in the aggregate (including shares of both an SLP-Prop and an SLMM of the same or an affiliated member organization) as a percent of NYSE CADV in the second quarter of 2018 or the third quarter of 2018, whichever is lower, receive an incremental credit of $0.0002 per share.

• SLPs that (1) meet the Quoting Requirement, and (2) add liquidity for all assigned SLP securities in the aggregate (including shares of both an SLP-Prop and an SLMM of the same or an affiliated member organization) of an ADV of more than 0.25% of NYSE CADV in the billing month over the SLP's adding liquidity for all assigned SLP securities in the aggregate (including shares of both an SLP-Prop and an SLMM of the same or an affiliated member organization) as a percent of NYSE CADV in the second quarter of 2018 or the third quarter of 2018, whichever is lower, receive an incremental credit of $0.0003 per share.

SLPs can only qualify for one of the three credits in a billing month. Further, the combined SLP credits are currently capped at $0.0032 per share in a billing month.

The Exchange proposes to modify the second prong of the Incremental SLP Step Up Tier by adopting an alternative qualification basis for SLPs to qualify for the incremental credit. As proposed, SLPs would continue to qualify for the one of the incremental credits if the SLP adds liquidity for all assigned SLP securities in the aggregate (including shares of both an SLP-Prop and an SLMM of the same or an affiliated member organization) of an ADV of more than 0.10%, 0.15%, or 0.25% of NYSE CADV in the billing month over the SLP's adding liquidity for all assigned SLP securities in the aggregate (including shares of both an SLP-Prop and an SLMM of the same or an affiliated member organization) as a percent of NYSE CADV in either the second quarter of 2018, the third quarter of 2018 or the month of January 2021, whichever is lowest.

The proposed change, which would allow the Exchange to use the lowest or more favorable (to the SLP) of the three baseline benchmarks, is intended to

allow a greater number of SLPs to qualify for the incremental credits.

The proposed changes are not otherwise intended to address other issues, and the Exchange is not aware of any significant problems that market participants would have in complying with the proposed changes.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[10] in general, and furthers the objectives of Sections 6(b)(4) and (5) of the Act,[11] in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Proposed Change Is Reasonable

As discussed above, the Exchange operates in a highly competitive market. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [12] While Regulation NMS has enhanced competition, it has also fostered a ''fragmented'' market structure where trading in a single stock can occur across multiple trading centers. When multiple trading centers compete for order flow in the same stock, the Commission has recognized that ''such competition can lead to the fragmentation of order flow in that stock.'' [13]

New Step UP Tier 5 Adding Credit

The new proposed Step Up Tier 5 Adding Credit is reasonable. Specifically, the Exchange believes that the proposed Step Up Tier 5 Adding Credit would provide an incentive for member organizations to send additional liquidity providing orders to the Exchange in Tape A securities. As noted above, the Exchange operates in a highly competitive environment, particularly for attracting non-marketable order flow that provides liquidity on an exchange.

The Exchange believes that requiring member organization to have Adding ADV, excluding any liquidity added by a DMM, that is at least 1.00% of Tape A CADV, and if the MPID or mnemonic has an Adding ADV as a percentage of Tape A CADV, excluding any liquidity added by a DMM, that is at least two times more than that MPID's or mnemonic's Adding ADV in January 2021 as a percentage of Tapes A CADV, and at least 0.10% of Tape A CADV over that MPID's or mnemonic's Adding ADV in in January 2021 as a percentage of Tape A CADV, in order to qualify for the proposed Step Up Tier 5 Adding Credit is reasonable because it would encourage additional displayed liquidity on the Exchange and because market participants benefit from the greater amounts of displayed liquidity present on the Exchange. Further, the Exchange believes it's reasonable to provide a $0.0001 incremental credit to the qualifying MPID or mnemonic for an increase of at least 0.10% and less than 0.175% of Tape A CADV or a $0.0002 incremental credit if an increase of at least 0.175% of Tape A CADV because this would encourage individual MPIDs or mnemonics of a member organization to send orders that provide liquidity to the Exchange, thereby contributing to robust levels of liquidity, which benefits all market participants, and promoting price discovery and transparency. Since the proposed Step Up Tier 5 would be new with a step up requirement, no member organization's MPID or mnemonic currently qualifies for the proposed pricing tier. As previously noted, without a view of member organization activity on other exchanges and off-exchange venues, the Exchange has no way of knowing whether the proposed rule change would result in any member organization's MPID or mnemonic qualifying for the tier. The Exchange believes the proposed credit is reasonable as it would provide an additional incentive for member organization's MPID or mnemonic to direct their order flow to the Exchange and provide meaningful added levels of liquidity in order to qualify for the higher credit, thereby contributing to depth and market quality on the Exchange.

Incremental SLP Step Up Tier

The Exchange believes that providing an additional way to qualify for the Incremental SLP Step Up Tier is reasonable because it would encourage additional liquidity on the Exchange and because members and member organizations benefit from the substantial amounts of liquidity that are present on the Exchange. The Exchange believes the proposed change to adopt an alternate baseline benchmark for the Incremental SLP Step Up Tier is reasonable because it provides existing SLPs (including SLPs that are also DMMs) with added incentive to bring additional order flow to a public market. In particular, the Exchange believes that making a third alternate baseline benchmark available to SLPs would provide SLPs with an increased opportunity to qualify for the incremental credit, and would continue to provide an incentive for SLPs to add liquidity to the Exchange, to the benefit of the investing public and all market participants.

The Proposal Is an Equitable Allocation of Fees

New Step UP Tier 5 Adding Credit

The Exchange believes that the proposed Step Up Tier 5 is equitable because the magnitude of the additional credit is less than the current Step Up Tier 2 credit in Tape A securities.

The Exchange believes the proposed rule change would improve market quality for all market participants on the Exchange and, as a consequence, attract more liquidity to the Exchange, thereby improving market wide quality and price discovery. Since the proposed Step Up Tier 5 would be new and includes a step up Adding ADV requirement, no member organization's MPID or mnemonic currently qualifies for it. As noted, without a view of member organization activity on other exchanges and off-exchange venues, the Exchange has no way of knowing whether this proposed rule change would result in any member organization's MPID or mnemonic qualifying for the tier. The Exchange believes the proposed credit is reasonable as it would provide an additional incentive for member organization's MPID or mnemonic to direct their order flow to the Exchange and provide meaningful added levels of liquidity in order to qualify for the credit, thereby contributing to depth and market quality on the Exchange. The proposal neither targets nor will it have a disparate impact on any particular category of market participant. All member organization's MPID or mnemonic that provide liquidity could be eligible to qualify for the credit proposed in Step Up Tier 5 if they increase their Adding ADV over

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(4) & (5).

[12] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37495, 37499 (June 29, 2005) (S7–10–04) (Final Rule) (''Regulation NMS'').

[13] *See* Securities Exchange Act Release No. 61358, 75 FR 3594, 3597 (January 21, 2010) (File No. S7–02–10) (Concept Release on Equity Market Structure).

their own baseline of order flow and the member organization meets the 1.0% Adding ADV of Tape CADV requirement. The Exchange believes that offering a step up credit for providing liquidity if the step up requirements for Tape A securities are met will continue to attract order flow and liquidity to the Exchange, thereby providing additional price improvement opportunities on the Exchange and benefiting investors generally. As to those market participants that do not presently qualify for the adding liquidity credits, the proposal will not adversely impact their existing pricing or their ability to qualify for other credits provided by the Exchange.

Incremental SLP Step Up Tier

The Exchange believes its proposal to offer an alternative way for member organizations to qualify for the Incremental SLP Step Up Tier equitably allocates its fees among its market participants. The Exchange is not proposing to adjust the amount of the Incremental SLP Step Up Tier, which will remain at the current level for all market participants. Rather, by providing an additional alternative way for member organizations to qualify for the adding credit, the proposal would continue to encourage member organizations to send orders that provide liquidity to the Exchange, thereby contributing to robust levels of liquidity, which benefits all market participants, and promoting price discovery and transparency. The proposed changes would also encourage the submission of additional liquidity to a national securities exchange, thereby promoting price discovery and transparency and enhancing order execution opportunities for member organizations from the substantial amounts of liquidity that are present on the Exchange. The proposed changes would also encourage the submission of additional orders that add liquidity, thus providing price improving liquidity to market participants and increasing the quality of order execution on the Exchange's market, which would benefit all market participants. Moreover, the proposed changes are equitable because they would apply equally to all qualifying SLPs that submit orders to the NYSE and add liquidity to the Exchange.

The Proposal Is Not Unfairly Discriminatory

New Step Up Tier 5 Adding Credit

The Exchange believes it is not unfairly discriminatory to provide an additional per share step up credit, as the proposed credit would be provided on an equal basis to all member organizations and their MPIDs or mnemonics that add liquidity by meeting the new proposed Step Up Tier 5's requirements and would equally encourage all member organizations and their MPIDs or mnemonics to provide additional displayed liquidity on the Exchange. As noted, the Exchange believes that the proposed credit would provide an incentive for member organizations and their MPIDs or mnemonics to send additional liquidity to the Exchange in order to qualify for the additional credits. The Exchange also believes that the proposed change is not unfairly discriminatory because it is reasonably related to the value to the Exchange's market quality associated with higher volume. Finally, the submission of orders to the Exchange is optional for member organizations and their MPIDs or mnemonics in that they could choose whether to submit orders to the Exchange and, if they do, the extent of its activity in this regard.

Incremental SLP Step Up Tier

The Exchange believes its proposal to offer an alternative way for member organizations to qualify for the Incremental SLP Step Up Tier is not unfairly discriminatory because the proposal would be provided on an equal basis to all member organizations that add liquidity by meeting the new proposed alternative requirements, who would all be eligible for the same credit on an equal basis. Accordingly, no member organization already operating on the Exchange would be disadvantaged by this allocation of fees. The proposal neither targets nor will it have a disparate impact on any particular category of market participant. The proposal does not permit unfair discrimination because the qualification criteria would be applied to all similarly situated member organizations, who would all be eligible for the same credit on an equal basis. Finally, as noted, the Exchange believes the proposal would provide an incentive for member organizations to continue to send orders that provide liquidity to the Exchange, to the benefit of all market participants.

For the foregoing reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[14] the Exchange believes that the proposed rule change would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Instead, as discussed above, the Exchange believes that the proposed changes would encourage the submission of additional liquidity to a public exchange, thereby promoting market depth, price discovery and transparency and enhancing order execution opportunities for member organizations. As a result, the Exchange believes that the proposed change furthers the Commission's goal in adopting Regulation NMS of fostering integrated competition among orders, which promotes ''more efficient pricing of individual stocks for all types of orders, large and small.'' [15]

Intramarket Competition. The proposed changes are designed to attract additional order flow to the Exchange. The Exchange believes that the proposed changes would continue to incentivize market participants to direct displayed order flow to the Exchange. Greater liquidity benefits all market participants on the Exchange by providing more trading opportunities and encourages member organizations to send orders, thereby contributing to robust levels of liquidity, which benefits all market participants on the Exchange. The current credits would be available to all similarly-situated market participants, and, as such, the proposed change would not impose a disparate burden on competition among market participants on the Exchange. As noted, the proposal would apply to all similarly situated member organizations on the same and equal terms, who would benefit from the changes on the same basis. Accordingly, the proposed change would not impose a disparate burden on competition among market participants on the Exchange.

Intermarket Competition. The Exchange operates in a highly competitive market in which market participants can readily choose to send their orders to other exchange and off-exchange venues if they deem fee levels at those other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees and rebates to remain competitive with other exchanges and with off-exchange venues. Because competitors are free to modify their own fees and credits in response, and because market participants may readily adjust their order routing practices, the Exchange does not believe its proposed fee change can impose any burden on intermarket competition.

[14] 15 U.S.C. 78f(b)(8).

[15] Regulation NMS, 70 FR at 37498–99.

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

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A) [16] of the Act and subparagraph (f)(2) of Rule 19b–4 [17] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of such 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 under Section 19(b)(2)(B) [18] of the Act 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–NYSE–2021–11 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–NYSE–2021–11. 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–NYSE–2021–11 and should be submitted on or before March 12, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2021–03340 Filed 2–18–21; 8:45 am]

BILLING CODE 8011–01–P

[16] 15 U.S.C. 78s(b)(3)(A).

[17] 17 CFR 240.19b–4(f)(2).

[18] 15 U.S.C. 78s(b)(2)(B).

[19] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–91128]

Order Extending the Annual Reports Filing Deadline for Certain Smaller Broker-Dealers

February 12, 2021.

I. Introduction

Broker-dealers registered with the U.S. Securities and Exchange Commission (''SEC'' or ''Commission'') are generally required to file with the Commission, within 60 calendar days after the end of the fiscal year of the broker-dealer, a financial report and either a compliance report or exemption report, along with reports prepared by an independent public accountant [1] covering the financial report and, as applicable, the compliance or exemption report (collectively the ''annual reports'').[2] Pursuant to paragraph (m)(3) of Exchange Act Rule 17a–5 (''Rule 17a–5''), the Financial Industry Regulatory Authority, Inc. (''FINRA'') has requested that the Commission extend by 30 calendar days the deadline for certain smaller broker-dealers to file the annual reports.[3] This order grants such an extension to certain smaller broker-dealers, subject to the conditions described in section III below.

II. Discussion

A. FINRA's Request

In a letter dated February 11, 2021, FINRA requested that the Commission issue an order pursuant to paragraph (m)(3) of Rule 17a–5 to extend by 30 calendar days the deadline for certain smaller broker-dealers to file their annual reports.[4] In FINRA's request, it indicated that it had been informed by smaller broker-dealers and auditors that permitting an additional 30 days for filing of the annual reports may help to reduce the burdens in obtaining audit services by providing an expanded time frame for the completion of such audits thereby easing the availability of auditors.[5] FINRA stated in the letter that the fiscal year for most broker-dealers ends on the last calendar day of the year (December 31), which results in the greatest demand for audit services in the 60 calendar days following that date. Further, much of the work required to complete these audits is performed after the broker-dealer files the final FOCUS Report (Form X–17A–5 Part II or IIA) for the audit year, which is due to be filed with the Commission 17 business days after the end of the prior month (*i.e.,* January 27 for broker-dealers with December 31 fiscal year ends). As a result, the required audit work is conducted within a compressed period when audit services are in greatest demand and the availability of independent public accountants and

[1] The independent public accountant must be qualified and independent in accordance with Rule 2–01 of Regulation S–X and must be registered with the Public Company Accounting Oversight Board (''PCAOB'') if required by the Sarbanes-Oxley Act of 2002 (''Sarbanes-Oxley Act''). *See* Public Law 107–204, 116 Stat. 745 (2002); 17 CFR 240.17a–5(f)(1).

[2] *See* 17 CFR 240.17a–5(d)(5).

[3] *See* 17 CFR 240.17a–5(m)(3) (stating that on written request of any national securities exchange, registered national securities association, broker-dealer, or on its own motion, the Commission may grant an extension of time or an exemption from any of the requirements of Rule 17a–5 either unconditionally or on specified terms and conditions).

[4] *See* Letter from Kris Dailey, Vice President, Office of Financial and Operational Risk Policy, FINRA to Michael A. Macchiaroli, Associate Director, SEC (February 11, 2021).

[5] *See id.* at 2.

other third-party professionals may be limited.

FINRA further identified a number of factors that compound the burden of smaller broker-dealers in preparing the annual reports and undergoing an audit of them. For example, the auditors of smaller broker-dealers typically do not perform interim audit work prior to the fiscal year end. Interim audit work typically includes the auditors testing items such as revenue, expenses, and internal controls. In addition, some smaller broker-dealers utilize outside professional and consulting services to assist them in preparing supporting materials for the audit and to respond to auditor requests. These outside professional and consulting service providers often have multiple smaller broker-dealer clients with the same fiscal year end. As a result, the service providers' may have a limited capacity during the audit period to provide their services to smaller broker-dealers. Furthermore, because many smaller broker-dealers do not have fully automated financial and operational recordkeeping and reporting infrastructures, they must rely on manual processes to prepare documents for the independent public accountant to audit or review, which can take additional time as compared to more automated processes.

FINRA also stated that some audit firms have chosen to forego registration with the PCAOB, resulting in fewer independent public accountants qualified under Rule 17a–5 to perform broker-dealer audits.[6] FINRA indicates that the additional 30 days to complete a smaller broker-dealer audit may alleviate capacity issues for PCAOB-registered auditors. FINRA stated that it has been informed by broker-dealers and auditors that the additional 30 days would help the limited number of PCAOB-registered auditors to perform the work necessary to complete reports covering them. FINRA stated the additional time could promote better quality of the annual reports.

B. FINRA's Proposed Conditions for the Requested Relief

FINRA proposed that the extension of 30 calendar days be made available only to broker-dealers that meet certain conditions. The first condition is that the broker-dealer must be in compliance with Exchange Act Rule 15c3–1 [7] (''Rule 15c3–1'') as of the date of its most recent fiscal year end. FINRA believes this condition is appropriate because the financial condition of a member that avails itself of the additional 30 days should not be such as to raise concerns about whether the member may continue to conduct its broker-dealer activities. The second condition is that as of the date of the broker-dealer's most recent fiscal year-end, the broker-dealer must have had total capital and allowable subordinated liabilities of less than $50 million, as reported in box 3530 of Part II or IIA of its FOCUS Report. FINRA believes this condition is appropriate because it helps to target the contemplated extension to the smaller firms that are in need of such relief. The third condition is that the extension be made available only to those broker-dealers eligible to file an exemption report as part of its most recent fiscal year end annual reports.[8] FINRA believes this condition is appropriate so as to ensure that the extension is only available to firms that, by virtue of their business activities, generally pose less risk to customers because they do not custody funds and securities. The fourth condition is that the broker-dealer submits written notification to FINRA of its intent to avail itself of the additional 30 calendar days for filing its annual reports on an ongoing basis for as long as it meets these conditions. FINRA believes that the notification is appropriate so as to enable FINRA to monitor effectively firms that avail themselves of the additional 30 days. The final condition is that the broker-dealer submits the annual reports electronically to the Commission using an appropriate process. FINRA believes this condition is appropriate because it permits greater efficiency and is consistent with SEC staff guidance.

C. Commission Analysis

According to FINRA, a smaller broker-dealer's window of time to prepare the annual reports and undergo an audit by an independent public accountant is often particularly compressed because much of the audit work does not commence until after the broker-dealer files its fiscal year-end FOCUS Report. According to FINRA, audit work for small broker-dealers is performed predominantly during the period of time between the due date for the fiscal year-end FOCUS Report (17 business days after the firm's fiscal year end) and the annual reports filing due date (60 calendar days after the fiscal year end). Further, according to FINRA, the auditors of smaller broker-dealers do not typically perform interim audit work prior to the broker-dealer's fiscal year end, unlike most larger broker-dealers. The lack of this interim audit work, which typically includes the testing of items such as revenue, expenses, and internal controls, compresses the time auditors have to perform required procedures in advance of the filing deadline. This also restricts the time frame for smaller broker-dealers and their auditors to identify and resolve issues.

Moreover, according to FINRA, many smaller broker-dealers use manual processes to prepare supporting documentation for the audit or review and respond to auditor inquiries, rather than the more automated processes typically used by larger broker-dealers. This can make the work necessary to prepare the annual reports and audit them more labor intensive and time consuming. In addition, according to FINRA, some smaller broker-dealers retain third-party professionals to assist them with their financial reporting. These professionals often provide services to multiple smaller broker-dealers with the same fiscal year end, resulting in these professionals having limited capacity during the relatively brief period between the FOCUS Report filing due date and the annual reports filing due date. These professionals' limited capacity can further compress the timeframe for performing the work necessary to prepare the annual reports.

[6] In its 2012 Annual Report on the Interim Inspection Program Related to the Audits of Brokers and Dealers (''Annual Inspection Report''), the PCAOB reported that there were 783 registered public accounting firms. In the 2019 Annual Inspection Report, that figure had declined to 411. *See* PCAOB, Information for Auditors of Broker-Dealers, *available at https://pcaobus.org/Pages/BrokerDealers.aspx.*

[7] *See* 17 CFR 240.15c3–1.

[8] *See* 17 CFR 240.17a–5(d)(1)(i)(B) (prescribing whether a broker-dealer must file the compliance report or the exemption report). A broker-dealer must file an exemption report if the firm claimed it was exempt from Rule 15c3–3 (17 CFR 240.15c3–3) throughout the most recent fiscal year and was not subject to paragraph (p) of Rule 15c3–3 (which addresses segregation requirements with respect to security-based swaps). Otherwise, the broker-dealer must file the compliance report. *See also Broker-Dealer Reports,* Exchange Act Release No. 70073 (July 30, 2013), 78 FR 51910, 51915 (Aug. 21, 2013) n. 74 (stating that a broker-dealer should file an exemption report if it has not held customer securities or funds during the fiscal year even if it does not fit into one of the exemption provisions of Rule 15c3–3 identified on the FOCUS Report).

See also Frequently Asked Questions Concerning the July 30, 2013 Amendments to the Broker-Dealer Financial Reporting Rule (updated July 1, 2020) (describing the Division and Trading and Markets staff's views regarding the eligibility of certain broker-dealers to file exemption reports in accordance with the circumstances described in footnote 74 of the 2013 *Broker-Dealer Reports* release, among other things). Staff statements, including Frequently Asked Questions, represent the views of the staff. They are not rules, regulations, or statements of the Commission. The Commission has neither approved nor disapproved their content. These staff statements, like all staff guidance, have no legal force or effect: They do not alter or amend applicable law, and they create no new or additional obligations for any person.

Paragraph (m)(3) of Rule 17a–5 provides that the Commission may grant an extension of time for broker-dealers to file their annual reports. After considering the points raised in FINRA's letter and the burdens faced by smaller broker-dealers in preparing and filing the annual reports, the Commission believes that it would be appropriate to extend the deadline for certain smaller broker-dealers to file their annual reports by 30 calendar days.[9] This additional time should expand the timeframe (from slightly more than one month) between the deadline for submitting the fiscal year-end FOCUS Report and the deadline to file the annual reports (*i.e.,* the timeframe in which much of the work is performed to prepare the annual reports). To the extent auditors are able to better focus on the audit and review of annual reports for the small broker-dealer clients who avail themselves of the extension, this relief could help promote quality financial reporting.

The Commission further believes it is appropriate to limit this relief to broker-dealers meeting the conditions described in FINRA's request, which should also maintain investor protections. Conditioning the extension on the broker-dealer being in compliance with the net capital requirements of Rule 15c3–1 as of the date of its fiscal year end is appropriate because a broker-dealer that is not in compliance with the rule poses a heightened risk to its customers and other securities market participants because of its financial condition. Excluding a net capital-deficient broker-dealer from this relief will assist the Commission and the broker-dealer's designated examining authority to monitor the financial condition of the firm on a timely basis, including analyzing whether the firm will be able to continue as a going concern. Therefore, a broker-dealer with a net capital deficiency will not be able to avail itself of the additional 30 days provided for in this Order.

The Commission also believes it is appropriate to limit the availability of the extension to smaller broker-dealers. As discussed above, the extension could alleviate unique burdens associated with the compressed timeframe for smaller broker-dealers to prepare their annual reports and their independent public accountants to perform the audit work necessary to prepare reports covering them. Moreover, broker-dealers that conduct a substantial securities business and thus are in a position to potentially pose significant risk to investors and to the fair, orderly, and efficient functioning of the markets, will not be eligible for the extension. Therefore, the Commission is limiting the relief to broker-dealers that have total capital and allowable subordinated liabilities of less than $50 million, as requested by FINRA. Broker-dealers falling below the $50 million threshold constitute approximately 3% of the total capital of all broker-dealers. The Commission believes that the $50 million threshold is appropriate in this context because smaller broker-dealers pose less significant risks to the fair, orderly, and efficient functioning of the markets.

Broker-dealers that maintain custody of customer securities and cash are not eligible to file exemption reports and are generally larger in size than broker-dealers that do not carry customer accounts. The Commission believes firms that file an exemption report—because of their relative size and the fact that they do not hold customer funds or securities, or owe money or securities to customers and do not carry customer accounts, or are exempt from Rule 15c3–3 pursuant to paragraph (k)(2) of that rule—present less risk to customers. Therefore, a broker-dealer must be permitted to file an exemption report as part of the annual reports to qualify for the relief. Based upon information included in broker-dealers' FOCUS Reports, the Commission believes that approximately 3,000 of the 3,620 broker-dealers registered with the Commission would meet the $50 million threshold and exemption report filing conditions.

The Commission believes that it is appropriate to make the 30-day extension available only to broker-dealers that have provided written notice to their designated examining authority of their intent to avail themselves of the extension. The designated examining authority is responsible for oversight of broker-dealers' adherence to the financial responsibility rules, including Rule 17a–5. This requirement will allow the broker-dealer's designated examining authority to more effectively monitor firms by enabling it to distinguish between broker-dealers that are filing their annual reports late as opposed to firms availing themselves of the relief in this Order.

Finally, the Commission believes it is appropriate to limit the availability of the relief in this order to broker-dealers that file the annual reports electronically with the Commission using an appropriate process.[10] The electronic filing condition promotes efficiency by ensuring broker-dealers that rely on the 30-day extension will have their annual reports made available to Commission staff and to the public more quickly than if they had been filed in paper within the deadline provided in Rule 17a–5. Paper filings must be manually processed, which is time consuming and delays the availability of annual reports to the staff of the Commission and to the public. By comparison, annual reports that are filed electronically need minimal or no manual processing. Therefore, to help ensure the annual reports are made promptly available, the Commission is conditioning the relief on electronic filing.

III. Conclusion

It is hereby ordered pursuant to section 17(a)(1) of the Exchange Act and paragraph (m)(3) of Rule 17a–5 thereunder that the deadline in paragraph (d)(5) of Rule 17a–5 for filing the annual reports is extended by 30 calendar days, provided that the broker-dealer:

(1) As of its most recent fiscal year end:

a. Was in compliance with Rule 15c3–1; and

b. Had total capital and allowable subordinated liabilities of less than $50 million, as reported in box 3530 of Part II or Part IIA of its FOCUS Report;

(2) Is permitted to file an exemption report as part of its most recent fiscal year end annual reports;

(3) Submits written notification to its designated examining authority of its intent to rely on this order on an ongoing basis for as long as it meets the conditions of the order; and

[9] FINRA requested relief on behalf of its member broker-dealers. This Order extends relief to all broker-dealers satisfying its conditions in order to treat similarly situated broker-dealers equally regardless of whether they are FINRA members.

[10] The Commission notes that the staff of the Division of Trading and Markets has previously issued no-action positions related to the electronic filing of broker-dealer annual reports. *See* Letter to Kris Daily, Vice President, FINRA from Michael A. Macchiaroli, Associate Director, Commission, dated January 27, 2017. Available at *https://www.sec.gov/divisions/marketreg/mr-noaction/2017/finra-012717-electronic-filing-annual-reports.pdf.* For further instructions relating to filing broker-dealer annual reports through EDGAR, *see Electronic Filing of Broker-Dealer Annual Reports.* Available at *https://www.sec.gov/divisions/marketreg/electronic-filing-broker-dealer-annual-reports.htm.*

See also Updated Division of Trading and Markets Staff Statement Regarding Requirements for Certain Paper Submissions in Light of COVID–19 Concerns. Available at *https://www.sec.gov/tm/paper-submission-requirements-covid-19-updates-061820.*

Staff statements represent the views of the staff. They are not rules, regulations, or statements of the Commission. The Commission has neither approved nor disapproved their content. These staff statements, like all staff guidance, have no legal force or effect: They do not alter or amend applicable law, and they create no new or additional obligations for any person.

(4) Files the annual report electronically with the Commission using an appropriate process.

By the Commission.

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2021–03353 Filed 2–18–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–91125; File No. SR–BX–2020–032]

Self-Regulatory Organizations; Nasdaq BX, Inc.; Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of Proposed Rule Change, as Modified by Amendment No. 1, To Amend Options 4, Section 5, To Limit Short Term Options Series Intervals Between Strikes That Are Available for Quoting and Trading on BX

February 12, 2021.

I. Introduction

On November 6, 2020, Nasdaq BX, Inc. (''BX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend Options 4, Section 5, ''Series of Options Contracts Open for Trading'' to limit Short Term Options Series intervals between strikes which are available for quoting and trading on BX. The proposed rule change was published for comment in the **Federal Register** on November 16, 2020.[3] On December 23, 2020, pursuant to Section 19(b)(2) of the Act,[4] the Commission extended the time period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to approve or disapprove the proposed rule change, to February 14, 2021.[5] On February 10, 2021, the Exchange filed Amendment No. 1 to the proposed rule change, which replaced and superseded the proposed rule change in its entirety.[6] The Commission is publishing this notice to solicit comments on the proposed rule change, as modified by Amendment No. 1, from interested persons, and is approving the proposed rule change, as modified by Amendment No. 1, on an accelerated basis.

II. Description of the Proposed Rule Change

Currently, under the Short Term Options Series (''STOS'') program (also referred to as the ''weekly series'' or ''weeklies''), BX may open for trading on a Thursday or Friday (''Short Term Option Opening Date'') a series of options that expires on each of the next five Fridays that are business days and are not Fridays in which monthly options series or Quarterly Options series expire (''Short Term Option Expiration Dates'').[7] Weeklies currently may have strike price intervals of $0.50, $1, or $2.50.[8]

In the proposed rule change, as modified by Amendment No. 1, the Exchange proposes to amend its STOS Program to increase, and thereby limit, the intervals between strikes in multiply listed equity options (excluding options on Exchange Traded Funds (''ETFs'') and Exchange Traded Notes (''ETNs'')) under the STOS program for those weeklies that have an expiration date more than twenty-one days from the listing date.[9] Accordingly, the proposal seeks to reduce the number of strikes in the weeklies furthest from expiration.

Specifically, the new applicable strike intervals will be as follows: [10]

Tier	Customer-range options average daily volume	Underlying share price				
		Less than $25	$25 to less than $75	$75 to less than $150	$150 to less than $500	$500 or greater
1	greater than 5,000	$0.50	$1.00	$1.00	$5.00	$5.00
2	1,000 to 5,000	1.00	1.00	1.00	5.00	10.00
3	0 to 1,000	2.50	5.00	5.00	5.00	10.00

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 90384 (November 9, 2020), 85 FR 73113 (November 16, 2020) (''Notice''). Comments on the proposed rule change can be found at *https://www.sec.gov/comments/sr-bx-2020-032/srbx2020032.htm.*

[4] 15 U.S.C. 78s(b)(2).

[5] *See* Securities Exchange Act Release No. 90796 (December 23, 2020), 85 FR 86590 (December 30, 2020).

[6] In Amendment No. 1, the Exchange: (1) Stated that the proposed changes in Supplementary Material .07 of Options 4, Section 5 supersede Supplementary Material .03(d) and that the Exchange will not be able to utilize the rule text within Supplementary Material .03(d) to permit additional series to be opened for trading on the Exchange that have an expiration date more than twenty-one days from the listing date despite the noted circumstances when such additional series could otherwise be added; (2) clarified how a Short Term Option Opening Date is calculated when the Exchange is not open for business on the applicable Thursday or Friday; (3) provided that that Short Term Options Series that are newly eligible for listing pursuant to Options 4, Section 3(a) will not be subject to proposed Supplementary Material .07 until after the end of the first full calendar quarter following the date the option class was first listed for trading on any options market; (4) discussed additional data underlying its proposal; (5) proposed to make publically available a report on a quarterly basis that indicates, for each Short Term Options Series eligible to be listed under proposed Supplementary Material .07 of Options 4, Section 5, the applicable tiering, which includes the closing price of the underlying, and the average daily Customer volume of the option; and (6) changed its implementation timeframe for the proposed rule change from prior to March 31, 2021 to prior to June 30, 2021. When the Exchange filed Amendment No. 1, it also submitted it as a comment to the filing so that the text of Amendment No. 1 promptly became available at *https://www.sec.gov/comments/sr-bx-2020-032/srbx2020032-8359799-229182.pdf.*

[7] *See* Supplementary Material .03 of Options 4, Section 5. There are limits on the number of series that can participate in STOS (*i.e.,* 30 initial series and up to 50 currently listed classes). *See* Supplementary Material .03 of Options 4, Section 5(c). In addition to the weeklies, the Exchange may list series of options for trading with monthly expirations (that expire on the third Friday of the month) or quarterly expirations. *See* Options 4, Section 5(g) and Supplementary Material .04 of Options 4, Section 5, respectively. Exchange rules set forth the intervals between strike prices of series of options on individual stocks, which generally are $2.50, $5, and $10. In addition to those intervals, the Exchange may list certain series of options in finer increments, including, *e.g.,* pursuant to the $1 Strike Price Interval Program (Supplementary Material .01 of Options 4, Section 5) and the $0.50 Strike Program (Supplementary Material .05 of Options 4, Section 5).

[8] Specifically, (i) $0.50 or greater where the strike price is less than $100, and $1 or greater where the strike price is between $100 and $150 for all option classes that participate in the Short Term Options Series Program; (ii) $0.50 for option classes that trade in one dollar increments and are in the Short Term Options Series Program; or (iii) $2.50 or greater where the strike price is above $150. *See* Amendment No. 1, *supra* note 6, at 34.

[9] The proposal does not apply to index options.

[10] The table supersedes Supplementary Material .03(d), which currently permits additional series to be opened for trading on the Exchange when the Exchange deems it necessary to maintain an orderly market, to meet customer demand, or when the market price of the underlying security moves substantially from the exercise price or prices of the series already opened. As a result, the Exchange will not be able to utilize the rule text within Supplementary Material .03(d) to permit additional series to be opened for trading on BX that have an expiration date more than twenty-one days from the listing date despite the noted circumstances when such additional series could otherwise be added.

As shown in the table, the proposal sets the strike increment for those weekly series with an expiration date of more than twenty-one days from the listing date (*e.g.,* weeks 4 and 5) through a matrix of 15 possible choices representing 5 different strike intervals (*i.e.,* $0.50, $1, $2.50, $5, or $10). The Exchange will determine the applicable strike interval through a combination of two factors: (1) The Customer-cleared average daily volume (''ADV'') tier for the option over the applicable quarter [11] and (2) the closing share price of the underlying stock on its primary market on the last day of the calendar quarter.

The Exchange states that STOS comprise a significant portion of listed options, as the weekly strikes increased at a 8.9% compound annual growth rate (''CAGR'') from 2015 to 2020, compared to a 4.3% CAGR for standard expirations using 3rd Friday expirations. Weeklies are available on 16% of underlying products, and weeklies with an expiration date greater than twenty-one days from the listing date account for 7.5% of the total number of strikes in the options market, equaling approximately 81,000 strikes.[12]

In its filing, the Exchange explains that it chose to use OCC Customer-cleared volume because the Exchange believes it represents a measure of customer demand, including for the weekly series.[13] Under the proposal, higher customer demand results in a tier that corresponds to a more granular strike interval (*e.g.,* $0.50 instead of $2.50).

The Exchange further explains that its proposal seeks to reduce the number of strikes in the furthest weekly options series, which the Exchange believes typically have wider markets and lower market quality.[14] The Exchange's proposal imposes more distanced strike intervals where the underlying stock has higher priced shares and where there is less customer volume as measured by the ADV tiers. Conversely, the proposal preserves finer strike intervals for options that have higher Customer ADV and lower priced underlying stocks.

BX also proposes to make publically and freely available a report on a quarterly basis that indicates, for each weekly series eligible to be listed under proposed Supplementary Material .07 of Options 4, Section 5, the applicable strike increment, the applicable closing price of the underlying stock sourced from the closing prices for Tape A, B and C securities published by the UTP and CTA/CQ Plans, and the applicable Customer ADV of the option sourced from OCC. BX will post the report by the close of business on the first trading day of the quarter.

The Exchange intends that its proposal will allow market makers to deploy capital more efficiently, while improving displayed market quality, by tailoring the granularity of strikes to correspond to the anticipated future customer demand for the option and the price of the underlying stock, thus reducing the number of listed weekly options in the later weeks of the STOS program.[15] The Exchange states that its proposal is responsive to concerns from industry members, including market makers, regarding the proliferation of strike prices.[16] The Exchange expects that its proposal will be the first step in a broader initiative to revisit the patchwork of strike listing rules.[17]

III. Discussion and Commission Findings

After careful review of the proposed rule change, as modified by Amendment No. 1, and the comment letters received on the proposal, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to national securities exchanges.[18] In particular, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with Section 6(b)(5) of the Act,[19] which requires that the rules of an exchange be designed, among other things, 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, and to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

The Commission received several comments expressing support for the proposed rule change.[20] Another commenter expressed general support for the goals of the proposal but suggested ideas to simplify and clarify the proposal.[21] In particular, that commenter recommends that the proposal be ''simplified in its application'' because it believes the ADV and underlying share price components could be ''unduly burdensome from an exchange operational perspective.'' [22] The commenter states that the proposal could ''create significant operational overhead with respect to implementing and maintaining this proposed strike listing regime'' but would only ''result in a limited strike reduction''.[23] Further, the commenter states that the proposal's ''complexity may also cause confusion among participants regarding permissible strikes.'' [24] As an alternative, the commenter suggests ''use of a single ADV component for classes to qualify for the STOS program'' such as 2,500 ADV.[25]

In response, the Exchange states that its proposal ''was not intended to amend the current STOS program'' but rather was to ''curtail certain strike intervals within STOS to avoid operational burdens to listing exchanges.'' [26] The Exchange believes that the commenter's suggested alternative ''may have a detrimental impact on of meeting customer demand in terms of the availability of STOS which are listed today.'' [27] The Commission believes the Exchange has

[11] The Customer-cleared ADV is the total number of options contracts traded in the Customer range in a given security for the applicable calendar quarter, divided by the number of trading days in the applicable calendar quarter. Beginning on the second trading day of each calendar quarter, the ADV will be calculated by using data from the prior calendar quarter based on volume cleared in the Customer range as reported by the Options Clearing Corporation (''OCC'').

[12] *See* Amendment No. 1, *supra* note 6, at 42.

[13] *See id.* at 22.

[14] *See id.* at 40–41, for the Exchange's data on average spreads in weekly options during the month of August 2020.

[15] *See id.* at 44.

[16] *See id.* at 45.

[17] *See id.* at 45–46.

[18] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[19] 17 U.S.C. 78f(b)(5).

[20] *See* Letters to Vanessa Countryman, Secretary, Commission, from Chris Halverson, Chairman of the Board, Security Traders Association and James Toes, President & CEO, Security Traders Association, dated December 9, 2020; from Joanna Mallers, Secretary, FIA Principal Traders Group, dated December 8, 2020; from Venu Palaparthi, Managing Director, Dash Financial Technologies LLC, dated December 7, 2020; from Andrew Stevens, General Counsel, IMC Chicago, LLC, dated December 7, 2020; from Joseph P. Kamnik, Chief Regulatory Counsel, Options Clearing Corporation, dated December 4, 2020; and from Ellen Greene, Managing Director, Equities & Options Market Structure, Securities Industry and Financial Markets Association, dated December 4, 2020.

[21] *See* Letter to Vanessa Countryman, Secretary, Commission, from Laura G. Dickman Vice President, Associate General Counsel, Cboe Exchange, Inc., dated February 1, 2021 (''Cboe Letter'').

[22] Cboe Letter, *supra* note 21 at 2.

[23] *Id.*

[24] *Id.*

[25] *Id.*

[26] *See* Letter to Vanessa Countryman, Secretary, Commission, from Kevin Kennedy, Senior Vice President, North American Markets, Nasdaq, Inc., dated February 10, 2021 (''BX Response''), at 1.

[27] *Id.*

addressed the commenter's concern. The Exchange's proposal, though modest in scope, is an attempt to rationalize strike listing rules in the furthest-out weekly series, which may serve as a starting point to a broader initiative to revisit, harmonize, and update the panoply of strike listing rules more broadly. The Exchange's proposal is but one of many possible alternative approaches that could address the same or similar goals. Nevertheless, the Exchange's proposal reflects its preferred approach, which the Commission finds is consistent with the Act.

The commenter also suggested certain aspects of the proposal that could be further clarified, including ''whether exceptions would apply to extremely active option classes or new options on equities that were subject to recent initial public offerings'' as such events ''often increase customer demand for more strikes, including at narrower intervals.'' [28] The commenter also suggested that the proposal be flexible to allow more granular strikes when ''necessary to maintain an orderly market, to meet customer demand, or when the market price of the underlying security moves substantially.'' [29]

In response, the Exchange proposed text in Amendment No. 1 to address the initial public offering situation by adding a 3-month curtailment period by which the new rule would not take effect for such options until after the end of the first full calendar quarter following the date the options class was first listed on any options market.[30] The Exchange states that the curtailment period will ''allow the initial customer demand to be met'' and ''price discovery to occur in the offering'' before the new strike intervals would apply in the further out weeklies.[31] Further, the Exchange added text in Amendment No. 1 to clarify that the proposal would not accommodate flexibility to add more granular strikes for stocks with volatile prices or in response to customer requests.[32] The Commission believes the Exchange has addressed the commenter's concerns. While the Exchange will not permit exceptions to its new rule, weeklies in the first few weeks are not impacted by the rule change, so the Exchange will continue to be able to list more granular strikes in those weeks as appropriate to meet customer demand in active classes or classes with volatile underlying stock prices.

Finally, the commenter states that ''exchanges should use quarterly ADV data from a centralized party when identifying classes subject to the strike interval limits to ensure fair and consistent application of the rule across the industry.'' [33] In response, the Exchange added detail in Amendment No. 1 to describe the report it will prepare and publicly post that details the applicable tier, Customer ADV, and closing price for each affected weekly series. The Exchange stated that the public availability of this report should ''provide consistency and relieve administrative burdens on other options markets'' who ''may elect to utilize [it] to validate their own information.'' [34] The Commission believes the Exchange has addressed the commenter's concerns. The Exchange will use OCC data to calculate the Customer ADV, which is available to all options exchanges, and will use the publicly-reported consolidated market data to determine the underlying share price, which also is available to all. Publishing each series subject to the new rule with its applicable strike increment, along with the inputs used to determine those increments, will promote transparency and certainty among all market participants of the application and effect of the Exchange's rule.

The Commission believes that the Exchange's proposal, as amended, promotes just and equitable principles of trade, fosters cooperation and coordination with persons engaged in facilitating transactions in securities, and removes impediments to and perfect the mechanism of a free and open market and a national market system. Specifically, the Commission believes that the Exchange's proposal to increase, and thus limit, the intervals between strikes listed under the STOS program that have an expiration date more than twenty-one days removes impediments to and perfects the mechanism of a free and open market and a national market system by seeking to strike an efficient balance between offering customers choice of appropriately granular strikes in less liquid weekly options with higher underlying stock prices and setting rational and consistent strike intervals that do not unduly burden the market makers that quote them, the broker-dealers and customers that view and trade them, or the infrastructure and systems that handle the transmission, processing, and dissemination of quotations, orders, and trades.

More efficient and better calibrated strike increment rules can have a positive impact on the options markets, as it can provide certainty, minimize confusion, and promote more efficient use of resources including among market makers that are obligated to continuously quote such series, all while still offering customers choice to meet their investment needs. The Exchange's proposal should eliminate certain clusters of relatively granular strikes in further out weekly series, whose characteristics (*e.g.,* risk properties) may closely resemble each other as a result of their close strike prices and length to time to expiration. Such clustering may not be necessary in less liquid further out weekly series where the price of the underlying stock is higher. The Exchange's proposal seeks to focus more granular strike increments on those series where they are more relevant, applicable, and likely more in demand from customers. Accordingly, the Exchange's proposal is designed to protect investors while also supporting market quality. For these reasons, the Commission finds that the proposed rule change is consistent with the Act.

IV. Solicitation of Comments on Amendment No. 1 to the Proposed Rule Change

Interested persons are invited to submit written data, views, and arguments concerning whether the proposal, as modified by Amendment No. 1, is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–BX–2020–032 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–BX–2020–032. 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

[28] Cboe Letter, *supra* note 21, at 3.

[29] *Id.*

[30] BX Response, *supra* note 26, at 2.

[31] *Id.*

[32] *Id.*

[33] Cboe Letter, *supra* note 21, at 3.

[34] BX Response, *supra* note 26, at 2.

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 this filing will also be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change.

Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BX–2020–032 and should be submitted on or before March 12, 2021.

V. Accelerated Approval of Proposed Rule Change, as Modified by Amendment No. 1

The Commission finds good cause to approve the proposed rule change, as modified by Amendment No. 1, prior to the thirtieth day after the date of publication of Amendment No. 1 in the **Federal Register**. In Amendment No. 1, the Exchange provided additional information to clarify and support the proposal, and did not materially change the substance of the proposal over what the Commission published in the **Federal Register**. Among other things, in the Amendment the Exchange committed to freely and publicly post a ''report'' in which it will detail the weekly series that it will list under the proposal, along with information on the applicable strike interval tier and the underlying Customer ADV and underlying share price values upon which it determined the applicable strike interval. That information should be useful to market participants, as well as other options exchanges, as it will provide transparency into how BX applied its rule and should remove any potential for confusion that could be presented by a lack of transparency into the applicable strike intervals BX will apply under the new rule. Further, the Exchange added detail to address when the new rule will apply to a new option (*e.g.,* an option on a recent initial public offering), which will provide certainty as to how the new rule applies in such cases. Accordingly, the Commission finds good cause, pursuant to Section 19(b)(2) of the Act,[35] to approve the proposed rule change, as modified by Amendment No. 1, on an accelerated basis.

VI. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[36] that the proposed rule change SR–BX–2020–032, as modified by Amendment No. 1 be, and hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[37]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2021–03342 Filed 2–18–21; 8:45 am]

BILLING CODE 8011–01–P

[35] 15 U.S.C. 78s(b)(2).

[36] 15 U.S.C. 78s(b)(2).

[37] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–91127; File No. SR–CBOE–2020–075]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Designation of a Longer Period for Commission Action on Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change, as Modified by Amendment No. 2, To Make Qualified Contingent Cross Orders Available for FLEX Option Trading

February 12, 2021.

On August 3, 2020, Cboe Exchange, Inc. 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 make Qualified Contingent Cross Orders available for FLEX option trading. The proposed rule change was published in the **Federal Register** on August 20, 2020.[3] On October 1, 2020, pursuant to Section 19(b)(2) of the Act,[4] the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.[5] On October 23, 2020, the Exchange submitted Amendment No. 1 to the proposed rule change, which replaced and superseded the proposed rule change as originally filed.[6] On November 18, 2020, the Commission instituted proceedings under Section 19(b)(2)(B) of the Act[7] to determine whether to approve or disapprove the proposed rule change, as modified by Amendment No. 1.[8] On February 2, 2021, the Exchange submitted Amendment No. 2 to the proposed rule change, which replaced and superseded the proposed rule change, as modified by Amendment No. 1.[9]

Section 19(b)(2) of the Act[10] provides that, after initiating proceedings, the Commission shall issue an order approving or disapproving the proposed rule change not later than 180 days after the date of publication of notice of filing of the proposed rule change. The Commission may extend the period for issuing an order approving or disapproving the proposed rule change, however, by not more than 60 days if the Commission determines that a longer period is appropriate and publishes the reasons for such determination. The proposed rule change was published for comment in the **Federal Register** on August 20, 2020.[11] The 180th day after publication of the Notice is February 16, 2021. The Commission is extending the time period for approving or disapproving the proposal for an additional 60 days.

The Commission finds that it is appropriate to designate a longer period within which to issue an order approving or disapproving the proposed rule change so that it has sufficient time to consider the proposed rule change, as modified by Amendment No. 2. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[12] designates April 17, 2021, as the date by which the Commission shall either approve or disapprove the proposed rule change (File Number SR–CBOE–2020–075), as modified by Amendment No. 2.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 89564 (August 14, 2020), 85 FR 51531 (''Notice'').

[4] 15 U.S.C. 78s(b)(2).

[5] *See* Securities Exchange Act Release No. 90062, 85 FR 63312 (October 7, 2020).

[6] Amendment No. 1 is available on the Commission's website at: *https://www.sec.gov/comments/sr-cboe-2020-075/srcboe2020075-7940531-224727.pdf.*

[7] 15 U.S.C. 78s(b)(2)(B).

[8] *See* Securities Exchange Act Release No. 90457, 85 FR 75071 (November 24, 2020).

[9] Amendment No. 2 is available on the Commission's website at: *https://www.sec.gov/comments/sr-cboe-2020-075/srcboe2020075-8330243-228699.pdf.*

[10] 15 U.S.C. 78s(b)(2).

[11] *See supra* note 3.

[12] 15 U.S.C. 78s(b)(2).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[13]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2021–03344 Filed 2–18–21; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–91120; File No. SR–NYSE–2020–90]

Self-Regulatory Organizations; New York Stock Exchange LLC; Order Instituting Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change To Amend the Requirement Applicable to Special Purpose Acquisition Companies Upon Consummation of a Business Combination Concerning Compliance With the Round Lot Shareholder Requirement

February 12, 2021.

I. Introduction

On October 27, 2020, New York Stock Exchange LLC (''NYSE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend its listing requirements applicable to special purpose acquisition companies (''SPACs'' or ''Acquisition Companies'') upon consummation of a business combination by allowing such companies 15 calendar days following the closing of a business combination to demonstrate compliance with the Exchange's round lot shareholder requirement. The proposed rule change was published for comment in the **Federal Register** on November 16, 2020.[3] On December 21, 2020, pursuant to Section 19(b)(2) of the Act,[4] the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change to February 14, 2021.[5] The Commission has received no comment letters on the proposed rule change. The Commission is instituting proceedings pursuant to Section 19(b)(2)(B) of the Act[6] to determine whether to approve or disapprove the proposed rule change.

II. Description of the Proposed Rule Change

An Acquisition Company or SPAC is a company whose business plan is to complete an initial public offering and engage in a merger or acquisition with one or more unidentified companies within a specific period of time.[7] NYSE's listing rules require, among other things, a SPAC to deposit and retain at least 90% of the proceeds from its initial public offering (''IPO'') in an escrow account, complete one or more business combinations having an aggregate fair market value of at least 80% of the value of the escrow account within 36 months of the effectiveness of its IPO registration statement, and provide the public shareholders, if a vote is held, who object to the business combination with the right to convert their common stock into a pro rata share of the funds held in escrow.[8]

Following each business combination, the combined company is subject to Section 801 and Section 802.01 of the Manual in its entirety and will be required immediately to meet those requirements, which include: (i) A price per share of at least $4.00; (ii) a global market capitalization of at least $150,000,000; (iii) an aggregate market value of publicly-held shares of at least $40,000,000; and (iv) the requirements with respect to shareholders and publicly-held shares set forth in Section 102.01A for companies listing in connection with an initial public offering, including the round lot shareholder requirement.[9] If the combined company does not meet the requirements of Sections 801 and 802.01 of the Manual following a business combination, Section 802.01B of the Manual provides that a SPAC will be promptly subject to suspension and delisting proceedings.

In its proposal, the Exchange stated that its existing rules require that ''an Acquisition Company must satisfy all initial listing requirements immediately upon consummation of its Business Combination.''[10] The Exchange asserted, however, that Section 802.01B of the Manual does not provide a timetable for the company to demonstrate that it satisfies those requirements. Accordingly, the Exchange proposed to specify that if the SPAC demonstrates that it will satisfy all requirements except the applicable round lot shareholder requirement, then the SPAC will receive 15 calendar days following the closing to demonstrate that it satisfied the applicable round lot shareholder requirement immediately following the transaction's closing.

In addition, the Exchange stated that, when a listed SPAC consummates its business combination, the Exchange also considers whether the business combination gives rise to a ''back door listing'' as described in Section 703.08(E) of the Manual. If the resulting company would not qualify for original listing, including by not meeting the applicable distribution standards, the Exchange will promptly initiate suspension and delisting of the SPAC. The Exchange proposed to modify its rule in relation to business combinations that give rise to a ''back door listing'' to specify that if the SPAC demonstrates that it will satisfy all requirements except the applicable round lot shareholder requirement, then the company will receive 15 calendar days following the closing to demonstrate that it satisfied the applicable round lot shareholder requirement immediately following the transaction's closing.[11]

The Exchange stated that it determines compliance with the round lot shareholder requirement at the time of a business combination by reviewing a company's public disclosures and information provided by the company about the transaction.[12] According to the Exchange, if it cannot determine compliance using public information, it will typically request the company to provide additional information such as registered shareholder lists from the company's transfer agent, data from Cede & Co. about shares held in street name, or data from broker-dealers and third parties that distribute information such as proxy materials for the broker-dealers. If the company can provide information demonstrating compliance before the business combination closes,

[13] 17 CFR 200.30–3(a)(57).

[1] 15 U.S.C.78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 90382 (November 9, 2020), 85 FR 73121 (''Notice'').

[4] 15 U.S.C. 78s(b)(2).

[5] *See* Securities Exchange Act Release No. 90739, 85 FR 85759 (December 29, 2020).

[6] 15 U.S.C. 78s(b)(2)(B).

[7] *See* Securities Exchange Act Release No. 57785 (May 6, 2008), 73 FR 27597 (May 13, 2008) (SR–NYSE–2008–17) (adopting Section 102.06 of the Listed Company Manual (''Manual''). *See also* Notice, supra note 3.

[8] *See* Section 102.06 of the Manual. Under Section 102.06 of the Manual, if a vote is not held on the business combination the company must provide all shareholders with the opportunity to redeem all their shares into a pro rata share of the funds held in escrow pursuant to Rule 13e–4 and Regulation 14E under the Securities Exchange Act of 1934, which regulates issuer tender offers.

[9] *See* Section 802.01B of the Manual. The applicable requirement is 400 holders of round lots.

[10] *See* Notice, *supra* note 3, at 73122.

[11] *See* proposed amendment to Section 802.01B of the Manual. *See also* Notice, *supra* note 3, at 73122.

[12] NYSE states, for example, that the merger agreement may result in the Acquisition Company issuing a round lot of shares to more than 400 holders of the target of the business combination at closing.

the Exchange stated that no further information would be required.

However, the Exchange asserted that in some cases it can be difficult for a company to obtain evidence demonstrating the number of shareholders that the company has or will have following a business combination. The Exchange stated that shareholders in a SPAC may redeem or tender their shares until just before the time of the business combination, and the SPAC may not know how many shareholders will choose to redeem until very close to the consummation of the business combination. The Exchange stated that this could impact its ability to determine compliance before the business combination closes, in cases where the number of round lot shareholders is close to the applicable requirement.

Accordingly, for a SPAC that has demonstrated that it will satisfy all of the initial listing requirements except for the round lot shareholder requirement before consummating the business combination (including the initial listing standards that are applicable in the event that the business combination gives rise to a ''back door listing''), the Exchange has proposed to allow the SPAC 15 calendar days after the closing of the business combination to demonstrate that it also complied with the round lot requirement at the time of the business combination. The Exchange stressed that under its proposal a SPAC must still demonstrate that it satisfied the round lot shareholder requirement immediately following the business combination, and that the proposal merely would give the SPAC 15 calendar days to provide evidence that it did.

The Exchange stated that the proposal ''balances the burden placed on the Acquisition Company to obtain accurate shareholder information for the new entity and the need to ensure that a company that does not satisfy the initial listing requirements following a Business Combination enters the delisting process promptly.'' [13] The Exchange further stated that if the company does not evidence compliance within the proposed time period, Exchange staff would immediately commence suspension and delisting proceedings with respect to the company.

[13] The Exchange stated that shareholders of the SPAC would be harmed if NYSE issued a delisting determination at a time when the company did, in fact, satisfy all initial listing requirements but could not yet provide proof.

III. Proceedings To Determine Whether To Approve or Disapprove SR–NYSE–2020–90 and Grounds for Disapproval Under Consideration

The Commission is instituting proceedings pursuant to Section 19(b)(2)(B) of the Act [14] to determine whether the proposed rule change should be approved or disapproved. Institution of such proceedings is appropriate at this time in view of the legal and policy issues raised by the proposed rule change. Institution of proceedings does not indicate that the Commission has reached any conclusions with respect to any of the issues involved.

Pursuant to Section 19(b)(2)(B) of the Act,[15] the Commission is providing notice of the grounds for disapproval under consideration. The Commission is instituting proceedings to allow for additional analysis of the proposed rule change's consistency with the Act, and in particular, Section 6(b)(5) of the Act, which requires, among other things, that the rules of a national securities exchange be ''designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, 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; and are not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.'' [16]

The Commission has consistently recognized the importance of the minimum number of holders and other similar requirements in exchange listing standards. Among other things, such listing standards help ensure that exchange listed securities have sufficient public float, investor base, and trading interest to provide the depth and liquidity necessary to promote fair and orderly markets.[17]

As discussed above, the Exchange proposed to provide a SPAC 15 calendar days following the closing of a business combination to demonstrate that it satisfied the applicable round lot holder requirement immediately following the closing. The Exchange asserted that it can be difficult for a SPAC to obtain evidence demonstrating the number of holders it will have following the business combination because SPAC shareholders have the right to redeem or tender their shares until just before the time of such business combination. The Exchange, however, has provided no data or other evidence to support its position that SPACs have particular difficulties demonstrating compliance with the minimum number of holders requirements. For example, the Exchange has not provided any data showing the extent to which SPACs have been unable to meet the applicable minimum number of holders requirement immediately following the business combination, or the extent to which this was due to last minute redemptions by SPAC shareholders. The Exchange also has provided no data or other evidence showing how long it has taken SPACs that have been unable to meet the applicable minimum number of holders requirement, whether or not due to last minute shareholder redemptions, to come into compliance with such requirements.

Further, the Exchange has not explained how providing a SPAC an additional 15 days following the closing of the business combination simply to demonstrate that it complied with the applicable minimum number of holders requirement immediately following the closing, would address the substantive compliance concerns associated with last minute shareholder redemptions by SPACs that are close to the minimum requirement. The Exchange also has not addressed the risk that, by waiting for SPACs to demonstrate compliance with the minimum number of holders requirements until after the closing of the business combination, non-compliant companies could be listed on the Exchange despite not meeting initial listing standards or those relating to a ''back door listing,'' and have their securities continue to trade until the delisting process has been completed. As a result, a SPAC could complete a business combination and very soon thereafter be subject to delisting proceedings, and during such time its securities may trade with a number of holders that is substantially less than the required minimum. The Exchange has not addressed the impact this could have on SPAC shareholders and other market participants, or explained why subjecting them to these risks is

[14] 15 U.S.C. 78s(b)(2)(B).

[15] *Id.*

[16] 15 U.S.C. 78f(b)(5).

[17] *See, e.g.,* Securities Exchange Act Release Nos. 57785 (May 6, 2008), 73 FR 27597 (May 13, 2008) (SR–NYSE–2008–17) (stating that the distribution standards, which includes exchange holder requirements ''. . . should help to ensure that the [SPAC's] securities have sufficient public float, investor base, and liquidity to promote fair and orderly markets''); 58228 (July 25, 2008), 73 FR 44794 (July 31, 2008) (SR–Nasdaq–2008–013) (approving a proposal to adopt listing standards for SPACs); and 86117 (June 14, 2018), 84 FR 28879 (June 20, 2018) (SR–NYSE–2018–46) (disapproving a proposal to reduce the minimum number of public holders continued listing requirement applicable to SPACs from 300 to 100).

consistent with the protection of investors and the public interest, and the other requirements of Section 6(b)(5) of the Act.

Under the Commission's Rules of Practice, the ''burden to demonstrate that a proposed rule change is consistent with the Exchange Act and the rules and regulations issued thereunder . . . is on the self-regulatory organization ['SRO'] that proposed the rule change.'' [18] The description of a proposed rule change, its purpose and operation, its effect, and a legal analysis of its consistency with applicable requirements must all be sufficiently detailed and specific to support an affirmative Commission finding, and any failure of an SRO to provide this information may result in the Commission not having a sufficient basis to make an affirmative finding that a proposed rule change is consistent with the Exchange Act and the applicable rules and regulations.[19]

For these reasons, the Commission believes it is appropriate to institute proceedings pursuant to Section 19(b)(2)(B) of the Act to determine whether the proposal should be approved or disapproved.

IV. Procedure: Request for Written Comments

The Commission requests that interested persons provide written submissions of their views, data, and arguments with respect to the issues identified above, as well as any other concerns they may have with the proposal. In particular, the Commission invites the written views of interested persons concerning whether the proposal is consistent with Section 6(b)(5) or any other provision of the Act, or the rules and regulations thereunder. Although there do not appear to be any issues relevant to approval or disapproval that would be facilitated by an oral presentation of views, data, and arguments, the Commission will consider, pursuant to Rule 19b–4, any request for an opportunity to make an oral presentation.[20]

Interested persons are invited to submit written data, views, and arguments regarding whether the proposal should be approved or disapproved by March 12, 2021. Any person who wishes to file a rebuttal to any other person's submission must file that rebuttal by March 26, 2021. The Commission asks that commenters address the sufficiency of the Exchange's statements in support of the proposal, in addition to any other comments they may wish to submit about the proposed rule change.

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–NYSE–2020–90 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–NYSE–2020–90. 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–NYSE–2020–90 and should be submitted by March 12, 2021. Rebuttal comments should be submitted by March 26, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[21]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2021–03337 Filed 2–18–21; 8:45 am]

BILLING CODE 8011–01–P

[18] Rule 700(b)(3), Commission Rules of Practice, 17 CFR 201.700(b)(3).

[19] *See id.*

[20] Section 19(b)(2) of the Act, as amended by the Securities Act Amendments of 1975, Public Law 94–29 (June 4, 1975), grants the Commission flexibility to determine what type of proceeding—either oral or notice and opportunity for written comments—is appropriate for consideration of a particular proposal by a self-regulatory organization. *See* Securities Act Amendments of 1975, Senate Comm. on Banking, Housing & Urban Affairs, S. Rep. No. 75, 94th Cong., 1st Sess. 30 (1975).

[21] 17 CFR 200.30–3(a)(57).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–91119; File No. SR–CBOE–2020–051]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing of Amendment No. 2 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment Nos. 1 and 2, To Amend the Automated Price Improvement Auction Rules in Connection With Agency Order Size Requirements

February 12, 2021.

I. Introduction

On June 11, 2020, Cboe Exchange, Inc. (''Exchange'' or ''Cboe'') 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 permitting the Exchange to impose a maximum size requirement for an agency order submitted into the Automated Price Improvement Mechanism (''AIM'') and the Complex Automated Price Improvement Mechanism (''C–AIM'') in S&P 500® Index Options (''SPX''). The proposed rule change was published for comment in the **Federal Register** on June 18, 2020.[3] On July 23, 2020, the Exchange submitted Amendment No. 1 to the proposed rule change, which replaced and superseded the proposed rule change in its entirety.[4] On July 27, 2020,

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 89058 (June 12, 2020), 85 FR 36918. Comments received on the proposed rule change are available on the Commission's website at: *https://www.sec.gov/comments/sr-cboe-2020-051/srcboe2020051.htm.*

[4] In Amendment No. 1, the Exchange: (1) Amended its proposal to modify the proposed maximum size requirement for AIM and C–AIM agency orders in SPX to ten contracts rather than a size determined by the Exchange of up to 100 contracts, specify that this size requirement would apply to all agency orders in SPX, and make related conforming changes to its proposed rule text; and (2) provided additional data, justification, and support for its modified proposal. The full text of Amendment No. 1 is available on the Commission's

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pursuant to Section 19(b)(2) of the Act,[5] the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.[6] On August 21, 2020, the Commission published notice of Amendment No. 1 and instituted proceedings under Section 19(b)(2)(B) of the Act[7] to determine whether to approve or disapprove the proposed rule change, as modified by Amendment No. 1.[8] On December 8, 2020, pursuant to Section 19(b)(2) of the Act,[9] the Commission designated a longer period within which to approve or disapprove the proposed rule change, as modified by Amendment No. 1.[10] On December 11, 2020, the Exchange submitted Amendment No. 2 to the proposed rule change.[11] This order approves the proposed rule change, as modified by Amendment Nos. 1 and 2, on an accelerated basis.

II. Description of the Proposal, as Modified by Amendment Nos. 1 and 2

The AIM and C–AIM are electronic auctions intended to provide an agency order with the opportunity to receive price improvement (over the National Best Bid or Offer in AIM, or the synthetic best bid or offer on the Exchange in C–AIM).[12] Upon submitting an agency order into one of these auctions, the initiating Trading Permit Holder (''TPH'') must also submit a contra-side second order (the ''initiating order'') for the same size as the agency order. The initiating order guarantees that the agency order will receive an execution. Upon commencement of an auction, market participants submit responses to trade against the agency order. At the conclusion of the auction, depending on the contra-side interest available, the initiating order may be allocated a certain percentage of the agency order.[13]

Rules 5.37(a)(3) and 5.38(a)(3), which govern the size requirements for AIM and C–AIM agency and initiating orders, provide that there is no minimum size for orders submitted into AIM and C–AIM auctions, respectively, and that the initiating order must be for the same size as the agency order. The Exchange proposes to amend Rule 5.37(a)(3) to provide that the Exchange may determine, per trading session,[14] that the maximum size for all agency orders in SPX is ten contracts, and to amend Rule 5.38(a)(3) to provide that the Exchange may determine, per trading session, that the maximum size for the smallest leg of all complex agency orders in SPX is ten contracts.[15] The Exchange states that it will announce any determination it makes in connection with the application of the maximum size requirement of ten contracts for agency orders in SPX to a trading session via Exchange notice pursuant to Rule 1.5.[16] The Exchange further states that it initially intends to establish the maximum size requirement of ten contracts for agency orders in SPX during RTH and not impose any maximum size requirement for agency orders in SPX during GTH.[17] The Exchange states that the proposed maximum size requirement for agency orders in SPX would apply to all agency orders in the entire SPX class (including SPX Weeklys).[18]

According to the Exchange, SPX options have a different and more complicated market model than other options classes, involve taking on greater risk than in other options classes, have a significantly higher notional value than options in other classes (*e.g.,* they are ten times the notional size of SPY options), trade in much larger size than other options classes, have a larger percentage of volume executed in open outcry than options in other classes, and effect increasingly more complex strategies than executed in other options classes (*e.g.,* SPX combo orders are more frequently submitted).[19] Accordingly, given the nature of SPX options the Exchange retail customer participation in SPX is concentrated in simpler strategies and smaller-sized orders.[20] The Exchange further states that smaller-sized orders in SPX are not commonly executed on the floor and, without an opportunity to execute in AIM and C–AIM, are primarily submitted to the book and trade at the market, whereas, with AIM and C–AIM, smaller-sized orders may receive price improvement.[21] The Exchange provides data demonstrating that, when AIM and C–AIM were activated for SPX, there was a greater number of SPX orders (and resulting number of contracts) containing quantities of one to ten contracts submitted through the electronic auctions than any other order size category.[22] After its trading floor reopened in June 2020 and AIM and C–AIM were again deactivated for SPX, the Exchange observed a decreased volume of customer orders in SPX for one to ten contracts submitted to the trading floor (approximately a 99% decrease in number of simple orders, total number of simple order contracts, and number of complex orders, and approximately a 91% decrease in total number of complex order contracts) from the volume that had previously been submitted to the electronic auctions.[23] In further support of its proposal, the Exchange measured price improvement statistics for a sample of SPX orders submitted into simple AIM auctions during a one-week period of trading in

website at: *https://www.sec.gov/comments/sr-cboe-2020-051/srcboe2020051-7470738-221292.pdf.*

[5] 15 U.S.C. 78s(b)(2).

[6] *See* Securities Exchange Act Release No. 89399, 85 FR 46202 (July 31, 2020). The Commission designated September 16, 2020 as the date by which the Commission shall approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change.

[7] 15 U.S.C. 78s(b)(2)(B).

[8] *See* Securities Exchange Act Release No. 89636, 85 FR 53029 (August 27, 2020).

[9] 15 U.S.C. 78s(b)(2).

[10] *See* Securities Exchange Act Release No. 90594, 85 FR 80853 (December 14, 2020). The Commission designated February 13, 2021 as the date by which the Commission shall approve or disapprove the proposed rule change, as modified by Amendment No. 1.

[11] In Amendment No. 2, the Exchange amended the proposal to specify that it may determine, per trading session, to establish the proposed maximum size of ten contracts for AIM and C–AIM agency orders in SPX. The full text of Amendment No. 2 is available on the Commission's website at: *https://www.sec.gov/comments/sr-cboe-2020-051/srcboe2020051-8135058-226517.pdf.*

[12] *See* Rules 5.38 (AIM) and 5.38 (C–AIM).

[13] *See* Rules 5.37(e) and 5.38(e).

[14] The term ''trading session'' means the hours during which the Exchange is open for trading for Regular Trading Hours (''RTH'') or Global Trading Hours (''GTH'') (each of which may referred to as a trading session), each as set forth in Rule 5.1. *See* Rule 1.1.

[15] Pursuant to Rule 1.5, the Exchange may, to the extent the Rules allow the Exchange to make a determination, including on a class-by-class basis, make a determination for GTH that differs from the determination it makes for RTH. In Amendment No. 2, Cboe indicated it would exercise its authority and establish a maximum size of ten SPX contracts for AIM during RTH but would continue to impose no maximum size during GTH, as it does today and as it did prior to the March floor closure, due to differences in the nature of the markets.

[16] *See* Amendment No. 2, *supra* note 11, at 6. The Exchange states that this distinction is due to the different trading characteristics between RTH and GTH, such as lower trading levels, reduced liquidity, fewer participants, higher volatility, and changing prices. *See id.* at 3. The Exchange further states that it has historically activated AIM and C–AIM in SPX during GTH (without any maximum size requirement for agency orders), but has not historically activated AIM and C–AIM in SPX during RTH. *See id.* at 4.

[17] *See id.* at 6.

[18] *See* Amendment No. 1, *supra* note 4, at 4.

[19] *See id.* at 5.

[20] *See id.* at 5.

[21] *See id.* at 6.

[22] *See id.* at 6–7 (providing more detailed data showing the number of SPX agency orders and contracts for various order sizes in AIM and C–AIM observed by the Exchange during April 2020 and May 2020 while the trading floor was inoperable and AIM and C–AIM were activated for SPX, as compared to the number of simple and complex customer orders and contracts executed on the reopened trading floor from June 15, 2020 to July 16, 2020).

[23] *See id.*

April 2020. Specifically, the Exchange observed that orders for one to ten contracts received an average price improvement of approximately $0.34 over their limit prices, whereas orders for 11 to 50 contracts received an average price improvement of approximately $0.22, orders for 51 to 250 contracts received an average price improvement of $0.08, and orders for 251 to 500 contracts received an average price improvement of approximately $0.15.[24]

Finally, the Exchange states that, pursuant to Rules 5.37.02 and 5.38.02, it is deemed conduct inconsistent with just and equitable principles of trade and a violation of Rule 8.1 to engage in a pattern of conduct where the initiating member breaks up an agency order into separate orders for the purpose of gaining a higher allocation percentage than the initiating TPH would have otherwise received in accordance with the allocation procedures contained in the AIM and C–AIM rules, respectively. In connection with the proposed maximum quantity requirements, the Exchange also proposes to amend Rules 5.37.02 and 5.38.02 to make it clear that initiating TPHs also may not break up an agency order into separate orders for the purpose of circumventing the maximum quantity requirement pursuant to Rules 5.37(a)(3) and 5.38(a)(3), as applicable. The Exchange represents that its surveillance program will monitor for such violations in the same manner in which it currently monitors for allocation-related break-up violations.[25]

III. Discussion and Commission Findings

The Commission finds that the proposed rule change, as modified by Amendment Nos. 1 and 2, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[26] In particular, the Commission finds that the proposed rule change, as modified by Amendment Nos. 1 and 2, is consistent with Section 6(b)(5) of the Act,[27] which requires, among other things, that the rules of a national securities exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest. The Commission also finds that the proposed rule change, as modified by Amendment Nos. 1 and 2, is consistent with Section 6(b)(8) of the Act,[28] which requires that the rules of a national securities exchange do not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

As described above, to support its proposal, Cboe provided the Commission with data demonstrating that, during the time period when AIM and C–AIM were temporarily activated for SPX, a greater number of SPX orders containing quantities of one to ten contracts were executed through the electronic auctions than were executed on the trading floor when the auctions were again deactivated for SPX.[29] The Exchange also provided data demonstrating that SPX orders containing quantities of one to ten contracts received higher levels of price improvement than other order size categories submitted to the electronic auctions.[30] Based on these observations, the Exchange believes AIM and C–AIM would provide opportunities for smaller-sized orders that are not being traded on the floor to be crossed in the electronic auction mechanisms and, specifically, that orders with sizes up to ten contracts generally represent the most volume and receive the most beneficial price improvement when AIM and C–AIM are activated for SPX.[31]

Two commenters supported the imposition of a maximum size limitation on SPX agency orders in AIM and C–AIM auctions, agreeing with Cboe's assertions that it would incentivize increased retail customer participation in SPX auctions and provide increased execution and price improvement opportunities for retail customers in SPX.[32] One of these commenters stated its clients recognized significant price improvement opportunities in AIM auctions of SPX orders from 1–100 contracts, but saw mixed results on orders greater than 100 contracts.[33] In contrast, two commenters questioned whether a maximum size limitation on orders in SPX entered in AIM and C–AIM auctions is necessary.[34] In its response to these comments, Cboe stated that the proposed maximum size for SPX orders in AIM and C–AIM is necessary to provide limited electronic auction functionality that customers found beneficial during the period when open outcry trading on the floor was closed and AIM and C–AIM auctions for orders in SPX were available.[35] Cboe stated that if market participants could submit SPX orders of all sizes into electronic crossing auctions, it could have a significant negative impact on the quality of the SPX market, which could reduce overall liquidity in the SPX market and harm all SPX investors.[36] Cboe further stated that it sought a balance between preserving open outcry liquidity while offering limited electronic auction functionality that some customers found beneficial.[37]

These commenters also suggested that Cboe's data analysis may be insufficient to support Cboe's proposal to impose a maximum size on agency orders in SPX.[38] Commenters stated that the data does not measure a time period during which both electronic auctions and floor-based liquidity are available,[39] and

[24] *See id.* at 8. The Exchange states that, although it did not observe as significant an increase in price improvement for complex orders from one to ten contracts in the sample it collected of SPX orders submitted to C–AIM, it did generally observe greater price improvement for smaller-sized complex orders as compared to larger-sized complex orders. *See id.*

[25] *See id.* at 11.

[26] 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). Please see the discussion at *infra* notes 49–66 and accompanying text.

[27] 15 U.S.C. 78f(b)(5).

[28] 15 U.S.C. 78f(b)(8).

[29] *See supra* note 23 and accompanying text.

[30] *See supra* note 24 and accompanying text.

[31] *See* Amendment No. 1, *supra* note 4, at 7, 9 n.10.

[32] *See* letters to Vanessa Countryman, Secretary, Commission, dated July 9, 2020 from Ellen Greene, Managing Director, Equities & Options Market Structure, The Securities Industry and Financial Markets Association, at 2 (''SIFMA Letter''); John S. Markle, Interim General Counsel, TD Ameritrade, Inc., at 1 (''TD Ameritrade Letter''). The SIFMA Letter and TD Ameritrade Letter commented on Cboe's original proposal, which would have given Cboe the ability to determine a maximum size of up to 100 contracts, prior to Amendment No. 1, which proposed a set maximum size of ten contracts.

[33] *See* TD Ameritrade Letter, *supra* note 32, at 1.

[34] *See* letters to Vanessa Countryman, Secretary, Commission, from Richard J. McDonald, Susquehanna International Group, LLP, dated July 8, 2020, at 3–4 (''SIG Letter''); Stephen John Berger, Managing Director and Global Head of Government & Regulatory Policy, Citadel Securities, dated July 9, 2020, at 1 (''Citadel Letter I''); and Stephen John Berger, Managing Director and Global Head of Government & Regulatory Policy, Citadel Securities, dated August 12, 2020, at 1 (''Citadel Letter II'').

[35] *See* letter to Vanessa Countryman, Secretary, Commission, from Rebecca Tenuta, Counsel, Cboe Global Markets, dated July 31, 2020, at 2–3 (''Cboe Response Letter'').

[36] *See id.* at 2–3.

[37] *See id.* at 3.

[38] *See* SIG Letter, *supra* note 34, at 3; Citadel Letter I, *supra* note 34, at 1. *See also* letter to Vanessa Countryman, Secretary, Commission, from Michael Golding, Head of Trading, Optiver US LLC, and Rutger Brinkhuis, Head of Trading, AMS Derivatives B.V., dated July 8, 2020, at 2 (''Optiver Letter'').

[39] *See* SIG Letter, *supra* note 34, at 3; Optiver Letter, *supra* note 38, at 2. SIG argued that Cboe's assertion that the trading floor may be better for larger-sized orders could not be proven because there has been no side-by-side comparison with AIM and C–AIM, adding that if larger-sized orders

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pointed out that Cboe's own data demonstrated that orders of all sizes in the electronic auction mechanisms received price improvement during the trading floor closure.[40] In response, Cboe stated that it provided sufficient additional data in the amended proposal to justify the proposed maximum size of ten contracts.[41] Cboe stated that the sample data was from a randomly selected time period when SPX AIM and C–AIM were activated[42] and further argued that all order sizes submitted into AIM and C–AIM during that time period would have been similarly impacted by any then-existing volatility, making the data sample an accurate comparison of price improvement opportunities for orders of all sizes executed in those auctions during that time.[43] While acknowledging that it could not provide an ''apples-to-apples'' comparison of price improvement for SPX orders executed on the trading floor versus orders executed in the AIM auction,[44] Cboe argued that smaller orders in general received more improvement when AIM and C–AIM were activated than when they are not activated.[45] Cboe also argued that its data[46] showed that once the trading floor became operable on June 15, 2020, and the Exchange disabled AIM and C–AIM for SPX, the volume of customer orders in SPX for ten or fewer contracts submitted into crossing auctions (on the trading floor) decreased significantly compared to the volume previously submitted into the electronic auctions, while larger order sizes experienced a notable increase in crossed volume compared to volume submitted into electronic auctions.[47] Cboe stated that when the electronic auctions are not available, brokers do not cross smaller-sized orders on the trading floor, but instead submit these orders for electronic execution in the book.[48]

The Commission believes that the data provided by the Exchange, including the data provided in Amendment No. 1, support the Exchange's conclusion that the proposal could provide additional execution and price improvement opportunities for smaller-sized customer orders in SPX options submitted through the Exchange's AIM or C–AIM auctions. With respect to commenters that favored allowing all SPX orders into AIM and C–AIM auctions, the Commission believes it is reasonable for the Exchange to set a maximum size for SPX orders in AIM and C–AIM auctions. Specifically, smaller-sized orders, as demonstrated in Cboe's data, are not regularly crossed on the trading floor and are sent to the electronic order book.[49] Thus, these smaller-sized orders may experience the most benefit from participation in the AIM and C–AIM auction mechanisms.[50] In addition, an agency order for less than 50 contracts is guaranteed price improvement in the AIM auction of at least one minimum increment better than the then-current National Best Bid or National Best Offer.[51] The Commission believes this requirement is based on an underlying assumption that price improvement auctions for multi-list options of fewer than 50 contracts are more likely to be retail customer orders. Although, as discussed below, the Exchange is proposing to adopt a maximum size for SPX AIM and C–AIM auctions of ten contracts rather than 50, the average notional size of SPX options is much greater than that of the average multi-list options contract, which thereby implies that a retail customer order in SPX is more likely to be fewer than 50 contracts.[52]

Because SPX has not traded concurrently on the trading floor and in the AIM and C–AIM electronic auctions during RTH, the data provided by the Exchange does not provide a comparison of price improvement between the electronic auctions and the trading floor in simultaneous operation. Nevertheless, the data does indicate that price improvement opportunities were available to orders in SPX submitted to the electronic auctions. The data provided by the Exchange shows that price improvement opportunities were observed for orders of all sizes in the electronic auction mechanisms during the trading floor closure. However, according to data provided by Cboe, significantly more orders for 1–10 contracts were entered into the AIM and C–AIM than larger-sized orders,[53] and orders for 1–10 contracts received greater average price improvement than larger-sized orders.[54] For example, Cboe stated that the average price improvement of approximately $0.34 for orders for 1–10 contracts submitted through AIM was approximately a 55% larger average price improvement than orders for 11–50 contracts, a 325% larger average price improvement than orders for 51–250 contracts and approximately 127% larger average price improvement than orders for 251–500 contracts.[55] The Commission believes that it is reasonable for Cboe to conclude from its data that a maximum size of ten contracts is appropriate.

Three commenters recommended that, to the extent any maximum size is established for SPX orders in AIM and C–AIM auctions, the level of the maximum size should be clearly stated in the proposed rule, with any future modifications subject to a separate proposed rule change.[56] In response to these comments, and as described above, Cboe amended its proposal to establish a set maximum size of ten contracts for AIM and C–AIM agency orders in SPX and provided additional data and analysis to support this proposed threshold.[57]

One commenter argued that the proposed ten contract maximum size is without a rational basis and will result in unfair discrimination that would deny significant price improvement to investors.[58] This commenter provided

are better suited for the trading floor, such orders would naturally gravitate towards the floor and obviate the need for any size limitations in the electronic mechanisms. *See* SIG Letter, *supra* note 34, at 3. Optiver questioned the validity of the data given the extreme volatility observed during the time period of the data. *See* Optiver Letter, *supra* note 38, at 2.

[40] *See* SIG Letter, *supra* note 34, at 3 & n.9; Citadel Letter I, *supra* note 34, at 1. As noted above, however, a separate commenter suggested price improvement opportunities were mixed for SPX orders greater than 100 contracts. *See* TD Ameritrade Letter, *supra* note 32, at 1.

[41] *See* Cboe Response Letter, *supra* note 35, at 6.

[42] *See id.*

[43] *See id.*

[44] *See id.*

[45] *See id. See also* TD Ameritrade Letter, *supra* note 32, at 1; SIFMA Letter, *supra* note 32, at 2.

[46] Cboe's data covered the period from June 15, 2020 through July 16, 2020. *See* Amendment No. 1, *supra* note 4, at 7.

[47] *See* Cboe Response Letter, *supra* note 35, at 6. *See also* Amendment No. 1, *supra* note 4, at 7–8.

[48] *See* Amendment No. 1, *supra* note 4, at 8. *See also* CBOE Response Letter, *supra* note 35, at 5.

[49] *See* Amendment No. 1, *supra* note 4, at 8. *See also* CBOE Response Letter, *supra* note 35, at 5.

[50] In Amendment No. 1, the Exchange stated that it observed a decreased volume of customer orders in SPX for one to ten contracts submitted to the trading floor compared to the volume that had previously been submitted to the electronic auctions while the trading floor was closed. *See* Amendment No. 1, *supra* note 4, at 7–8.

[51] *See* Rule 5.37(b).

[52] For example, on January 28, 2021, an SPX options expiring on January 29, 2021 was valued at $31.00. Thus, purchasing 10 SPX options contracts would require a $31,000 investment ($31.00 per option contract × 100 × 10 contracts = $31,000). In comparison, a similar SPY option would require a $3,120 investment ($3.12 per option contract × 100 × 10 contracts = $3,120).

[53] *See* Amendment No. 1, *supra* note 4, at 6.

[54] *See id.* at 8.

[55] *See id.*

[56] *See* TD Ameritrade Letter, *supra* note 32, at 2; Citadel Letter I, *supra* note 34, at 2; Optiver Letter, *supra* note 38, at 2. The TD Ameritrade Letter and Citadel Letter I, commenting on Cboe's initial proposal, both suggested that Cboe commit to allowing orders of up to 100 contracts to participate in the electronic auctions. *See* TD Ameritrade Letter, *supra* note 32, at 2; Citadel Letter I, *supra* note 34, at 2.

[57] *See* Cboe Response Letter, *supra* note 35, at 2.

[58] *See* Citadel Letter I, *supra* note 34, at 2; Citadel Letter II, *supra* note 34, at 1.

data showing that more than fifty percent of the AIM-eligible retail simple marketable SPX orders that it routed to Cboe from mid-March 2020 to mid-May 2020 were larger than ten contracts.[59] This commenter also argued that its data demonstrates that retail orders of more than ten contracts and up to 100 contracts received price improvement in the AIM auction and requested that Cboe either eliminate the proposed maximum size threshold or increase the threshold from ten to 100 contracts.[60]

Based on the Exchange's data, as specifically discussed above, the Commission believes that Cboe has reasonably set a maximum size for SPX orders in AIM or C–AIM auctions and that ten contracts is a reasonable maximum, as an initial step to benefit investors, because this level is commensurate with the greatest amount of volume representative of retail investors and corresponding price improvement.[61] The Commission also believes that the proposal is not unfairly discriminatory, because market participants may execute agency orders in SPX of greater than ten contracts on the trading floor and the electronic order book, as they do today.

The Commission acknowledges a commenter that supports allowing SPX options in AIM auctions has provided data indicating that there also was price improvement for SPX orders of more than ten contracts and up to 100 contracts in the AIM auction during the period of Cboe's floor closure. As described above, however, Cboe's data compiled during a week of trading in April 2020 showed that SPX orders containing quantities of one to ten contracts represented more executed volume and received higher levels of price improvement than other order size categories submitted to the electronic auctions.[62] This is consistent with the data provided by the commenter, which finds greater executed volume and price improvement for SPX orders containing quantities of one to ten contracts than for other order size categories.[63] In addition, as stated above, a retail customer order in SPX is more likely to be a smaller-sized order because the notional size of an SPX options contract is much greater than that of other contracts, including the average multi-list options contract. Furthermore, smaller-sized SPX orders, as demonstrated in Cboe's data, are not regularly crossed on the trading floor and may therefore experience the most benefit from participation in the electronic auction mechanisms.[64] The Commission believes if Cboe were to activate these auctions for SPX orders of one to ten contracts following approval of this proposal, it would provide a substantial benefit to the smaller-sized orders, which are more likely to be retail orders.[65] The Commission therefore believes Cboe's proposed maximum size of ten contracts is consistent with the requirements of the Act. While Cboe could have proposed a different maximum size limit, Cboe's decision not to propose a different or higher maximum size limit does not render the proposed rule change unfairly discriminatory or without a rational basis.[66]

Another commenter opposed activating AIM and C–AIM auctions for orders in SPX, regardless of size, arguing that price discovery is best served when orders are exposed to all market participants simultaneously, such that no one participant has a distinct advantage over another.[67] The commenter argued that firms initiating an AIM auction have a competitive advantage. First, the initiator is able to gain insight into the order prior to the auction and then determine its participation level based on characteristics that are not known to the rest of the market. The commenter also argued that only an initiator can use AIM's auto-match functionality[68] to match a competitor's best price.[69] Although the initiator's use of auto-match may result in a responder sharing a percentage of the execution with the initiator, the Commission believes that this allocation process is very similar to the pro rata allocation for orders on the Cboe floor,[70] except that in the AIM and C–AIM, the customer may receive price improvement relative to the displayed market. Finally, the commenter is concerned that after the proposed rule change is implemented, too much order flow will be controlled by too few market participants, to the detriment of market makers who do not have client order flow.[71] Based on its knowledge of the relevant market, the Commission believes that these initiators already control this order flow. Under the proposed rule change, these initiators will now have a new venue to execute orders with a maximum size of ten contracts, where other market participants can compete to try to provide price improvement.

Accordingly, the Commission finds that the proposed rule change, as modified by Amendment Nos. 1 and 2, is consistent with the requirements of the Act.

IV. Solicitation of Comments on Amendment No. 2 to the Proposed Rule Change

Interested persons are invited to submit written data, views, and arguments concerning whether Amendment No. 2 is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CBOE–2020–051 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–CBOE–2020–051. 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

[59] *See* Citadel Letter II, *supra* note 34, at 1–2.

[60] *See id.* at 2.

[61] *See supra* notes 49–55 and accompanying text.

[62] *See supra* note 24 and accompanying text.

[63] *See* Citadel Letter II, *supra* note 34, at 1–2.

[64] *See supra* note 47.

[65] *See supra* note 20.

[66] The Commission expects Cboe to monitor trading in SPX and after gaining experience, including a review of relevant data, to consider whether any adjustments such as increasing the maximum order size may be necessary to maximize the benefit to investors that trade SPX options. During discussions with Cboe staff, Cboe staff communicated its intention to review and evaluate, in the ordinary course, the trading of SPX options in AIM and C–AIM, and to consider proposing any changes as may be appropriate in the future.

[67] *See* Optiver Letter, *supra* note 38, at 1.

[68] *See* Rules 5.37(b)(5) (AIM) and 5.38(b)(4) (C–AIM). An initiating TPH that utilizes auto-match will automatically match the price and size of all AIM or C–AIM responses and other contra-side trading interest at each price up to a designated limit price (or match all prices).

[69] *See* Optiver Letter, *supra* note 38, at 2.

[70] *See* Rule 5.85(a).

[71] *See* Optiver Letter, *supra* note 38, at 2.

Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CBOE–2020–051, and should be submitted on or before March 12, 2021.

V. Accelerated Approval of Proposed Rule Change, as Modified by Amendment Nos. 1 and 2

The Commission finds good cause to approve the proposed rule change, as modified by Amendment Nos. 1 and 2, prior to the thirtieth day after the date of publication of notice of the filing of Amendment No. 2 in the **Federal Register**. As discussed above, in Amendment No. 2, the Exchange amended the proposal to specify that it may determine, per trading session, to establish the proposed maximum size of ten contracts for AIM and C–AIM agency orders in SPX. The Commission believes that Amendment No. 2 provides additional specificity to the proposal that would allow the Exchange to make a determination, pursuant to Rule 1.5, to establish the proposed maximum size requirement of ten contracts for agency orders in SPX during RTH, while not imposing any maximum size requirement for agency orders in SPX during GTH, as it does today. Consequently, the Commission believes Amendment No. 2 does not raise any novel regulatory issues. Accordingly, the Commission finds good cause, pursuant to Section 19(b)(2) of the Act,[72] to approve the proposed rule change, as modified by Amendment Nos. 1 and 2, on an accelerated basis.

VI. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[73] that the proposed rule change, as modified by Amendment Nos. 1 and 2 (SR–CBOE–2020–051), be, and hereby is, approved on an accelerated basis.

[72] 15 U.S.C. 78s(b)(2).

[73] *Id.*

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[74]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2021–03336 Filed 2–18–21; 8:45 am]

BILLING CODE 8011–01–P

[74] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–91121; File No. SR–NYSE–2020–93]

Self-Regulatory Organizations; New York Stock Exchange LLC; Order Instituting Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change To Amend Rules 7.35 and 7.35A

February 12, 2021.

I. Introduction

On November 3, 2020, New York Stock Exchange LLC (''Exchange'' or ''NYSE'') filed with the Securities and Exchange Commission (''Commission'') pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend Rule 7.35 regarding dissemination of Auction Imbalance Information if a security is an IPO or Direct Listing and has not had its IPO Auction or Direct Listing Auction, and Rule 7.35A regarding DMM consultations in connection with an IPO or Direct Listing. The proposed rule change was published for comment in the **Federal Register** on November 17, 2020.[3]

On December 18, 2020, the Commission extended to February 15, 2020, the time period in which to approve the proposal, disapprove the proposal, or institute proceedings to determine whether to approve or disapprove the proposal.[4] The Commission has received no comments on the proposal. This order institutes proceedings under Section 19(b)(2)(B) of the Act to determine whether to approve or disapprove the proposal.

II. Description of the Proposal

Rule 7.35—Auction Imbalance Information

The Exchange proposes to amend Rule 7.35 to eliminate, on a permanent basis, the restriction on the Exchange disseminating Auction Imbalance Information if a security is an IPO or Direct Listing and has not had its IPO Auction or Direct Listing Auction.[5] The Exchange asserts that disseminating Auction Imbalance Information in advance of an IPO Auction or Direct Listing Auction would promote transparency in advance of these Auctions, which would benefit investors and other market participants.[6]

As part of the proposed change, the Exchange proposes that the Imbalance Reference Price for determining the Auction Imbalance Information for either an IPO Auction or a Direct Listing Auction would be determined in the same manner as currently provided for under the temporary Commentaries .01 and .02 to Rule 7.35, respectively.[7] Specifically, the Imbalance Reference Price for determining the Auction Imbalance Information for a Core Open Auction under Rule 7.35A(e)(3) is the Consolidated Last Sale Price, bound by the bid and offer of any published pre-opening indication.[8] Because this definition of Imbalance Reference Price does not currently specify what the Consolidated Last Sale Price would be for an IPO Auction or Direct Listing Auction (which does not exist because the security has not been previously listed on an exchange), the Exchange proposes to amend the definition of Consolidated Last Sale Price in Rule 7.35(a)(11)(A) to provide that: (i) For an IPO that has not had its IPO Auction, the Consolidated Last Sale Price would mean the security's offering price; and (ii) for a Direct Listing that has not had its Direct Listing Auction, the Consolidated Last Sale Price would mean the Indication Reference Price for such security.[9]

Rule 7.35A—DMM Consultations

The Exchange proposes to amend Rule 7.35A(g)(1) to provide for DMM consultations with an underwriter or financial advisor for initial listings and follow-on offerings.[10] The Exchange represents that the proposed rule text reflects long-standing practice relating to the type of consultations that a DMM

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 90387 (Nov. 10, 2020), 85 FR 73322 (Nov. 17, 2020) (''Notice'').

[4] *See* Securities Exchange Act Release No. 90723 (Dec. 18, 2020), 85 FR 84446 (Dec. 28, 2020).

[5] *See* Notice, *supra* note 3, at 73323. Commentaries .01 and .02 to Rule 7.35, currently in effect on a temporary basis through April 30, 2021, provide for the dissemination of Auction Imbalance Information if a security is an IPO or Direct Listing and has not had its IPO Auction or Direct Listing Auction. *See* Securities Exchange Act Release No. 90795 (Dec. 23, 2020), 85 FR 86608 (Dec. 30, 2020).

[6] *See id.*

[7] *See id.*

[8] *See id.*

[9] *See id.*

[10] *See* Notice, *supra* note 3, 85 FR at 73324.

may have with an underwriter or financial advisor.[11] The Exchange further proposes to specify that any such consultations may be conveyed to the DMM via either a Floor broker or Exchange staff. The Exchange represents that, as with current practice, the only consultations that would be required in Exchange rules would be in connection with a Direct Listing that has not had recent sustained history of trading in a Private Placement Market prior to listing.[12] The Exchange states that it believes that this proposed rule text would promote transparency and clarity in Exchange rules by specifying the existing process whereby a DMM may consult with an underwriter or financial advisor in connection with a security having its initial listing on the Exchange or for a follow-on offering.[13]

III. Proceedings To Determine Whether To Disapprove SR–NYSE–2020–93 and Grounds for Disapproval Under Consideration

The Commission is instituting proceedings pursuant to Section 19(b)(2)(B) of the Act[14] to determine whether the proposal should be disapproved. Institution of such proceedings is appropriate at this time in view of the legal and policy issues raised by the proposal, as discussed below. Institution of disapproval proceedings does not indicate that the Commission has reached any conclusions with respect to any of the issues involved. Rather, as described in greater detail below, the Commission seeks and encourages interested persons to provide additional comment on the proposal.

Pursuant to Section 19(b)(2)(B) of the Act, the Commission is providing notice of the grounds for disapproval under consideration. The Commission is instituting proceedings to allow for additional analysis of the proposed rule change's consistency with Section 6(b)(5) of the Act,[15] which requires that the rules of an exchange be designed, among other things, to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest. In addition, Section 6(b)(5) of the Act prohibits the rules of an exchange from being designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

Under the proposal, the Exchange seeks to amend Rule 7.35A with respect to the consultations a DMM may have with an underwriter or financial advisor. The Exchange further proposes to specify that any such consultations may be conveyed to the DMM via either a Floor broker or Exchange staff. Accordingly, the Commission seeks public comment on the nature of the communications permitted between the DMM and the underwriter or financial advisor. Specifically, the Commission seeks public comment on the following topics:

(1) Should the proposed rule specify what is a permitted consultation provided for in the proposed amendments to NYSE Rule 7.35A—that is, specify what is a permitted consultation ''to effect a fair and orderly opening on the first day of trading of a security having its initial listing on the Exchange or for a follow-on offering''[16]—so that the permitted consultations are limited to conveying only such information?

(2) Are there any types of information that the underwriter or financial advisor should be prohibited from conveying to the DMM in these consultations? Would any other types of limitations be appropriate with respect to the consultations between DMMs and underwriters or financial advisors?

(3) Should a DMM be permitted to communicate directly with the underwriter or financial advisor with respect to these consultations, rather than through a Floor broker or a member of the Exchange's staff? If so, what, if any, different restrictions should apply to such consultations?

(4) Should the Exchange's rules distinguish between DMM consultations with underwriters or financial advisors with respect to follow-on offerings for securities that have a market value reflected in trading prices as opposed to initial offerings? If so, why and in what way? What types of consultations, if any, would be appropriate for a follow-on offering and why? Would the types of appropriate consultations differ between a follow-on offering conducted through a firm-commitment underwriting and a follow-on offering conducted through a direct offering?

IV. Procedure: Request for Written Comments

The Commission requests that interested persons provide written submissions of their views, data, and arguments with respect to the issues identified above, as well as any other concerns they may have with the proposal. In particular, the Commission invites the written views of interested persons concerning whether the proposal is consistent with Section 6(b)(5)[17] of the Act or any other provision of the Act, or the rules and regulations thereunder. Although there do not appear to be any issues relevant to approval or disapproval that would be facilitated by an oral presentation of views, data, and arguments, the Commission will consider, pursuant to Rule 19b–4 under the Act,[18] any request for an opportunity to make an oral presentation.[19]

Interested persons are invited to submit written data, views and arguments regarding whether the proposal should be disapproved by March 12, 2021. Any person who wishes to file a rebuttal to any other person's submission must file that rebuttal by March 26, 2021.

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–NYSE–2020–93 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 Numbers SR–NYSE–2020–93. The 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 proposal that are filed with the Commission, and all written communications relating to the proposal 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

[11] See *id.*

[12] *See id.*

[13] *See id.*

[14] 15 U.S.C. 78s(b)(2)(B).

[15] 15 U.S.C. 78f(b)(5).

[16] Notice, *supra* note 3, 85 FR at 73324.

[17] 15 U.S.C. 78f(b)(5).

[18] 17 CFR 240.19b–4.

[19] Rule 700(c)(2) of the Commission's Rules of Practice provides that ''[t]he Commission, in its sole discretion, may determine whether any issues relevant to approval or disapproval would be facilitated by the opportunity for an oral presentation of views.'' 17 CFR 201.700(c)(2).

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 also will be available for inspection and copying at the principal office of the Exchanges. 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–NYSE–2020–93 and should be submitted on or before March 12, 2021. Rebuttal comments should be submitted by March 26, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[20]

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2021–03338 Filed 2–18–21; 8:45 am]

BILLING CODE 8011–01–P

[20] 17 CFR 200.30–3(a)(57).

SMALL BUSINESS ADMINISTRATION

Meeting of the Advisory Committee on Veterans Business Affairs

AGENCY: U.S. Small Business Administration (SBA).

ACTION: Notice of open Federal Advisory Committee Meeting.

SUMMARY: The SBA is issuing this notice to announce the date, time, and agenda for a meeting of the Advisory Committee on Veterans Business Affairs (ACVBA).

DATES: Thursday, March 4, 2021, from 9:00 a.m. to 3:30 p.m. EST.

ADDRESSES: Due to the coronavirus pandemic, the meeting will be held via Microsoft Teams using a call-in number listed below.

FOR FURTHER INFORMATION CONTACT: The meeting is open to the public; however advance notice of attendance is strongly encouraged. To RSVP and confirm attendance, the general public should email *veteransbusiness@sba.gov* with subject line—''RSVP for 3/4/2021 ACVBA Public Meeting.'' To submit a written comment, individuals should email *veteransbusiness@sba.gov* with subject line—''Response for 3/4/2021 ACVBA Public Meeting'' no later than February 26, 2021 or contact Timothy Green, Deputy Associate Administrator, Office of Veterans Business Development (OVBD) at (202) 205–6773. Comments received in advanced will be addressed as time allows during the public comment period. All other submitted comments will be included in the meeting record. During the live meeting, those who wish to comment will be able to do so during the public comment period.

To join the ACVBA—March 4, 2021 √ 9:00 a.m.–3:30 p.m. ET Participants may join the ACVBA meeting via computer (*http://bit.ly/ACVBAMar2021*) or phone. Call in (audio only): Dial In: 202–765–1264: Phone Conference ID: 422 462 191#.

Special accommodation requests should be directed to OVBD at (202) 205–6773 or *veteransbusiness@sba.gov.* All applicable documents will be posted on the ACVBA website prior to the meeting: *https://www.sba.gov/page/advisory-committee-veterans-business-affairs.* For more information on veteran owned small business programs, please visit *www.sba.gov/ovbd.*

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C., Appendix 2), SBA announces the meeting of the Advisory Committee on Veterans Business Affairs. The ACVBA is established pursuant to 15 U.S.C. 657(b) note and serves as an independent source of advice and policy. The purpose of this meeting is to discuss efforts that support veteran-owned small businesses, updates on past and current events, and the ACVBA's objectives for fiscal year 2021.

Dated: February 16, 2021.

Andrienne Johnson,

Committee Management Officer.

[FR Doc. 2021–03416 Filed 2–18–21; 8:45 am]

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SMALL BUSINESS ADMINISTRATION

Meeting of the Interagency Task Force on Veterans Small Business Development

AGENCY: U.S. Small Business Administration (SBA).

ACTION: Notice of open Federal Advisory Committee Meeting.

SUMMARY: The SBA is issuing this notice to announce the date, time, and agenda for the next meeting of the Interagency Task Force on Veterans Small Business Development (IATF).

DATES: Wednesday, March 3, 2021, from 1:00 p.m. to 3:00 p.m. EST.

ADDRESSES: Due to the coronavirus pandemic, the meeting will be held via Microsoft Teams.

FOR FURTHER INFORMATION CONTACT: The meeting is open to the public; however advance notice of attendance is strongly encouraged. To RSVP and confirm attendance, the general public should email *veteransbusiness@sba.gov* with subject line—''RSVP for 3/3/2021 IATF Public Meeting.'' To submit a written comment, individuals should email *veteransbusiness@sba.gov* with subject line—''Response for 3/3/2021 IATF Public Meeting'' no later than February 26, 2021 or contact Timothy Green, Deputy Associate Administrator, Office of Veterans Business Development (OVBD) at (202) 205–6773. Comments received in advanced will be addressed as time allows during the public comment period. All other submitted comments will be included in the meeting record. During the live meeting, those who wish to comment will be able to do so during the public comment period.

To join the IATF—March 3, 2021 √ 1:00 p.m.–3:00 p.m. ET Participants can join the meeting via computer (*http://bit.ly/IATFMar2021*) or phone. Call in (audio only): Dial In: 202–765–1264: Phone Conference ID: 422 331 000#.

Special accommodation requests should be directed to OVBD at (202) 205–6773 or *veteransbusiness@sba.gov.* All applicable documents will be posted on the IATF website prior to the meeting: *https://www.sba.gov/page/interagency-task-force-veterans-small-business-development.* For more information on veteran owned small business programs, please visit *www.sba.gov/ovbd.*

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C., Appendix 2), SBA announces the meeting of the Interagency Task Force on Veterans Small Business Development (IAFT). The IATF is established pursuant to Executive Order 13540 to coordinate the efforts of Federal agencies to improve capital, business development opportunities, and pre-established federal contracting goals for small business concerns owned and controlled by veterans and service-disabled veterans.

The purpose of this meeting is to discuss efforts that support veteran-owned small businesses, updates on past and current events, and the IATF's objectives for fiscal year 2021.

Dated: February 16, 2021.

Andrienne Johnson,

Committee Management Officer.

[FR Doc. 2021–03415 Filed 2–18–21; 8:45 am]

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SURFACE TRANSPORTATION BOARD

[Docket No. FD 36469]

Armstrong Hospitality Group, Ltd., Invictus Maneo Ltd., Oceaneer Investments Ltd., No. 245 Dynamic Endeavors Inc., The PRBA Alter Ego Trust, and Peter R.B. Armstrong—Continuancein Control—American Rocky Mountaineer LLC

Armstrong Hospitality Group, Ltd., Invictus Maneo Ltd., Oceaneer Investments Ltd., No. 245 Dynamic Endeavors Inc., The PRBA Alter Ego Trust, and Peter R.B. Armstrong, (collectively, Armstrong Group), all noncarriers, have filed a verified notice of exemption pursuant to 49 CFR 1180.2(d)(2) to continue in control of American Rocky Mountaineer LLC (American Rocky Mountaineer), upon American Rocky Mountaineer's becoming a Class III rail carrier.[1]

This transaction is related to a concurrently filed petition for exemption by American Rocky Mountaineer in *American Rocky Mountaineer, LLC—Petition for Exemption from 49 U.S.C. Subtitle IV,* Docket No. FD 36468. In that docket, American Rocky Mountaineer is seeking an exemption from most of the provisions of 49 U.S.C. Subtitle IV, with respect to its proposed operation of passenger rail services between Moab, Utah, and Denver, Colo., on lines of Union Pacific Railroad Company.

The exemption will become effective on March 5, 2021 (30 days after the verified notice of exemption was filed). The verified notice states that the control exemption will be utilized when American Rocky Mountaineer becomes a rail carrier, subject to Board approval of the petition for exemption filed in Docket No. FD 36468.

Armstrong Group certifies that: (1) The lines of railroad on which American Rocky Mountaineer will operate will not connect with the rail lines operated by Great Canadian Railtour;[2] (2) the continuance in control is not part of a series of anticipated transactions that would result in a connection between lines operated or to be operated by American Rocky Mountaineer or Great Canadian Railtour in the United States; and (3) no Class I carrier is involved in the transaction. Therefore, the transaction is exempt from the prior approval requirements of 49 U.S.C. 11323. *See* 49 CFR 1180.2(d)(2).

Under 49 U.S.C. 10502(g), the Board may not use its exemption authority to relieve a rail carrier of its statutory obligation to protect the interests of its employees. However, 49 U.S.C. 11326(c) does not provide for labor protection for transactions under 49 U.S.C. 11324 and 11325 that involve only Class III carriers. Accordingly, the Board may not impose labor protective conditions here, because all the carriers involved are Class III carriers.

If the verified notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions for stay must be filed no later than February 26, 2021 (at least seven days before the exemption becomes effective).

All pleadings, referring to Docket No. FD 36469, should be filed with the Surface Transportation Board via e-filing on the Board's website. In addition, a copy of each pleading must be served on Armstrong Group's representative, Kevin M. Sheys, Hogan Lovells US LLP, 555 13th St. NW, Washington, DC 20004.

Board decisions and notices are available at *www.stb.gov.*

Decided: February 16, 2021.

By the Board, Allison C. Davis, Director, Office of Proceedings.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2021–03417 Filed 2–18–21; 8:45 am]

BILLING CODE 4915–01–P

[1] According to the verified notice, Armstrong Group owns and controls Great Canadian Railtour Ltd. (Great Canadian Railtour), a Class III rail carrier. *See Great Canadian Railtour Co. Ltd.—Pet. for Exemption from 49 U.S.C. Subtitle IV,* FD 35851 (STB served June 3, 2015). The verified notice states that Armstrong Hospitality Group, Ltd., will control the railroads, and is itself controlled by Invictus Maneo Ltd., which is controlled by Oceaneer Investments Ltd., which is controlled by No. 245 Dynamic Endeavors Inc., which is controlled by the PRBA Alter Ego Trust, which is controlled by Peter R.B. Armstrong.

[2] The verified notice states that Great Canadian Railtour is authorized to operate in Washington but has not operated in the United States since 2019 and has no present plans to operate in the United States.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2020–1046]

Agency Information Collection Activities: Requests for Comments; Clearance of a Renewed Approval of Information Collection: Federal Aviation Regulation Part 119—Certification: Air Carriers and Commercial Operators

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on November 4, 2020. Organizations that desire to become or remain certified as air carriers or commercial operators are mandated to report information to the FAA. The information collected reflects requirements necessary under parts 135, 121, and 125 to comply with Federal Aviation Regulation part 119—Certification: Air Carriers and Commercial Operators. The FAA will use the information it collects and reviews to ensure compliance and adherence to regulations and, if necessary, to take enforcement action on violators of the regulations.

DATES: Written comments should be submitted by March 22, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Steve Hanes by email at: *steven.a.hanes@faa.gov;* phone: 517–260–9179

SUPPLEMENTARY INFORMATION:

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity

of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information.

OMB Control Number: 2120–0593.

Title: Federal Aviation Regulation part 119—Certification: Air Carriers and Commercial Operators.

Form Numbers: N/A.

Type of Review: Renewal of an information collection.

Background: The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on November 4, 2020 (85 FR 70222). One comment was received, however it was political in nature and does not relate to this information collection. The request for clearance reflects requirements necessary under parts 135, 121, and 125 to comply with part 119. The FAA will use the information it collects and reviews to ensure compliance and adherence to regulations and, if necessary, to take enforcement action on violators of the regulations.

Respondents: 1,695 Air Carrier and Commercial Operators.

Frequency: Varies per Requirement.

Estimated Average Burden per Response: 5,174.5 Hours.

Estimated Total Annual Burden: $155,016.73.

Issued in Washington, DC, on February 16, 2021.

Sheri A. Martin,

Management and Program Analyst, FAA, Air Transportation Division, AFS–200.

[FR Doc. 2021–03414 Filed 2–18–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE TREASURY

Community Development Financial Institutions Fund

Notice of Funds Availability Inviting Applications for Financial Assistance Awards or Technical Assistance Grants under the Community Development Financial Institutions Program Fiscal Year 2021 Funding Round

Funding Opportunity Title: Notice of Funds Availability (NOFA) inviting Applications for Financial Assistance (FA) awards or Technical Assistance (TA) grants under the Community Development Financial Institutions Program (CDFI Program) fiscal year (FY) 2021 Funding Round.

Announcement Type: Announcement of funding opportunity.

Funding Opportunity Number: CDFI–2021–FATA

Catalog of Federal Domestic Assistance (CFDA) Number: 21.020

Dates:

TABLE 1—FY 2021 CDFI PROGRAM FUNDING ROUND CRITICAL DEADLINES FOR APPLICANTS

Description	Deadline	Time (eastern time-ET)	Submission method
Last day to create an Awards Management Information Systems (AMIS) Account (all Applicants).	March 22, 2021	11:59 p.m	AMIS.
Last day to enter EIN and DUNS numbers in AMIS (all Applicants).	March 22, 2021	11:59 p.m	AMIS.
Last day to submit SF–424 Mandatory (Application for Federal Assistance).	March 22, 2021	11:59 p.m	Electronically via *Grants.gov.*
Last day for Applicants that meet the SECA requirements, but wish to apply for CORE–FA, to request creation of a Core-FA Application (if requesting more than $700,000).	March 22, 2021	11:59 p.m	Service Request [1] via AMIS.
Last day to contact CDFI Program staff	April 29, 2021	5:00 p.m	Service Request via AMIS Or CDFI Fund Helpdesk: 202–653–0421.
Last day to contact AMIS–IT Help Desk (regarding AMIS technical problems only).	May 3, 2021	5:00 p.m	Service Request via AMIS or 202–653–0422 Or *AMIS@cdfi.treas.gov.*
Last day to submit CDFI Program Application for Financial Assistance (FA) *or* Technical Assistance (TA).	May 3, 2021	11:59 p.m	AMIS.

Executive Summary: Through the CDFI Program, the CDFI Fund provides (i) FA awards of up to $1 million to Certified Community Development Financial Institutions (CDFIs) to build their financial capacity to lend to Eligible Markets and/or their Target Markets, and (ii) TA grants of up to $125,000 to build Certified, and Emerging CDFIs' organizational capacity to serve Eligible Markets and/or their Target Markets. All awards provided through this NOFA are subject to funding availability.

[1] Service Request shall mean a written inquiry or notification submitted to the CDFI Fund via AMIS.

I. Program Description

A. History: The CDFI Fund was established by the Riegle Community Development Banking and Financial Institutions Act of 1994 to promote economic revitalization and community development through investment in and assistance to CDFIs. The CDFI Program made its first awards in 1996 and the Native American CDFI Assistance (NACA) Program made its first awards in 2002.

B. Priorities: Through the CDFI Program's FA awards and TA grants, the CDFI Fund invests in and builds the capacity of for-profit and non-profit community based lending organizations known as CDFIs. These organizations, certified as CDFIs by the CDFI Fund, serve rural and urban Low-Income people, and communities across the nation that lack adequate access to affordable Financial Products and Financial Services.

C. Authorizing Statutes and Regulations: The CDFI Program is authorized by the Riegle Community Development Banking and Financial Institutions Act of 1994 (Pub. L. 103–325, 12 U.S.C. 4701 *et seq.*) (Authorizing Statute). The regulations governing the CDFI Program are found at 12 CFR parts 1805 and 1815 (the Regulations) and set forth evaluation criteria and other program requirements. The CDFI Fund

encourages Applicants to review the Regulations; this NOFA; the CDFI Program Application for Financial Assistance or Technical Assistance (the Application); all related materials and guidance documents found on the CDFI Fund's website (Application materials); and the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (2 CFR part 1000), which is the Department of the Treasury's codification of the Office of Management and Budget (OMB) government-wide framework for grants management at 2 CFR part 200 (the Uniform Requirements) for a complete understanding of the program. Capitalized terms in this NOFA are defined in the Authorizing Statute, the Regulations, this NOFA, the Application, Application materials, or the Uniform Requirements. Details regarding Application content requirements are found in the Application and Application materials.

D. Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (2 CFR Part 1000): The Uniform Requirements codify financial, administrative, procurement, and program management standards that Federal award agencies must follow. When evaluating Applications, awarding agencies must evaluate the risks posed by each Applicant, and each Applicant's merits and eligibility. These requirements are designed to ensure that Applicants for Federal assistance receive a fair and consistent review prior to an award decision. This review will assess items such as the Applicant's financial stability, quality of management systems, the soundness of its business plan, history of performance, ability to achieve measurable impacts through its products and services, and audit findings. In addition, the Uniform Requirements include guidance on audit requirements and other award compliance requirements for Recipients.

E. Funding limitations: The CDFI Fund reserves the right to fund, in whole or in part, any, all, or none of the Applications submitted in response to this NOFA.

II. Federal Award Information

A. Funding Availability:

1. FY 2021 Funding Round: The CDFI Fund expects to award, through this NOFA, approximately $188 million as indicated in the following table:

TABLE 2—FY 2021 FUNDING ROUND ANTICIPATED CATEGORY AMOUNTS

Funding categories (See definition in table 7 for TA or table 8 for FA)	Estimated total amount to be awarded (millions)	Award amount		Estimated number of awards for FY 2021	Estimate average amount awarded in FY 2021	Average amount awarded in FY 2020
		Minimum [2]	Maximum			
Base-FA: Category I/Small and/or Emerging CDFI Assistance (SECA).	$25	$125,000	$700,000	83	$300,000	$424,000
Base-FA: Category II/Core	105.2	$500,000, or if portfolio outstanding is less than $1,666,700 as of the most recent historic fiscal year end, then 30% of portfolio outstanding.	1,000,000	179	589,000	592,000
Persistent Poverty Counties—Financial Assistance (PPC–FA).	18.8	100,000	300,000	106	175,000	174,000
Disability Funds—Financial Assistance (DF–FA) *.	6	100,000	500,000	17	353,000	235,000
TA	10	10,000	125,000	80	125,000	125,000
Healthy Food Financing Initiative—Financial Assistance (HFFI–FA) *.	23	500,000	5,000,000	14	1,643,000	1,692,000
Total	188			479		

* DF–FA and HFFI–FA appropriation will be allocated in one competitive round between the NACA and CDFI Program NOFAs.

The CDFI Fund reserves the right to award more or less than the amounts cited above in each category, based upon available funding and other factors, as appropriate.

2. Funding Availability for the FY 2021 Funding Round: As of the date of this NOFA the CDFI Fund is operating under the Consolidated Appropriations Act, 2021 (Pub. L. 116–260).

3. Anticipated Start Date and Period of Performance: The Period of Performance for TA grants begins with the date of the award announcement and includes either (i) an Emerging CDFI Recipient's three full consecutive fiscal years after the date of the award announcement, or (ii) a Certified CDFI Recipient's two full consecutive fiscal years after the date of the award announcement, during which the Recipient must meet the Performance Goals and Measures (PG&Ms) set forth in the Assistance Agreement. The Period of Performance for FA awards begins with the date of the award announcement and includes a Recipient's three full consecutive fiscal years after the date of the award announcement, during which time the Recipient must meet the PG&Ms set forth in the Assistance Agreement.

B. Types of Awards: Through the CDFI Program, the CDFI Fund provides two types of awards: Financial Assistance (FA) and Technical Assistance (TA) awards. An Applicant may submit an Application for a TA grant or an FA award under the CDFI Program, but not both. FA Awards include the Base Financial Assistance (Base-FA) award and the following awards that are provided as a supplement to the Base-FA award: Healthy Food Financing Initiative-Financial Assistance (HFFI–FA), Persistent Poverty Counties-Financial Assistance (PPC–FA), and Disability Funds-Financial Assistance (DF–FA). The HFFI–FA, PPC–FA, and DF–FA Applications will be evaluated independently from the Base-FA Application, and will not affect the

[2] The FA Application Guidance defines ''the most recent historic fiscal year'' based on an Applicant's fiscal year end.

Base-FA Application evaluation or Base-FA award amount.

However, Applicants that qualify for the NACA Program may submit two Applications: *One* Application—either for a TA grant or an FA award, but not both—through the CDFI Program, and *one* Application—either for a TA grant or an FA award, but not both—through the NACA Program. NACA qualified Applicants that choose to apply for awards through both the CDFI Program and the NACA Program may either apply for the same type of award under each Program or for a different type of award under each Program. NACA qualified FA Applicants that choose to apply for an FA award under both the NACA Program and CDFI Program and are selected for an award under both Programs will be provided the FA award under the CDFI Program. NACA qualified TA Applicants that choose to apply for a TA award under both the NACA Program and CDFI Program and are selected for an award under both Programs will be provided the TA award under the NACA Program. NACA qualified Applicants that choose to apply for a TA award and a FA award under separate programs will be provided the larger of the two awards. NACA Applicants cannot receive an award under both Programs within the same funding round.

Category II (Core) FA Applicants applying for Base-FA, PPC–FA, and/or DF–FA must provide evidence of acceptable Matching Funds [3] (see Table 9 for more information), except Native American CDFIs [4] applying under this NOFA, which are exempt from the Matching Funds requirement.[5] Native American CDFIs that qualify as a Category II (Core) FA Applicant are not required to submit Matching Funds for their award requests. Additionally, the Matching Funds requirement for HFFI–FA and SECA FA Applicants is waived in the enacted FY 2021 Consolidated Appropriations Act. Therefore, HFFI–FA and SECA FA Applicants are not required to submit Matching Funds for their award requests. TA Applicants are not required to provide Matching Funds.

1. Base-FA Awards: Base-FA awards can be in the form of loans, grants, Equity Investments, deposits and credit union shares. The form of the Base-FA award is based on the form of the Matching Funds that the Applicant includes in its Application, unless Congress waived the Matching Funds requirement. The Matching Funds requirement was waived for the FY 2021 Funding Round for SECA FA Applicants and permanently waived for Native American CDFIs. Therefore, the Base-FA award will be in the form of a grant for SECA FA and Native American CDFI Applicants. Matching Funds are required for Category II (Core) Applicants applying for Base-FA awards, with the exception of Native American CDFIs, and must be from non-Federal sources, and cannot have been used as Matching Funds for any other Federal award. The CDFI Fund reserves the right, in its sole discretion, to provide a Base-FA award in an amount other than that which the Applicant requests; however, the award amount will not exceed the Applicant's award request as stated in its Application.

2. Persistent Poverty Counties—Financial Assistance (PPC–FA) Awards: PPC–FA awards will be provided as a supplement to Base-FA awards; therefore, only those Applicants that are selected to receive a Base-FA award through the CDFI Program FY 2021 Funding Round will be eligible to receive a PPC–FA award. PPC–FA awards can be in the form of loans, grants, Equity Investment, deposits and credit union shares. The form of the PPC–FA award is based on the form of the Matching Funds that the Applicant includes in its Application, unless Congress waived the Matching Funds requirement. The Matching Funds requirement was waived for the FY 2021 Funding Round for SECA FA Applicants and permanently waived for Native American CDFIs. Therefore, the PPC–FA award will be in the form of a grant for SECA FA and Native American CDFI Applicants. Matching Funds are required for Category II (Core) Applicants applying for PPC–FA awards, with the exception of Native American CDFIs, and must be from non-Federal sources, and cannot have been used as Matching Funds for any other Federal award. The CDFI Fund reserves the right, in its sole discretion, to provide a PPC–FA award in an amount other than that which the Applicant requests; however, the award amount will not exceed the Applicant's award request as stated in its Application.

3. Disability Funds—Financial Assistance (DF–FA) Awards: DF–FA awards will be provided as a supplement to Base-FA awards; therefore, only those Applicants that have been selected to receive a Base-FA award through the CDFI Program FY 2021 Funding Round will be eligible to receive a DF–FA award. DF–FA awards can be in the form of loans, grants, Equity Investments, deposits and credit union shares. The form of the DF–FA award is based on the form of the Matching Funds that the Applicant includes in its Application, unless Congress waived the Matching Funds requirement. The Matching Funds requirement was waived for the FY 2021 Funding Round for SECA FA Applicants and permanently waived for Native American CDFIs. Therefore, the DF–FA award will be in the form of a grant for SECA FA and Native American CDFI Applicants. Matching Funds are required for Category II (Core) Applicants applying for DF–FA awards, with the exception of Native American CDFIs, and must be from non-Federal sources, and cannot have been used as Matching Funds for any other Federal award. The CDFI Fund reserves the right, in its sole discretion, to provide a DF–FA award in an amount other than that which the Applicant requests; however, the award amount will not exceed the Applicant's award request as stated in its Application.

4. Healthy Food Financing Initiative—Financial Assistance (HFFI–FA) Awards: HFFI–FA awards will be provided as a supplement to Base-FA awards; therefore, only those Applicants that have been selected to receive a Base-FA award through the CDFI Program FY 2021 Funding Round will be eligible to receive an HFFI–FA award. HFFI–FA awards can be in the form of loans, grants, Equity Investments, deposits and credit union shares. The form of the HFFI–FA award is based on the form of the Matching Funds that the Applicant includes in its Application, unless Congress waived the Matching Funds requirement. The Matching Funds requirement was waived for the FY 2021 Funding Round for HFFI–FA Applicants and permanently waived for Native American CDFIs. Therefore, all HFFI–FA awards will be in the form of a grant. The CDFI Fund reserves the right, in its sole discretion, to provide an HFFI–FA award in an amount other than that which the Applicant requests; however, the award amount will not exceed the Applicant's award request as stated in its Application.

[3] Matching Funds shall mean funds from sources other than the Federal government as defined in accordance with the CDFI Program Regulations at 12 CFR 1805.500.

[4] A Native American CDFI (Native CDFI) is one that Primarily Serves a Native Community. Primarily Serves is defined as 50% or more of an Applicant's activities being directed to a Native Community. For purposes of this NOFA, a Native Community is defined as Native American, Alaska Native, or Native Hawaiian populations or Native American areas defined as Federally-designated reservations, Hawaiian homelands, Alaska Native Villages and U.S. Census Bureau-designated Tribal Statistical Areas.

[5] The Indian Community Economic Enhancement Act of 2020 (Pub. L. 116–261) permanently waives the Matching Funds requirement for Native American CDFIs that receive Assistance from the CDFI Fund.

5. TA Grants: TA is provided in the form of grants. The CDFI Fund reserves the right, in its sole discretion, to provide a TA grant in an amount other than that which the Applicant requests; however, the TA grant amount will not exceed the Applicant's request as stated in its Application.

C. Eligible Activities

1. FA Awards: Base-FA, PPC–FA, DF–FA, and HFFI–FA award funds may be expended for activities serving Commercial Real Estate, Small Business, Microenterprise, Community Facilities, Consumer Financial Products, Consumer Financial Services, Commercial Financial Products, Commercial Financial Services, Affordable Housing, Intermediary Lending to Non-Profits and CDFIs, and other lines of business as deemed appropriate by the CDFI Fund in the following five categories: (i) Financial Products; (ii) Financial Services; (iii) Loan Loss Reserves; (iv) Development Services; and (v) Capital Reserves. The FA Budget is the amount of the award and must be expended in the five eligible activity categories prior to the end of the Budget Period.[6] None of the eligible activity categories will be authorized for Indirect Costs or an associated Indirect Cost Rate. Base-FA Recipients must meet PG&Ms, which will be derived from projections and attestations provided by the Applicant in its Application, to achieve one or more of the following FA Objectives: (i) Increase Volume of Financial Products in an Eligible Market(s) and/or in the Applicant's approved Target Market and/or Increase Volume of Financial Services in an Eligible Market(s) and/or in the Applicant's approved Target Market; (ii) Serve Eligible Market(s) or the Applicant's approved Target Market in New Geographic Area or Areas; (iii) Provide New Financial Products in an Eligible Market(s) and/or in the Applicant's approved Target Market, Provide New Financial Services in an Eligible Market(s) and/or in the Applicant's approved Target Market, or Provide New Development Services in an Eligible Market(s) and/or in the Applicant's approved Target Market; and (iv) Serve New Targeted Population or Populations. FA awards may only be used for Direct Costs associated with an eligible activity; no indirect expenses are allowed. Up to 15% of the FA award may be used for Direct Administrative Expenses associated with an eligible FA activity. ''Direct Administrative Expenses'' shall mean Direct Costs, as described in 2 CFR 200.413 of the Uniform Requirements, which are incurred by the Recipient to carry out the Financial Assistance. Direct Costs incurred to provide Development Services or Financial Services do not constitute Direct Administrative Expenses.

The Recipient must comply, as applicable, with the Buy American Act of 1933, 41 U.S.C. 8301–8303 and 2 CFR 200.216 of the Uniform Requirements,[7] with respect to any Direct Costs. For purposes of this NOFA, the five eligible activity categories are defined below:

TABLE 3—BASE–FA, PPC–FA, DF–FA, AND HFFI–FA ELIGIBLE ACTIVITY CATEGORIES

FA eligible activity	FA eligible activity definition *	Eligible CDFI institution types
i. Financial Products	FA expended as loans, Equity Investments and similar financing activities (as determined by the CDFI Fund) including the purchase of loans originated by Certified CDFIs and the provision of loan guarantees. In the case of CDFI Intermediaries, Financial Products may also include loans to CDFIs and/or Emerging CDFIs, and deposits in Insured Credit Union CDFIs, Emerging Insured Credit Union CDFIs, and/or State-Insured Credit Union CDFIs. For HFFI–FA, however, the purchase of loans originated by Certified CDFIs, loan refinancing, or any type of financing for prepared food outlets are not eligible activities.	All.
ii. Financial Services	FA expended for providing checking, savings accounts, check cashing, money orders, certified checks, automated teller machines, deposit taking, safe deposit box services, and other similar services.	Regulated Institutions[8] only. Not applicable for HFFI-FA Recipients.
iii. Loan Loss Reserves	FA set aside in the form of cash reserves, or through accounting-based accrual reserves, to cover losses on loans, accounts, and notes receivable or for related purposes that the CDFI Fund deems appropriate.	All.
iv. Development Services	FA expended for activities undertaken by a CDFI, its Affiliate or contractor that (i) promote community development and (ii) prepare or assist current or potential borrowers or investees to use the CDFI's Financial Products or Financial Services. For example, such activities include financial or credit counseling; homeownership counseling; business planning; and management assistance.	All.
v. Capital Reserves	FA set aside as reserves to support the Applicant's ability to leverage other capital, for such purposes as increasing its net assets or providing financing, or for related purposes as the CDFI Fund deems appropriate.	Regulated Institutions only. Not applicable for DF–FA.

* *All FA eligible activities must be in an Eligible Market or the Applicant's approved Target Market.* Eligible Market is defined as (i) a geographic area meeting the requirements set forth in 12 CFR 1805.201(b)(3)(ii), or (ii) individuals that are Low-Income, African American, Hispanic, Native American, Native Hawaiians residing in Hawaii, Alaska Natives residing in Alaska, or Other Pacific Islanders residing in American Samoa, Guam or the Northern Mariana Islands.

[6] Budget Period means the time interval from the start date of a funded portion of an award to the end date of that funded portion during which Recipients are authorized to expend the funds awarded.

[7] 2 CFR 200.216 prohibits Recipients and Subrecipients from obligating or expending loan or grant funds to procure or obtain, by contract or otherwise, equipment, services, or systems that use ''covered telecommunications equipment''. As used herein, ''covered telecommunications equipment'' is telecommunications equipment produced by Huawei Technologies Company or ZTE Corporation (or any Subsidiary or Affiliate of such entities).

[8] Regulated Institutions include Insured Credit Unions, Insured Depository Institutions, State-Insured Credit Unions and Depository Institution Holding Companies.

2. DF–FA Award: DF–FA award funds may only be expended for eligible FA activities (referenced in Table 3) to directly or indirectly benefit individuals with disabilities. The DF–FA Recipient must close Financial Products for the primary purpose of directly or indirectly benefiting people with disabilities, where the majority of the DF–FA supported loans or investments benefit individuals with disabilities, in an amount equal to or greater than 85% of the total DF–FA provided. Eligible DF–FA financing activities may include, among other activities, loans to develop or purchase affordable, accessible, and safe housing; loans to provide or facilitate employment opportunities; and loans to purchase assistive technology.

For the purposes of DF–FA, a person with a Disability is a person who has a physical or mental impairment that substantially limits one or more major life activities, a person who has a history or record of such an impairment, or a person who is perceived by others as having such an impairment, as defined by the American Disabilities Act (ADA) at *https://www.ada.gov/cguide.htm.*

3. TA Grants: TA grant funds may be expended for the following eight eligible activity categories: (i) Compensation—Personal Services; (ii) Compensation—Fringe Benefits; (iii) Professional Service Costs; (iv) Travel Costs; (v) Training and Education Costs; (vi) Equipment; (vii) Supplies; and (viii) Incorporation Costs. The TA Budget is the amount of the award and must be expended in the eight eligible activity categories before the end of the Budget Period. None of the eligible activity categories will be authorized for Indirect Costs or an associated Indirect Cost Rate. Any expenses that are prohibited by the Uniform Requirements are unallowable and are generally found in Subpart E-Cost Principles. The Recipient must comply, as applicable, with the Buy American Act of 1933, 41 U.S.C. 8301–8303 and 2 CFR 200.216 of the Uniform Requirements, with respect to any Direct Costs. For purposes of this NOFA, the eight eligible activity categories are defined below:

TABLE 4—TA ELIGIBLE ACTIVITY CATEGORIES, SUBJECT TO THE APPLICABLE PROVISIONS OF THE UNIFORM REQUIREMENTS

(i) Compensation—personal services ..	TA paid to cover all remuneration, paid currently or accrued, for services of Applicant's employees rendered during the Period of Performance under the TA grant in accordance with § 200.430 of the Uniform Requirements. Any work performed directly but unrelated to the purposes of the TA grant may not be paid as Compensation through a TA grant. For example, the salaries for building maintenance would not carry out the purpose of a TA grant and would be deemed unallowable.
(ii) Compensation—Fringe Benefits	TA paid to cover allowances and services provided by the Applicant to its employees as Compensation in addition to regular salaries and wages, in accordance with § 200.431 of the Uniform Requirements. Such expenditures are allowable as long as they are made under formally established and consistently applied organizational policies of the Applicant.
(iii) Professional Service Costs	TA used to pay for professional and consultant services (e.g., such as strategic and marketing plan development), rendered by persons who are members of a particular profession or possess a special skill (e.g., credit analysis, portfolio management), and who are not officers or employees of the Applicant, in accordance with § 200.459 of the Uniform Requirements. Payment for a consultant's services may not exceed the current maximum of the daily equivalent rate paid to an Executive Schedule Level IV Federal employee. Professional and consultant services must build the capacity of the CDFI. For example, professional services that provide direct Development Services to the customers does not build the capacity of the CDFI to provide those services and would not be eligible. The Applicant must comply, as applicable, with 2 CFR 200.216 of the Uniform Requirements, with respect to payment of Professional Service Costs.
(iv) Travel Costs	TA used to pay costs of transportation, lodging, subsistence, and related items incurred by the Applicant's personnel who are on travel status on business related to the TA award, in accordance with § 200.475 of the Uniform Requirements. Travel Costs do not include costs incurred by the Applicant's consultants who are on travel status. Any payments for travel expenses incurred by the Applicant's personnel but unrelated to carrying out the purpose of the TA grant would be deemed unallowable. As such, documentation must be maintained that justifies the travel as necessary to the TA grant.
(v) Training and Education Costs	TA used to pay the cost of training and education provided by the Applicant for employees' development in accordance with § 200.473 of the Uniform Requirements. TA can only be used to pay for training costs incurred by the Applicant's employees. Training and Education Costs may not be incurred by the Applicant's consultants.
(vi) Equipment	TA used to pay for tangible personal property, having a useful life of more than one year and a per-unit acquisition cost of at least $5,000, in accordance with § 200.1 of the Uniform Requirements. For example, items such as office furnishings and information technology systems are allowable as Equipment costs. The Applicant must comply, as applicable, with the Buy American Act of 1933, 41 U.S.C. 8301–8303 and 2 CFR 200.216 of the Uniform Requirements, with respect to the purchase of Equipment.
(vii) Supplies	TA used to pay for tangible personal property with a per unit acquisition cost of less than $5,000, in accordance with § 200.1 of the Uniform Requirements. For example, a desktop computer costing $1,000 is allowable as a Supply cost. The Applicant must comply, as applicable, with the Buy American Act of 1933, 41 U.S.C. 8301–8303 and 2 CFR 200.216 of the Uniform Requirements, with respect to the purchase of Supplies.
(viii) Incorporation Costs (*Sponsoring Entities only).*	TA used to pay for incorporation fees in connection with the establishment or reorganization of an organization as a CDFI, in accordance with § 200.455 of the Uniform Requirements. Incorporation Costs are allowable for NACA Program Sponsoring Entity Applicants only.

4. HFFI–FA Award: HFFI–FA award funds may only be expended for eligible FA activities referenced in Table 3. The HFFI–FA investments must comply with the following guidelines:

a. Recipient must close Financial Products for Healthy Food Retail Outlets and Healthy Food Non-Retail Outlets in its approved Target Market in an amount equal to or greater than 100% of the total HFFI Financial Assistance provided. Eligible financing activities to Healthy Food Retail Outlets and Healthy Food Non-Retail Outlets require that the majority of the loan or investment be devoted to offering a range of Healthy Food choices, which may include, among other activities, investments supporting an existing retail store or wholesale operation upgrade to offer an expanded range of Healthy Food choices, or supporting a nonprofit organization that expands the availability of Healthy Foods in underserved areas.

b. Recipient must demonstrate that it has closed Financial Products to Healthy Food Retail Outlets located in Food Deserts in the Recipient's approved Target Market in an amount equal to 75% of the total HFFI Financial Assistance provided.

Definitions

Healthy Foods: Healthy Foods include unprepared nutrient-dense foods and beverages as set forth in the USDA Dietary Guidelines for Americans 2020–2025 including whole fruits and vegetables, whole grains, fat free or low-fat dairy foods, lean meats and poultry (fresh, refrigerated, frozen or canned). Healthy Foods should have low or no added sugars, and be low-sodium, reduced sodium, or no-salt-added. (See USDA Dietary Guidelines: *http://www.dietaryguidelines.gov*).

Healthy Food Retail Outlets: Commercial sellers of Healthy Foods including, but not limited to, grocery stores, mobile food retailers, farmers markets, retail cooperatives, corner stores, bodegas, stores that sell other food and non-food items along with a range of Healthy Foods.

Healthy Food Non-Retail Outlets: Wholesalers of Healthy Foods including, but not limited to, wholesale food outlets, wholesale cooperatives, or other non-retail food producers that supply for sale a range of Healthy Food options; entities that produce or distribute Healthy Foods for eventual retail sale, and entities that provide consumer education regarding the consumption of Healthy Foods.

Food Deserts: Distressed geographic areas where either a substantial number or share of residents has low access to a supermarket or large grocery store. For the purpose of satisfying this requirement, a Food Desert must either: (1) Be a census tract determined to be a Food Desert by the U.S. Department of Agriculture (USDA), in its USDA Food Access Research Atlas; (2) be a census tract adjacent to a census tract determined to be a Food Desert by the USDA, in its USDA Food Access Research Atlas; which has a median family income less than or equal to 120% of the applicable Area Median Family Income; or (3) be a Geographic Unit as defined in 12 CFR part 1805.201(b)(3)(ii)(B), which (i) individually meets at least one of the criteria in 12 CFR 1805.201(b)(3)(ii)(D), and (ii) has been identified as having low access to a supermarket or grocery store through a methodology that has been adopted for use by another governmental or philanthropic healthy food initiative.

5. PPC–FA Award: PPC–FA award funds may only be expended for eligible FA activities referenced in Table 3. The PPC–FA Recipient must close Financial Products in PPC in an Eligible Market or in the Applicant's approved Target Market in an amount equal to or greater than 100% of the total PPC Financial Assistance provided. The specific counties that meet the criteria for ''persistent poverty'' can be found at: *https://www.cdfifund.gov/Documents/CDFIPPCFeb19-2020.xls.*

III. Eligibility Information

A. Eligible Applicants: For the purposes of this NOFA, the following tables set forth the eligibility criteria to receive an award from the CDFI Fund, along with certain definitions of terms. There are four categories of Applicant eligibility criteria: (1) CDFI certification criteria (Table 5); (2) requirements that apply to all Applicants (Table 6); (3) requirements that apply to TA Applicants (Table 7); and (4) requirements that apply to FA Applicants (Table 8).

TABLE 5—CDFI CERTIFICATION CRITERIA DEFINITIONS

Certified CDFI	An entity that the CDFI Fund has officially notified that it meets all CDFI certification requirements.
Emerging CDFI (TA Applicants)	• A non-Certified entity that demonstrates to the CDFI Fund in its Application that it has an acceptable plan to meet CDFI certification requirements by the end of its Period of Performance, or another date that the CDFI Fund selects. • An Emerging CDFI that has prior award(s) must comply with CDFI certification PG&M(s) stated in its prior Assistance Agreement(s). An Emerging CDFI selected to receive a TA grant will be required to become a Certified CDFI by a date specified in the Assistance Agreement.

TABLE 6—ELIGIBILITY REQUIREMENTS FOR ALL APPLICANTS

Applicant	• Only the entity that will carry out the proposed award activities may apply for an award (other than Depository Institution Holding Companies (DIHC) [9]—see below). Recipients may not create a new legal entity to carry out the proposed award activities. • The information in the Application should only reflect the activities of the Applicant, including the presentation of financial and portfolio information. Do not include financial or portfolio information from parent companies, Affiliates, or Subsidiaries in the Application unless it relates to the provision of Development Services. • An Applicant that applies on behalf of another organization will be rejected without further consideration, other than Depository Institution Holding Companies (see below).
Application type and submission overview through *Grants.gov* and Awards Management Information System (AMIS).	• Applicants must submit the Required Application Documents listed in Table 10.

[9] Depository Institution Holding Company or DIHC means a Bank Holding Company or a Savings and Loan Holding Company.

TABLE 6—ELIGIBILITY REQUIREMENTS FOR ALL APPLICANTS—Continued

	• The CDFI Fund will only accept Applications that use the official Application templates provided on the *Grants.gov* and AMIS websites. Applications submitted with alternative or altered templates will not be considered. • Applicants undergo a two-step process that requires the submission of Application documents by two separate deadlines in two different locations: (1) The SF–424 in *Grants.gov* and (2) all other Required Application Documents in AMIS. • *Grants.gov* and the SF–424: ○ *Grants.gov*: Applicants must submit the Standard Form (SF) SF–424, Application for Federal Assistance. ○ All Applicants must register in the *Grants.gov* system to successfully submit an Application. The *Grants.gov* registration process can take 30 days or more to complete. The CDFI Fund strongly encourages Applicants to register as early as possible. ○ The CDFI Fund will not extend the SF–424 application deadline for any Applicant that started the *Grants.gov* registration process on, before, or after the date of the publication of this NOFA, but did not complete it by the deadline except in the case of a Federal government administrative or technological error that directly resulted in a late submission of the SF–424. ○ The SF–424 must be submitted in *Grants.gov* on or before the deadline listed in Table 1 and Table 12. Applicants are strongly encouraged to submit their SF–424 as early as possible in the *Grants.gov* portal. ○ The deadline for the *Grants.gov* submission is before the AMIS submission deadline. ○ The SF–424 must be submitted under the CDFI Program Funding Opportunity Number for the CDFI Program Application. *CDFI Program Applicants should be careful to not select the NACA Program Funding Opportunity Number when submitting their SF–424 for the CDFI Program.* CDFI Program Applicants that submit their SF–424 for the CDFI Program Application under the NACA Program Funding Opportunity Number will be deemed ineligible for the CDFI Program Application. ○ If the SF–424 is not accepted by *Grants.gov* by the deadline, the CDFI Fund will not review any material submitted in AMIS and the Application will be deemed ineligible. • AMIS and all other Required Application Documents listed in Table 10: ○ AMIS is an enterprise-wide information technology system. Applicants will use AMIS to submit and store organization and Application information with the CDFI Fund. ○ Applicants are only allowed one CDFI Program Application submission in AMIS. ○ Each Application in AMIS must be signed by an Authorized Representative. ○ Applicants must ensure that the Authorized Representative is an employee or officer of the Applicant, authorized to sign legal documents on behalf of the organization. *Consultants working on behalf of the organization may not be designated as Authorized Representatives.* ○ Only the Authorized Representative or Application Point of Contact, included in the Application, may submit the Application in AMIS. ○ All Required Application Documents must be submitted in AMIS on or before the deadline specified in Tables 1 and 12. ○ The CDFI Fund will not extend the deadline for any Applicant except in the case of a Federal government administrative or technological error that directly resulted in the late submission of the Application in AMIS.
Employer Identification Number (EIN)	• Applicants must have a unique EIN assigned by the Internal Revenue Service (IRS). • The CDFI Fund will reject an Application submitted with the EIN of a parent or Affiliate organization. • The EIN in the Applicant's AMIS account must match the EIN in the Applicant's System for Award Management (SAM) account. The CDFI Fund reserves the right to reject an Application if the EIN in the Applicant's AMIS account does not match the EIN in its SAM account. • Applicants must enter their EIN into their AMIS profile on or before the deadline specified in Tables 1 and 12.
Dun & Bradstreet, (DUNS) number	• Pursuant to OMB guidance (68 FR 38402), an Applicant must apply using its unique DUNS number in *Grants.gov*. • The CDFI Fund will reject an Application submitted with the DUNS number of a parent or Affiliate organization. • The DUNS number in the Applicant's AMIS account must match the DUNS number in the Applicant's *Grants.gov* and SAM accounts. The CDFI Fund will reject an Application if the DUNS number in the Applicant's AMIS account does not match the DUNS number in its *Grants.gov* and SAM accounts. • Applicants must enter their DUNS number into their AMIS profile on or before the deadline specified in Tables 1 and 12.
System for Award Management (SAM)	• SAM is a web-based, government-wide application that collects, validates, stores, and disseminates business information about the federal government's trading partners in support of the contract awards, grants, and electronic payment processes. • Applicants must register in SAM as part of the *Grants.gov* registration process. • Applicants must have a DUNS number and an EIN number in order to register in SAM. • Applicants must be registered in SAM in order to submit an SF–424 in *Grants.gov*. • The CDFI Fund reserves the right to deem an Application ineligible if the Applicant's SAM account expires during the Application evaluation period, or is set to expire before September 30, 2021, and the Applicant does not re-activate, or renew, as applicable, the account within the deadlines that the CDFI Fund communicates to affected Applicants during the Application evaluation period.
AMIS Account	• Each Applicant must register as an organization in AMIS and submit all Required Application Documents listed in Table 10 through the AMIS portal. • The Application of any organization that does not properly register in AMIS by the deadline set forth in Table 1—FY 2021 CDFI Program Funding Round Critical Deadlines for Applicants—will be rejected without further consideration.

TABLE 6—ELIGIBILITY REQUIREMENTS FOR ALL APPLICANTS—Continued

	• The Authorized Representative and/or Application Point of Contact must be included as "users" in the Applicant's AMIS account. • An Applicant that fails to properly register and update its AMIS account may miss important communication from the CDFI Fund and/or may not be able to successfully submit an Application.
501 (c)(4) status	• Pursuant to 2 U.S.C. 1611, any 501(c)(4) organization that engages in lobbying activities is not eligible to receive a CDFI or NACA Program award.
Compliance with Nondiscrimination and Equal Opportunity Statutes, Regulations, and Executive Orders.	• An Applicant may not be eligible to receive an award if proceedings have been instituted against it in, by, or before any court, governmental agency, or administrative body, and a final determination within the last three years indicates the Applicant has violated any of the following laws, including but not limited to: Title VI of the Civil Rights Act of 1964, as amended (42 U.S.C.2000d); Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794); the Age Discrimination Act of 1975, (42 U.S.C. 6101–6107), and Executive Order 13166, Improving Access to Services for Persons with Limited English Proficiency.
Depository Institution Holding Company Applicant.	• In the case where a CDFI Depository Institution Holding Company Applicant intends to carry out the activities of an award through its Subsidiary CDFI Insured Depository Institution, the Application must be submitted by the CDFI Depository Institution Holding Company and reflect the activities and financial performance of the Subsidiary CDFI Insured Depository Institution. • Authorized Representatives of both the Depository Institution Holding Company and the Subsidiary CDFI Insured Depository Institution must certify that the information included in the Application represents that of the Subsidiary CDFI Insured Depository Institution, and that the award funds will be used to support the Subsidiary CDFI Insured Depository Institution for the eligible activities outlined in the Application.
Use of award	• All awards made through this NOFA must be used to support the Applicant's activities in at least one of the FA or TA Eligible Activity Categories (see Section II. (C)). • With the exception of Depository Institution Holding Company Applicants, awards may not be used to support the activities of, or otherwise be passed through, transferred, or co-awarded to, third-party entities, whether Affiliates, Subsidiaries, or others, unless done pursuant to a merger or acquisition or similar transaction, and with the CDFI Fund's prior written consent. The Recipient of any award made through this NOFA must comply, as applicable, with the Buy American Act of 1933, 41 U.S.C. 8301–8303 and 2 CFR 200.216 of the Uniform Requirements, with respect to any Direct Costs.
Requested award amount	• An Applicant must state its requested award amount in the Application in AMIS. An Applicant that does not include this amount will not be allowed to submit an Application.
Pending resolution of noncompliance	• The CDFI Fund will consider an Application submitted by an Applicant that has pending noncompliance issues on any of its previously executed award agreement(s), if the CDFI Fund has not yet made a final compliance determination.
Noncompliance or default status	• The CDFI Fund will not consider an Application submitted by an Applicant that has a previously executed award agreement(s) if, as of the date of the Application, (i) the CDFI Fund has made a final determination that such entity is noncompliant or found in default with a previously executed agreement, and (ii) the CDFI Fund has provided written notification that such entity is ineligible to apply for or receive any future CDFI Fund awards or allocations. Such entities will be ineligible to submit an Application for such time period as specified by the CDFI Fund in writing. • The CDFI Fund will not consider any Applicant that has defaulted on a loan from the CDFI Fund within five years of the Application deadline.
Debarment/Do Not Pay Verification	• The CDFI Fund will conduct a debarment check and will not consider an Application submitted by an Applicant (or Affiliate of an Applicant) if the Applicant is delinquent on any Federal debt. • The Do Not Pay Business Center was developed to support Federal agencies in their efforts to reduce the number of improper payments made through programs funded by the Federal government. The Do Not Pay Business Center provides delinquency information to the CDFI Fund to assist with the debarment check.

TABLE 7—ELIGIBILITY REQUIREMENTS FOR TA APPLICANTS

CDFI certification status	(1) Emerging CDFIs (see definition in Table 5), or (2) Certified CDFIs (see Table 5) that meet the following SECA Applicant criteria: (1) Have total assets as of the end of the Applicant's most recent historic fiscal year[10] in accordance with the FA Application Guidance (as stated in the Applicant's AMIS account and verified by internally prepared financial statements and/or audits) in the following amounts: • Insured Depository Institutions and Depository Institution Holding Companies: up to $250 million; • Insured Credit Unions and State-Insured Credit Unions: Up to $100 million; • Venture Capital Funds: ** Up to $5 million; • Other CDFIs: Up to $5 million; OR (2) Have begun operations (as indicated by the financing activity start date field in the Applicant's AMIS account) on or after January 1, 2017.
Matching Funds	• Matching Funds documentation is not required for TA awards.
Limitation on Awards	• An Emerging CDFI may not receive more than three TA awards as an uncertified CDFI.
Proposed Activities	• Applicants must propose to directly undertake eligible activities with TA awards. For example, an uncertified CDFI Applicant must propose to become certified as part of its Application and a Certified CDFI Applicant must propose activities that build its capacity to serve its Target Market or an Eligible Market. • With the exception of Sponsoring Entities in the NACA Program, Applicants may not propose to use a TA award to create a separate legal entity to become a Certified CDFI or otherwise carry out the TA award activities.

TABLE 7—ELIGIBILITY REQUIREMENTS FOR TA APPLICANTS—Continued

Regulated Institution	• Each Regulated Institution TA Applicant must have a CAMELS/CAMEL rating (rating for banks and credit unions, respectively) or equivalent type of rating by its regulator (collectively referred to as "CAMELS/CAMEL rating") of at least "4". • TA Applicants with CAMELS/CAMEL ratings of "5" will not be eligible for awards. • The CDFI Fund will also evaluate material concerns identified by the Appropriate Federal Banking Agency in determining the eligibility of Regulated Institution Applicants.

** A Venture Capital Fund is an organization that predominantly invests funds in businesses, typically in the form of either Equity Investments or subordinated debt with equity features such as a revenue participation or warrants, and generally seeks to participate in the upside returns of such businesses in an effort to at least partially offset the risk of its investments.

TABLE 8—ELIGIBILITY REQUIREMENTS FOR FA APPLICANTS

CDFI certification status	• Each FA Applicant must be a Certified CDFI prior to the date of the release of this NOFA. • The CDFI Fund will consider an Application submitted by an Applicant that has pending noncompliance issues with its Annual Certification Report if the CDFI Fund has not yet made a final compliance determination. • If a Certified CDFI loses its certification at any point prior to the award announcement, the Application will no longer be considered by the CDFI Fund.
Matching Funds documentation	• Native American CDFIs are not required to provide Matching Funds. • Applicants must submit acceptable documentation attesting that they have received or will receive Matching Funds. Applicants that do not complete the Matching Funds section in the FA Application in AMIS, documenting the source(s) of their Matching Funds, will not be evaluated. See Table 9 for additional information on Matching Funds requirements for FY 2021 Funding Round. The Matching Funds requirement for Category I (SECA) FA Applicants and HFFI–FA Applicants was waived in the final FY 2021 appropriations. Therefore HFFI–FA and SECA FA applicants are not required to submit Matching Funds for their award requests. Unless Congress waived the Matching Funds requirement, Applicants must document their Matching Funds in the Matching Funds section in the FA Application in AMIS. Matching Funds information provided in another format will not be considered. • Unless Congress waived the Matching Funds requirement, awards will be limited to no more than two times the amount of In-Hand or Committed Matching Funds documentation provided at the time of Application. See Table 9 for the definitions of Committed and In-Hand. • Unless Congress waived the Matching Funds requirement, awards will be obligated in like form to the Matching Funds provided at time of Application. See Table 9. Matching Funds "Determination of Award Form" for additional guidance. • Unless Congress waived the Matching Funds requirement, award payments from the CDFI Fund will require eligible dollar-for-dollar In-Hand Matching Funds for the total payment amount. Recipients will not receive a payment until 100% of their Matching Funds are In-Hand. • Unless Congress waived the Matching Funds requirement, the CDFI Fund will reduce and de-obligate the remaining balance of any award that does not demonstrate full dollar-for-dollar Matching Funds equal to the announced award amount by the end of the Matching Funds Window.
Consideration as a Native American CDFI.	• The Indian Community Economic Enhancement Act of 2020 (Pub. L. 116–261) permanently waived the Matching Funds requirements for Native American CDFIs. For consideration as a Native American CDFI under this NOFA, an FA Applicant must Primarily Serve a Native Community. Primarily Serves is defined as 50% or more of an Applicant's activities being directed to a Native Community. • For purposes of this NOFA, a Native Community is defined as Native American, Alaska Native, or Native Hawaiian populations or Native American areas defined as Federally-designated reservations, Hawaiian homelands, Alaska Native Villages and U.S. Census Bureau-designated Tribal Statistical Areas. • Applicants that do not meet the above conditions will not be considered as a Native American CDFI under this NOFA. • Native American CDFI FA Applicants are not required to provide Matching Funds. Therefore, if the CDFI Fund determines that a Category II (Core) FA Applicant that attests in its Application to meeting the above conditions does not meet the criteria to be considered a Native American CDFI, the Application will be deemed ineligible for failure to provide Matching Funds.
$5 Million funding cap	• The CDFI Fund is prohibited from obligating more than $5 million in CDFI and NACA Program awards, in the aggregate, to any one organization and its Subsidiaries and Affiliates during any three-year period from the Announcement Date. • For TA Applicants, for purposes of this NOFA and per final FY 2021 appropriations language, the CDFI Fund will include CDFI and NACA Program final awards in the cap calculation that were provided to an Applicant (and/or its Subsidiaries or Affiliates) under the FY 2019, and 2020 funding rounds, as well as the requested FY 2021 award, excluding DF–FA and HFFI–FA awards.

[10] For the purposes of this NOFA, an Applicant's most recent historic fiscal year end is determined as follows:

(A) Applicants with a 3/31 fiscal year end date will treat FY 2020 as their most recent historic fiscal year and FY 2021 as their current year.

(B) Applicants with a 6/30 fiscal year end date will treat FY 2020 as their most recent historic fiscal year and FY 2021 as their current year.

(C) Applicants with a 9/30 fiscal year end date and a completed FY 2020 audit will treat FY 2020 as their most recent historic fiscal year and FY 2021 as their current year.

(D) Applicants with a 9/30 fiscal year end date but without a completed FY 2020 audit will treat FY 2019 as their most recent historic fiscal year and FY 2020 as their current year.

(E) Applicants with a 12/31 fiscal year end date, with or without a completed FY 2020 audit, will treat FY 2019 as their most recent historic fiscal year and FY 2020 as their current year.

TABLE 8—ELIGIBILITY REQUIREMENTS FOR FA APPLICANTS—Continued

	• For FA Applicants, for purposes of this NOFA and per final FY 2021 appropriations language, the CDFI Fund will include CDFI and NACA Program final awards in the cap calculation that were provided to an Applicant (and/or its Subsidiaries or Affiliates) under the FY 2019 and 2020 funding rounds, as well as the requested FY 2021 award, excluding DF–FA and HFFI–FA awards.
FA Category I (SECA)	• To be an eligible SECA Applicant, an Applicant must meet the following criteria: (1) Be a Certified CDFI; (2) Request $700,000 or less in Base-FA funds; AND EITHER (3) Have total assets as of the end of the Applicant's most recent historic fiscal year in accordance with the FA Application Guidance (as stated in the Applicant's AMIS account and verified by internally prepared financial statements and/or audits) in the following amounts: • Insured Depository Institutions and Depository Institution Holding Companies: Up to $250 million; • Insured Credit Unions and State-Insured Credit Unions: Up to $100 million; • Venture Capital Funds: Up to $5 million; • Other CDFIs: Up to $5 million; OR • Have begun operations (as indicated by the financing activity start date field in the Applicant's AMIS account) on or after January 1, 2017.
FA Category II (Core)	• A Core Applicant must be a Certified CDFI as defined in Table 5. • An Applicant that meets the SECA requirements stated above, and that requests more than $700,000 in Base-FA award funds is categorized as an FA Category II (Core) Applicant, regardless of its total assets and/or years in operation. • Such Applicants who meet SECA requirements but wish to apply as a Core FA Applicant, by requesting more than $700,000, must submit a Service Request in AMIS to request that a Core-FA Application be created by the dates specified in Tables 1 and 12. The CDFI Fund will not change an Application back to a SECA FA Application after a request to create a Core FA Application has been submitted to the CDFI Fund.
FA Applicants with Community Partners.	• A CDFI Applicant can apply for assistance jointly with a Community Partner. The CDFI Applicant must complete the CDFI Program Application and address the Community Partnership in its business plan and other sections of the Application as specified in the Application materials. • The CDFI Applicant must be a Certified CDFI as defined in Table 5. • An Application with a Community Partner must: ○ Describe how the CDFI Applicant and Community Partner will each participate in the partnership and how the partnership will enhance eligible activities serving the Investment Area and/or Targeted Population. ○ Demonstrate that the Community Partnership activities are consistent with the strategic plan submitted by the CDFI Applicant. • Assistance provided upon approval of an Application with a Community Partner shall only be entrusted to the CDFI Applicant and shall not be used to fund any activity carried out directly by the Community Partner or an Affiliate or Subsidiary thereof.
Regulated Institution	• Each Regulated Institution FA Applicant must have a CAMELS/CAMEL rating (rating for banks and credit unions, respectively) or equivalent type of rating by its regulator (collectively referred to as "CAMELS/CAMEL rating") of at least "3". • FA Applicants with CAMELS/CAMEL ratings of "4 or 5" will not be eligible for awards. • The CDFI Fund will also evaluate material concerns identified by the Appropriate Federal Banking Agency in determining the eligibility of Regulated Institution Applicants.
PPC–FA	• All PPC–FA Applicants must: ○ Submit a CDFI or NACA Program FA Application; ○ Meet all FA award eligibility requirements; and ○ Provide a PPC–FA award request amount in AMIS.
DF–FA	• All DF–FA Applicants must: ○ Submit a CDFI or NACA Program FA Application; ○ Meet all FA award eligibility requirements; ○ Submit the DF–FA Application; and ○ Provide a DF–FA award request amount in AMIS.
HFFI–FA	• All HFFI–FA Applicants must: ○ Submit a CDFI or NACA Program FA Application; ○ Meet all FA award eligibility requirements; ○ Submit the HFFI–FA Application; and ○ Provide a HFFI–FA award request amount in AMIS.

B. Matching Funds Requirements: In order to receive a Base–FA, PPC–FA, or DF–FA award, an Applicant must provide evidence of eligible dollar-for-dollar Matching Funds and attest that it can provide acceptable documentation upon the CDFI Fund's request as part of the Application, unless Congress waived the Matching Funds requirement. The Matching Funds requirement was waived for the FY 2021 Funding Round for SECA FA and HFFI–FA Applicants and permanently waived for Native American CDFIs.

Therefore, HFFI–FA, SECA FA, and Native American CDFI Applicants are not required to submit Matching Funds for their award requests. Matching Funds are not required for Native American CDFIs. An Applicant that represents that it has Equity Investments and/or deposits Matching Funds In-Hand at the time of Application submission must provide documentation of such as part of the Application. An Applicant that uses retained earnings as Matching Funds must provide supporting documentation of In-Hand and/or Committed Matching Funds at the time of Application submission. The CDFI Fund will review Matching Funds information, attestations, and supporting Matching

Funds documentation, if applicable, prior to award payment and will disburse funds based upon eligible In-Hand Matching Funds. The CDFI Fund encourages Applicants to review the Regulations, the Uniform Requirements, and the Matching Funds guidance materials available on the CDFI Fund's website. Table 9 provides a summary of the Matching Funds requirements for Category II (Core) FA Applicants, with the exception of Native American CDFIs, applying for Base–FA, PPC–FA, and DF–FA. The Matching Funds requirement for HFFI–FA, and SECA FA Applicants is waived for the FY 2021 Funding Round. The Matching Funds requirement for Native American CDFIs is permanently waived. Additional details are set forth in the Application materials.

TABLE 9—MATCHING FUNDS REQUIREMENTS *

In-Hand Matching Funds definition	• Matching Funds are In-Hand when the Applicant receives payment for the Matching Funds from the Matching Funds source and has acceptable documentation that can be provided to the CDFI Fund upon request. Acceptable In-Hand documentation must show the source, form (e.g., grant, loan, deposit, and Equity Investment), amount received, and the date the funds came into physical possession of the Applicant.
	• The following documentation, depending on the Matching Funds type, must be available to be provided to the CDFI Fund upon request:
	  • loan—the loan agreement and/or promissory note;
	  • grant—the grant letter or agreement;
	  • Equity Investment—the stock certificate, documentation of total equity outstanding, and shareholder agreement;
	  • retained earnings—Retained Earnings Calculator and audited financial statements or call reports from regulating entity for each fiscal year reported in the Retained Earnings Calculator;
	  • third party in-kind contribution—evidence of receipt of contribution and valuation;
	  • deposits—certificates of deposit agreement;
	  • secondary capital—secondary capital agreement and disclosure and acknowledgement statement; AND
	  • clearly legible documentation that demonstrates actual receipt of the Matching Funds including the date of the transaction and the amount, such as a copy of a check or a wire transfer statement.
	• Unless Congress waived the Matching Funds requirement, Applicants must provide information on their In-Hand Matching Funds in the Matching Funds section of the FA Application in AMIS (refer to Table 10—Required Application Documents) at the time of Application submission.
	• Although Applicants are not required to provide further documentation for In-Hand Matching Funds at the time of Application submission (other than supporting documentation for retained earnings, deposits, and Equity Investments, which must be provided at the time of Application submission), they must be able to provide documentation to the CDFI Fund upon request.

Matching Funds requirements by Application type.	The following Applicants must provide evidence of acceptable Matching Funds: • Category II/Core FA Applicants, with the exception of Native American CDFIs, applying for Base–FA, PPC–FA, and DF–FA. TA Applicants and Native American CDFI FA Applicants are not required to provide Matching Funds. The Matching Funds requirement for HFFI–FA and SECA FA Applicants was waived in the final FY 2021 appropriations. Therefore, HFFI–FA and SECA FA Applicants are not required to provide Matching Funds.
Amount of required match	Unless waived by Congress, Applicants must provide evidence of eligible, In-Hand, dollar-for-dollar, non-Federal Matching Funds for every award dollar to be paid by the CDFI Fund. If awarded, Applicants that do not demonstrate 100% In-Hand Matching Funds at the time of Application submission may experience a longer payment timeline.
Determination of award form	Unless the Matching Funds requirement is waived by Congress, awards will be made in comparable form and value to the eligible In-Hand and/or Committed Matching Funds submitted by the Applicant. For awards where Congress has waived the Matching Funds requirement, the form of the award will be a grant. • For example, if an Applicant provides documentation of eligible loan Matching Funds for $200,000 and eligible grant Matching Funds of $400,000, the CDFI Fund will obligate $200,000 of the FA award as a loan and $400,000 as a grant. • The CDFI Fund will not permit a Recipient to change the form of a loan award. For awards where Congress waives the Matching Funds requirement, the form of the award will be a grant.
Matching Funds Window definition	• The Applicant must receive eligible In-Hand Matching Funds between January 1, 2019 and January 15, 2022. • A Recipient must provide the CDFI Fund with all documentation demonstrating the receipt of In-Hand Matching Funds by January 31, 2022.
Matching Funds and form of award	• Recipients will be approved for a maximum award size of two times the total amount of eligible In-Hand and/or Committed Matching Funds included in the Application, so long as they do not exceed the requested award amount. • The form of the Matching Funds documented in the Application determines the form of the award.
Committed Matching Funds definition ..	• Matching Funds are Committed when the Applicant has entered into or received a legally binding commitment from the Matching Funds source showing that the Matching Funds will be disbursed to the Applicant at a future date. • The Applicant must provide information on their Committed Matching Funds in the Matching Funds section of the FA Application in AMIS (refer to Table 10—Required Application Documents) at the time of Application submission.

TABLE 9—MATCHING FUNDS REQUIREMENTS *—Continued

	• Although the Applicant is not required to provide further documentation for Committed Matching Funds at the time of Application submission (other than supporting documentation for retained earnings, deposits, and Equity Investments, which must be provided at the time of Application submission), it must be able to provide the CDFI Fund, upon request, acceptable written documentation showing the source, form, and amount of the Committed Matching Funds (including, in the case of a loan, the terms thereof), as well as the anticipated payment date of the Committed funds.
Limitations on Matching Funds	• Matching Funds must be from non-Federal sources. • Applicants cannot proffer Matching Funds that were accepted as Matching Funds for a prior award that required Matching Funds under the CDFI Program, NACA Program, or under another Federal grant or award program. • Matching Funds must comply with the Regulations. • Matching Funds must be attributable to at least one of the five eligible FA activities (see Section II (C) of this NOFA).
Rights of the CDFI Fund	• The CDFI Fund reserves the right to contact the Matching Funds source to discuss the Matching Funds and the documentation that the Applicant provided. • The CDFI Fund may grant an extension of the Matching Funds Window (defined in Table 9), on a case-by-case basis, if the CDFI Fund deems it appropriate. • The CDFI Fund reserves the right to rescind all or a portion of an award requiring Matching Funds and re-allocate the rescinded award amount to other qualified Applicant(s) if a Recipient fails to provide evidence of In-Hand Matching Funds obtained during the Matching Funds Window totaling its award amount.
Matching Funds in the form of third-party in-kind contributions.	• Third party in-kind contributions are non-cash contributions (i.e., property or services) provided by non-Federal third parties to the Applicant. • Third party in-kind contributions will be considered to be in the form of a grant for Matching Funds purposes. • Third party in-kind contributions may be in the form of real property, equipment, supplies, and other expendable property. The value of goods and services must directly benefit the eligible FA activities. • For third party in-kind contributions, the fair market value of goods and services must be documented as the grant match. • Applicants will be responsible for documenting the value of all in-kind contributions pursuant to the Uniform Requirements.
Matching Funds in the form of a loan	• An award made in the form of a loan will have the following standardized terms: i. A 13-year term with semi-annual interest-only payments due in years 1 through 10, and fully amortizing payments due each year in years 11 through 13; and ii. A fixed interest rate of 0.66%, which was calculated by the CDFI Fund based on the U.S. Department of the Treasury's 10-year Treasury note. • The Applicant's Matching Funds loan(s) must: i. have a minimum of a 3-year term (loans presented as Matching Funds with less than a 3-year term will not qualify as eligible match); and ii. be from a non-Federal source.
Matching Funds in the form of Equity Investments.	• An Equity Investment source must meet the terms outlined in 12 CFR 1805.401(a): Equity: The CDFI Fund may make non-voting equity investments in a Recipient, including, without limitation, the purchase of non-voting stock. Such stock shall be transferable and, in the discretion of the CDFI Fund, may provide for convertibility to voting stock upon transfer. The CDFI Fund shall not own more than 50 percent of the equity of a Recipient and shall not control its operations. • The CDFI Fund's ownership of equity is calculated by dividing the shares owned by the CDFI Fund by the total number of shares issued by the Recipient. • The CDFI Fund reserves the right, in its sole discretion, to perform its own valuation of Equity Investment source(s) and to determine if the equity value is acceptable to the CDFI Fund.
Severe Constraints Waiver	• In the case of an Applicant demonstrating severe constraints on available sources of Matching Funds, the CDFI Fund, in its sole discretion, may provide a Severe Constraints Waiver, which permits such Applicant to comply with the Matching Funds requirements by reducing such requirements by up to 50%. • In order to be considered eligible for a Severe Constraints Waiver, an Applicant must meet all of the SECA eligibility criteria described in Table 8. Instructions for requesting a Severe Constraints Waiver will be made available if required. • No more than 25% of the total funds available for obligation under this funding round may qualify for a Severe Constraints Waiver.
Ineligible Matching Funds	• Applicants will not be given the opportunity to correct or amend the Matching Funds information included in the FA Application after Application submission if the CDFI Fund determines that any portion of the Applicant's Matching Funds is ineligible.
Use of Matching Funds from a prior CDFI Program Recipient.	If an Applicant offers Matching Funds documentation from an organization that was a prior Recipient under the CDFI Program or NACA Program, the Applicant must be able to prove to the CDFI Fund's satisfaction that such funds do not consist, in whole or in part, of CDFI Program funds, NACA Program funds, or other Federal funds.

TABLE 9—MATCHING FUNDS REQUIREMENTS *—Continued

Matching Funds in the form of retained earnings.	• Retained earnings are eligible for use as Matching Funds in an amount equal to the CDFI Fund's calculation of: i. the increase in retained earnings that occurred over any one of the Applicant's fiscal years within the Matching Funds Window, adjusted to remove revenue and expenses derived from Federal sources and Matching Funds used for an award; or ii. the annual average of such increases that occurred over any three consecutive fiscal years of the Applicant with at least one of the fiscal years occurring within the Matching Funds Window, adjusted to remove revenue and expenses derived from Federal sources and Matching Funds used for an award; or iii. any combination of (i) and (ii) above that does not include Matching Funds used for an award. • Retained earnings will be matched in the form of a grant. • Depository Institution Holding Company Applicants must provide call reports for the Depository Institution Holding Company in order to verify their retained earnings, even if the requested award will support its Subsidiary CDFI Insured Depository Institution.
Special rule for Regulated Institutions	• A Regulated Institution's retained earnings are eligible for use as Matching Funds in an amount equal to the CDFI Fund's calculation of: i. the increase in retained earnings that occurred over any one of the Applicant's fiscal years within the Matching Funds Window, adjusted to remove revenue from Federal sources and Matching Funds used for an award; or ii. the annual average of such increases that occurred over any three consecutive fiscal years of the Applicant with at least one of the fiscal years occurring within the Matching Funds Window, adjusted to remove revenue and expenses derived from Federal sources and Matching Funds used for an award; or iii. the entire retained earnings that have been accumulated since the inception of the Applicant, as provided in the Regulations. • If option (iii) is used for Insured Credit Unions or State-Insured Credit Unions, the Applicant must increase its member and/or non-member shares and/or total loans outstanding by an amount equal to the amount of retained earnings committed as Matching Funds. • This increase (1) will be measured on a quarterly basis from March 31, 2021; (2) must occur by December 31, 2022; and (3) will be based on amounts reported in the Applicant's National Credit Union Administration (NCUA) form 5300 Call Report, or equivalent. • The CDFI Fund will assess the likelihood of this increase during the Application review process. • An award will not be made to any Applicant that has not demonstrated in the relevant NCUA form 5300 call reports or equivalent that it has increased shares and/or total loans outstanding by at least 25% of the requested FA award amount (including all awards requiring Matching Funds) between December 31, 2019, and December 31, 2020. • The Matching Funds are not In-Hand until the Recipient has increased its member and/or non-member shares, deposits and/or total loans outstanding by the amount of retained earnings since inception that are being used as Matching Funds. • If option (iii) is used for Insured Depository Institutions or Depository Institution Holding Companies, the Applicant or its Subsidiary CDFI Insured Depository Institution (in the case of a Depository Institution Holding Company) must increase deposits and/or total loans outstanding by an amount equal to the amount of retained earnings committed as Matching Funds. Depository Institution Holding Company Applicants must use the call reports of the Subsidiary CDFI Insured Depository Institution that the requested the FA award will support. • This increase (1) will be measured on a quarterly basis from March 31, 2021; (2) must occur by December 31, 2022; and (3) will be based on amounts reported in the call report. • The CDFI Fund will assess the likelihood of this increase during the Application review process. • An award will not be made to any Applicant that has not demonstrated in the relevant call reports that it has increased deposits and/or total loans outstanding by at least 25% of the requested FA award amount (including all awards requiring Matching Funds) between December 31, 2019, and December 31, 2020. • The Matching Funds are not In-Hand until the Recipient has increased its deposits and/or total loans outstanding by the amount of retained earnings since inception that are being used as Matching Funds. • All regulated Applicants utilizing the option (iii) should refer to the Retained Earnings Guidance included in the Retained Earnings Calculator Excel Workbook found on the CDFI Fund's website.

* The requirements set forth in Table 9 are applicable to Category II (Core) FA Applicants, with the exception of Native American CDFIs, applying for Base-FA, PPC–FA, and DF–FA. The Matching Funds requirements for HFFI–FA and SECA FA Applicants were waived for the FY 2021 Funding Round and permanently waived for Native American CDFIs. Therefore, the requirements set forth in Table 9 are not applicable to HFFI–FA, SECA FA, and Native American CDFI Applicants for the FY 2021 Funding Round.

IV. Application and Submission Information

A. Address to Request an Application Package: Application materials can be found on the CDFI Fund's website at *www.cdfifund.gov/cdfi.* Applicants may request a paper version of any Application material by contacting the CDFI Fund Help Desk at *cdfihelp@cdfi.treas.gov.* Paper versions of Application materials will only be provided if an Applicant cannot access the CDFI Fund's website.

B. Content and Form of Application Submission: All Applications must be prepared using the English language, and calculations must be computed in U.S. dollars. The following table lists the Required Application Documents for the FY 2021 Funding Round. The CDFI Fund reserves the right to request and review other pertinent or public information that has not been specifically requested in this NOFA or the Application. Information submitted by the Applicant that the CDFI Fund has not specifically requested will not be

reviewed or considered as part of the Application. Financial data, portfolio, and activity information provided in the Application should only include the Applicant's activities. Information submitted must accurately reflect the Applicant's activities.

TABLE 10—REQUIRED APPLICATION DOCUMENTS

Application documents	Applicant type	Submission format
Active AMIS Account	All Applicants	AMIS.
SF–424	All Applicants	Fillable PDF in *Grants.gov.*
CDFI Program Application Components: • Funding Application Detail • Data, Charts, and Narrative sections as listed in AMIS and outlined in Application materials. • Matching Funds (FA Core Applicants, with the exception of Native American CDFIs).	All Applicants	AMIS.
PPC–FA Application Components: • Funding Application Detail • Narratives • AMIS Charts	PPC–FA Applicants	AMIS.
DF–FA Application Components: • Funding Application Detail • Narratives • AMIS Charts	DF–FA Applicants	AMIS.
HFFI–FA Application Components: • Funding Application Detail • Narratives • AMIS charts	HFFI–FA Applicants	AMIS.
ATTACHMENTS TO THE APPLICATION: Add to "Related Attachments" related list in Application		
Key Staff Resumes	All Applicants	PDF or Word document in AMIS.
Organizational Chart	All Applicants	PDF in AMIS.
Audited financial statements for the Applicant's Three Most Recent Historic Fiscal Years.	FA Applicants: Loan funds, Venture Capital Funds, and other non-Regulated Institutions. TA Applicants, if available: Loan funds, Venture Capital Funds, and other non-Regulated Institutions.	PDF in AMIS.
Management Letter for the Applicant's Most Recent Historic Fiscal Year. ... The Management Letter is prepared by the Applicant's auditor and is a communication on internal control over financial reporting, compliance, and other matters. The Management Letter contains the auditor's findings regarding the Applicant's accounting policies and procedures, internal controls, and operating policies, including any material weaknesses, significant deficiencies, and other matters identified during auditing. The Management Letter may include suggestions for improving on identified weaknesses and deficiencies and/or best practice suggestions for items that may not be considered to be weaknesses or deficiencies. The Management Letter may also include items that are not required to be disclosed in the annual audited financial statements. The Management Letter is distinct from the auditor's Opinion Letter, which is required by Generally Accepted Accounting Principles (GAAP). Management Letters are not required by GAAP, and are sometimes provided by the auditor as a separate letter from the audit itself.	FA Applicants: Loan funds, Venture Capital Funds, and other non-Regulated Institutions. TA Applicants, if audited financial statements are available: Loan funds, Venture Capital Funds, and other non-Regulated Institutions.	PDF in AMIS.
Statement(s) in Lieu of Management Letter for Applicant's Most Recent Historic Fiscal Year issued by the Board Treasurer or other Board member using the template provided in the Application materials. (required only if Management Letters are not available for audited financial statements).	FA Applicants: Loan funds, Venture Capital Funds, and other non-Regulated Institutions. TA Applicants, if audited financial statements ARE available but the Management Letters are NOT available: Loan funds, Venture Capital Funds, and other non-Regulated Institutions.	AMIS.
Unaudited financial statements for Applicant's Three Most Recent Historic Years. (required only if audited financial statements are not available)	TA Applicants: Loan funds, Venture Capital Funds, and other non-Regulated Institutions.	PDF in AMIS.
Current Year to Date—December 31, 2020 Unaudited financial statements	FA and TA Applicants: Loan funds, Venture Capital Funds, and other non-Regulated Institutions.	PDF in AMIS.
Community Partnership Agreement	FA Applicants, if applicable	PDF or Word document in AMIS.
Retained Earnings Calculator Excel Workbook (required only if using retained earnings as Matching Funds)	FA Core Applicants, if applicable	Excel in AMIS.

TABLE 10—REQUIRED APPLICATION DOCUMENTS—Continued

Application documents	Applicant type	Submission format
Call reports for each fiscal year reported in the Retained Earnings Calculator.	FA Core Applicants: Regulated Institutions that are using retained earnings as Matching Funds.	PDF in AMIS.
Equity Investment Matching Funds Documentation	FA Core Applicants: For-profit CDFIs that are using In-Hand Equity Investment(s) as Matching Funds.	PDF or Word document in AMIS.
Deposits Matching Funds Documentation	FA Core Applicants: Regulated Institutions that are using In-Hand Deposits as Matching Funds.	PDF or Word document in AMIS.

C. Application Submission: The CDFI Fund has a two-step process that requires the submission of Required Application Documents (listed in Table 10) on separate deadlines and locations. The SF–424 must be submitted through *Grants.gov* and all other Required Application Documents through the AMIS portal. The CDFI Fund will not accept Applications via email, mail, facsimile, or other forms of communication, except in extremely rare circumstances that have been pre-approved in writing by the CDFI Fund. The deadline for submitting the SF–424 is listed in Tables 1 and 12.

All Applicants must register in the *Grants.gov* system to successfully submit the SF–424. The *Grants.gov* registration process can take 45 days or longer to complete and the CDFI Fund strongly encourages Applicants to start the *Grants.gov* registration process as early as possible (refer to the following link: *http://www.grants.gov/web/grants/register.html*). Since the *Grants.gov* registration process requires Applicants to have DUNS and EIN numbers, Applicants without these required numbers should allow for additional time to complete the *Grants.gov* registration process. Further, as described in Section IV. (E) of this NOFA, new requirements for registration in the System for Awards Management (SAM), which is required as part of the *Grants.gov* registration process, may take more time than in recent years. The CDFI Fund will not extend the Application deadline for any Applicant that started the *Grants.gov* registration process but did not complete it by the deadline. An Applicant that has previously registered with *Grants.gov* must verify that its registration is current and active. Applicants should contact *Grants.gov* directly with questions related to the registration or submission process as the CDFI Fund does not maintain the *Grants.gov* system.

Each Application must be signed by a designated Authorized Representative in AMIS before it can be submitted. Applicants must ensure that an Authorized Representative is an employee or officer and is authorized to sign legal documents on behalf of the Applicant. Consultants working on behalf of the Applicant may not be designated as Authorized Representatives. Only a designated Authorized Representative or Application Point of Contact, included in the Application, may submit the Application in AMIS. If an Authorized Representative or Application Point of Contact does not submit the Application, the Application will be deemed ineligible.

D. Dun & Bradstreet Universal Numbering System: Pursuant to the Uniform Requirements, each Applicant must provide as part of its Application submission, a Dun and Bradstreet Universal Numbering System (DUNS) number. Applicants without a DUNS number will not be able to register and submit an Application in the *Grants.gov* system. Allow sufficient time for Dun & Bradstreet to respond to inquiries and/or requests for DUNS numbers.

E. System for Award Management (SAM): Any entity applying for Federal grants or other forms of Federal financial assistance through *Grants.gov* must be registered in SAM before submitting its Application. Registration in SAM is required as part of the *Grants.gov* registration process. The SAM registration process may take one month or longer to complete. A signed notarized letter identifying the SAM authorized entity administrator for the entity associated with the DUNS number is required. This requirement is applicable to new entities registering in SAM, as well as to existing entities with registrations being updated or renewed in SAM. Applicants without DUNS and/or EIN numbers should allow for additional time as an Applicant cannot register in SAM without those required numbers. Applicants that have previously completed the SAM registration process must verify that their SAM accounts are current and active. Each Applicant must continue to maintain an active SAM registration with current information at all times during which it has an active Federal award or an Application under consideration by a Federal awarding agency. The CDFI Fund will deem ineligible any Applicant that fails to properly register or activate its SAM account and, as a result, is unable to submit the SF–424 in *Grants.gov* or Application in AMIS by the applicable Application deadlines. These restrictions also apply to organizations that have not yet received a DUNS or EIN number. Applicants must contact SAM directly with questions related to registration or SAM account changes as the CDFI Fund does not maintain this system and has no ability to make changes or correct errors of any kind. For more information about SAM, visit *https://www.sam.gov.*

TABLE 11—Grants.gov REGISTRATION TIMELINE SUMMARY

Step	Agency	Estimated minimum time to complete
Obtain a DUNS number	Dun & Bradstreet	One (1) Week.*
Obtain an EIN Number	Internal Revenue Service (IRS)	Two (2) Weeks.*
Register in *SAM.gov*	System for Award Management (*SAM.gov*)	Four (4) Weeks.*

TABLE 11—Grants.gov REGISTRATION TIMELINE SUMMARY—Continued

Step	Agency	Estimated minimum time to complete
Register in *Grants.gov*	*Grants.gov*	One (1) Week.**

* Applicants are advised that the stated durations are estimates only and represent minimum timeframes. Actual timeframes may take longer. The CDFI Fund will deem ineligible any Applicant that fails to properly register or activate its SAM account, has not yet received a DUNS or EIN number, and/or fails to properly register in *Grants.gov.*

** This estimate assumes an Applicant has a DUNS number, an EIN number, and is already registered in *SAM.gov.*

F. Submission Dates and Times

1. Submission Deadlines: The following table provides the critical deadlines for the FY 2021 Funding Round.

TABLE 12—FY 2021 CDFI PROGRAM FUNDING ROUND CRITICAL DEADLINES FOR APPLICANTS

Description	Deadline	Time (eastern time—ET)	Submission method
Last day to create an Awards Management Information Systems (AMIS) Account (all Applicants).	March 22, 2021	11:59 p.m	AMIS.
Last day to enter EIN and DUNS numbers in AMIS (all Applicants).	March 22, 2021	11:59 p.m	AMIS.
Last day to submit SF–424 (Application for Federal Assistance).	March 22, 2021	11:59 p.m	Electronically via *Grants.gov.*
Last day for SECA FA Applicants to request creation of a Core-FA Application (if requesting more than $700,000).	March 22, 2021	11:59 p.m	Service Request via AMIS.
Last day to contact CDFI Program staff	April 29, 2021	5:00 p.m	Service Request via AMIS; Or CDFI Fund Helpdesk: 202–653–0421.
Last day to contact AMIS–IT Help Desk (regarding AMIS technical problems only).	May 3, 2021	5:00 p.m	Service Request via AMIS; Or 202–653–0422; Or *AMIS@cdfi.treas.gov.*
Last day to submit CDFI Program Application for Financial Assistance (FA) *or* Technical Assistance (TA).	May 3, 2021	11:59 p.m	AMIS.

2. Confirmation of Application Submission in Grants.gov and AMIS: Applicants are required to submit the SF–424, Application for Federal Assistance through the *Grants.gov* system, under the CDFI Program Funding Opportunity Number by the applicable deadline. All other Required Application Documents (listed in Table 10) must be submitted through the AMIS website by the applicable deadline. Applicants must submit the SF–424 prior to submitting the Application in AMIS. If the SF–424 is not successfully accepted by *Grants.gov* by the deadline, the CDFI Fund will not review the Application submitted in AMIS, and the Application will be deemed ineligible.

a. *Grants.gov* Submission Information: Each Applicant will receive an email from *Grants.gov* immediately after submitting the SF–424 confirming that the submission has entered the *Grants.gov* system. This email will contain a tracking number for the submitted SF–424. Within 48 hours, the Applicant will receive a second email, which will indicate if the submitted SF–424 was either successfully validated or rejected with errors. However, Applicants should not rely on the email notification from *Grants.gov* to confirm that their SF–424 was validated. Applicants are strongly encouraged to use the tracking number provided in the first email to closely monitor the status of their SF–424 by contacting the helpdesk at *Grants.gov* directly. The Application material submitted in AMIS is not officially accepted by the CDFI Fund until *Grants.gov* has validated the SF–424.

b. AMIS Submission Information: AMIS is a web-based portal where Applicants will directly enter their Application information and add the required attachments listed in Table 10. AMIS will verify that the Applicant provided the minimum information required to submit an Application. Applicants are responsible for the quality and accuracy of the information and attachments included in the Application submitted in AMIS. The CDFI Fund strongly encourages Applicants to allow for sufficient time to review and complete all Required Application Documents listed in Table 10, and remedy any issues prior to the Application deadline. Each Application must be signed by an Authorized Representative in AMIS before it can be submitted. Applicants must ensure that the Authorized Representative is an employee or officer and is authorized to sign legal documents on behalf of the Applicant. Consultants working on behalf of the Applicant may not be designated as Authorized Representatives. Only an Authorized Representative or an Application Point of Contact may submit an Application. If an Authorized Representative or Application Point of Contact does not submit the Application, the Application will be deemed ineligible. Applicants may only submit one Base-FA or TA Application under the CDFI Program. Upon submission, the Application will be locked and cannot be resubmitted, edited, or modified in any way. The CDFI Fund will not unlock or allow multiple Application submissions.

3. Late Submission: The CDFI Fund will not accept an Application if the SF–424 is not submitted and accepted by *Grants.gov* by the SF–424 deadline. Additionally, the CDFI Fund will not accept an Application if it is not signed by an Authorized Representative and submitted in AMIS by the Application deadline. In either case, the CDFI Fund

will not review any material submitted, and the Application will be deemed ineligible.

However, in cases where a Federal government administrative or technological error directly resulted in a late submission of the SF–424 or the Application, Applicants are provided two opportunities to submit a written request for acceptance of late submissions. The CDFI Fund will not consider the late submission of the SF–424 or the Application that was a direct result of a delay in a Federal Government process, unless such delay was the result of a Federal government administrative or technological error.

a. SF–424 Late Submission: In cases where a Federal government administrative or technological error directly resulted in the late submission of the SF–424, the Applicant must submit a written request for acceptance of the late SF–424 submission and include documentation of the error no later than two business days after the SF–424 deadline. The CDFI Fund will not respond to requests for acceptance of late SF–424 submissions after that time period. Applicants must submit late SF–424 submission requests to the CDFI Fund via an AMIS Service Request to the CDFI Program with a subject line of ''Late SF–424 Submission Request.''

b. Application Late Submission: In cases where a Federal government administrative or technological error directly resulted in a late submission of the Application in AMIS, the Applicant must submit a written request for acceptance of the late Application submission and include documentation of the error no later than two business days after the Application deadline. The CDFI Fund will not respond to requests for acceptance of late Application submissions after that time period. Applicants must submit late Application submission requests to the CDFI Fund via an AMIS Service Request to the CDFI Program with a subject line of ''Late Application Submission Request.''

G. Funding Restrictions: Base-FA, PPC–FA, DF–FA, HFFI–FA and TA awards are limited by the following:

1. Base-FA Awards:

a. A Recipient shall use Base-FA funds only for the eligible activities described in Section II. (C)(1) of this NOFA and its Assistance Agreement.

b. With the exception of Depository Institution Holding Company Applicants, Base-FA awards may not be used to support the activities of, or otherwise be passed through, transferred, or co-awarded to, third-party entities, whether Affiliates, Subsidiaries, or others, unless done pursuant to a merger or acquisition or similar transaction, and with the CDFI Fund's prior written consent.

c. Base-FA funds shall only be paid to the Recipient.

d. The CDFI Fund, in its sole discretion, may pay Base-FA funds in amounts, or under terms and conditions, which are different from those requested by an Applicant.

e. The Recipient must comply, as applicable, with the Buy American Act of 1933, 41 U.S.C. 8301–8303 and 2 CFR 200.216 of the Uniform Requirements, with respect to any Direct Costs.

2. PPC–FA Awards:

a. A Recipient shall use PPC–FA funds only for the eligible activities described in Section II. (C)(5) of this NOFA and its Assistance Agreement.

b. With the exception of Depository Institution Holding Company Applicants, PPC–FA awards may not be used to support the activities of, or otherwise be passed through, transferred, or co-awarded to, third-party entities, whether Affiliates, Subsidiaries, or others, unless done pursuant to a merger or acquisition or similar transaction, and with the CDFI Fund's prior written consent.

c. PPC–FA funds shall only be paid to the Recipient.

d. The CDFI Fund, in its sole discretion, may pay PPC–FA funds in amounts, or under terms and conditions, which are different from those requested by an Applicant.

e. The Recipient must comply, as applicable, with the Buy American Act of 1933, 41 U.S.C. 8301–8303 and 2 CFR 200.216 of the Uniform Requirements, with respect to any Direct Costs.

3. DF–FA Awards:

a. A Recipient shall use DF–FA funds only for the eligible activities described in Section II. (C)(2) of this NOFA and its Assistance Agreement.

b. With the exception of Depository Institution Holding Company Applicants, DF–FA awards may not be used to support the activities of, or otherwise be passed through, transferred, or co-awarded to, third-party entities, whether Affiliates, Subsidiaries, or others, unless done pursuant to a merger or acquisition or similar transaction, and with the CDFI Fund's prior written consent.

c. DF–FA funds shall only be paid to the Recipient.

d. The CDFI Fund, in its sole discretion, may pay DF–FA funds in amounts, or under terms and conditions, which are different from those requested by an Applicant.

e. The Recipient must comply, as applicable, with the Buy American Act of 1933, 41 U.S.C. 8301–8303 and 2 CFR 200.216 of the Uniform Requirements, with respect to any Direct Costs.

2. HFFI–FA Awards:

a. A Recipient shall use HFFI–FA funds only for the eligible activities described in Section II. (C)(4) of this NOFA and its Assistance Agreement.

b. With the exception of Depository Institution Holding Company Applicants, HFFI–FA awards may not be used to support the activities of, or otherwise be passed through, transferred, or co-awarded to, third-party entities, whether Affiliates, Subsidiaries, or others, unless done pursuant to a merger or acquisition or similar transaction, and with the CDFI Fund's prior written consent.

c. HFFI–FA funds shall only be paid to the Recipient.

d. The CDFI Fund, in its sole discretion, may pay HFFI–FA funds in amounts, or under terms and conditions, which are different from those requested by an Applicant.

e. The Recipient must comply, as applicable, with the Buy American Act of 1933, 41 U.S.C. 8301–8303 and 2 CFR 200.216 of the Uniform Requirements, with respect to any Direct Costs.

3. TA Grants:

a. A Recipient shall use TA funds only for the eligible activities described in Section II. (C) (3) of this NOFA and its Assistance Agreement.

b. With the exception of Depository Institution Holding Company Applicants, TA awards may not be used to support the activities of, or otherwise be passed through, transferred, or co-awarded to, third-party entities, whether Affiliates, Subsidiaries, or others, unless done pursuant to a merger or acquisition or similar transaction, and with the CDFI Fund's prior written consent.

c. TA funds shall only be paid to the Recipient.

d. The CDFI Fund, in its sole discretion, may pay TA funds in amounts, or under terms and conditions, which are different from those requested by an Applicant.

e. The Recipient must comply, as applicable, with the Buy American Act of 1933, 41 U.S.C. 8301–8303 and 2 CFR 200.216 of the Uniform Requirements, with respect to any Direct Costs.

V. Application Review Information

A. Criteria: If the Applicant has submitted an eligible Application, the CDFI Fund will conduct a substantive review in accordance with the criteria and procedures described in the Regulations, this NOFA, the Application guidance, and the Uniform Requirements. The CDFI Fund reserves the right to contact the Applicant by telephone, email, or mail for the

purpose of clarifying or confirming Application information. If contacted, the Applicant must respond within the time period communicated by the CDFI Fund or risk that its Application will be rejected. The CDFI Fund will review the Base-FA, DF–FA, PPC–FA, HFFI–FA, and TA Applications in accordance with the process below. All internal and external reviewers will complete the CDFI Fund's conflict of interest process. The CDFI Fund's Application conflict of interest policy is located on the CDFI Fund's website.

1. Base-FA Application Scoring, Award Selection, Review, and Selection Process: The CDFI Fund will evaluate each Application using a five-step review process illustrated in the sections below. Applicants that meet the minimum criteria will advance to the next step in the review process. Applicants applying as a Community Partnership must describe the partnership in the Application pursuant to the requirements set forth in Table 8, and will be evaluated in accordance with the review process described below.

a. Step 1: Eligibility Review: The CDFI Fund will evaluate each Application to determine its eligibility status pursuant to Section III of this NOFA.

b. Step 2: Financial Analysis and Compliance Risk Evaluation:

i. Step 2: Financial Analysis: For Regulated Institutions, the CDFI Fund will consider financial safety and soundness information from the Appropriate Federal or State Banking Agency. As detailed in Table 8, each Regulated Institution FA Applicant must have a CAMELS/CAMEL rating of at least ''3'' and/or no significant materials concerns from its regulator.

For non-regulated Applicants, the CDFI Fund will evaluate the financial health and viability of each non-regulated Applicant using financial information provided by the Applicant. For the Financial Analysis, each non-regulated Applicant will receive a Total Financial Composite Score on a scale of one (1) to five (5), with one (1) being the highest rating. The Total Financial Composite Score is based on the analysis of twenty-three (23) financial indicators. Applications will be grouped based on the Total Financial Composite Score. Applicants must receive a Total Financial Composite Score of one (1), two (2), or three (3) to advance to Step 3. Applicants that receive an initial Total Financial Composite Score of four (4) or five (5) will be re-evaluated and re-scored by CDFI Fund staff. If the Total Financial Composite Score remains four (4) or five (5) after CDFI Fund staff review, the Applicant will not advance to Step 3.

ii. Step 2: Compliance Risk Evaluation: For the compliance analysis, the CDFI Fund will evaluate the compliance risk of each Applicant using information provided in the Application as well as an Applicant's reporting history, reporting capacity, and performance risk with respect to the CDFI Fund's PG&Ms. Each Applicant will receive a Total Compliance Composite Score on a scale of one (1) to five (5), with one (1) being the highest rating. Applicants that receive an initial Total Compliance Composite Score of four (4) or five (5) will be re-evaluated by CDFI Fund staff. If the Applicant is deemed a high compliance risk after CDFI Fund staff review, the Applicant will not advance to Step 3.

c. Step 3: Business Plan Review: Applicants that proceed to Step 3 will be evaluated on the soundness of their comprehensive business plan. Two external non-CDFI Fund Reviewers will conduct the Step 3 evaluation. Reviewers will evaluate the Application sections listed in Table 13. All Applications will be reviewed in accordance with standard reviewer evaluation materials. Applications will be ranked based on Total Business Plan Scores, in descending order. In order to advance to Step 4, Applicants must receive a Total Business Plan Score that is either (1) equal to receiving a point score equivalent to a ''Good'' out of a ranking scale in descending order of Excellent, Good, Fair, Limited or Poor, in each section listed in Table 13, or (2) within the top 60% of the Core Applicant pool for Core Applicants or within the top 70% of the SECA Applicant pool for SECA Applicants, whichever is greater. In the case of tied Total Business Plan Scores that would prevent an Applicant from moving to Step 4, all Applicants with the same score will progress to Step 4. Lastly, the CDFI Fund may consider the geographic diversity of Applicants when determining the Step 4 Applicant pool.

TABLE 13—STEP 3: BASE-FA BUSINESS PLAN REVIEW SCORING CRITERIA

Base-FA application sections	Possible score	Score needed to advance
Executive Summary	Not Scored	N/A.
Business Strategy	12	N/A.
Market and Competitive Analysis	7	N/A.
Products and Services	12	N/A.
Management and Track Record	12	N/A.
Growth and Projections	7	N/A.
Total Business Plan Score	50	Core Applicants: Top 60% of all Core Applicant Step 3 Scores. SECA Applicants: Top 70% of all SECA Applicant Step 3 Scores.

d. Step 4: Policy Objective Review: The CDFI Fund internal reviewers will evaluate each Application to determine its ability to meet policy objectives of the CDFI Fund. Each Applicant will be evaluated in each of the categories listed in Table 14 below, and will receive a Total Policy Objective Review Composite Score on a scale of one (1) to five (5), with one (1) being the highest score. Applicants are then grouped according to Total Policy Objective Review Scores.

The CDFI Fund also conducts a due diligence review for Applications that includes an analysis of programmatic risk factors including, but not limited to: History of performance in managing Federal awards (including timeliness of reporting and compliance); ability to meet FA Objective(s) selected by Base-FA Applicants in their Applications; reports and findings from audits; and the Applicant's ability to effectively implement Federal requirements, each of which could impact the Total Policy Objective Review Score.

TABLE 14—STEP 4: BASE-FA POLICY REVIEW SCORING CRITERIA

Section	Possible scores	High score	Score needed to advance
Economic Distress	1, 2, 3, 4, or 5	1	N/A.
Economic Opportunities	1, 2, 3, 4, or 5	1	N/A.
Community Collaboration	1, 2, 3, 4, or 5	1	N/A.
Total Policy Objective Review Composite Score	1, 2, 3, 4, or 5	1	All Scores Advance.

e. Step 5: Award Amount Determination: The CDFI Fund determines an award amount for each Application based on the Step 4 Total Policy Objective Review Score, the Applicant's request amount, and on certain other factors, including but not limited to, the Applicant's deployment track record, minimum award size, and funding availability. Award amounts may be reduced from the requested award amount as a result of this analysis. For Core FA Applicants, the award cannot exceed 30% of the Applicant's total portfolio outstanding as of the Applicant's most recent historic fiscal year end. For SECA FA Applicants, the award cannot exceed 75% of the Applicant's total portfolio outstanding as of the Applicant's most recent historic fiscal year end, or the minimum award size as noted in Table 2, whichever is greater.

2. Healthy Food Financing Initiative-FA (HFFI–FA) Application Scoring, Award Selection, Review, and Selection Process: A CDFI Fund internal reviewer will evaluate each HFFI–FA Application associated with a Base-FA Application that progresses to Step 4 of the FA Application review process. The reviewer will evaluate the Application sections listed in Table 15 and assign a Total HFFI- FA Score up to 60 points. The CDFI Fund will make awards to the highest scoring Applicants first. All Applications will be reviewed in accordance with standard reviewer evaluation materials. Applicants that fail to receive a Base-FA award will not be considered for a HFFI–FA award.

The CDFI Fund conducts additional levels of due diligence for Applications that are under consideration for an HFFI–FA award. Award amounts may be reduced from the requested award amount as a result of this analysis. The CDFI Fund may reduce awards sizes from requested amounts based on certain variables, including but not limited to, an Applicant's loan disbursement activity, total portfolio outstanding, or compliance with prior HFFI–FA awards. Lastly, the CDFI Fund may consider the geographic diversity of Applicants when making its funding decisions.

TABLE 15—STEP 4 HFFI–FA APPLICATION SCORING CRITERIA

Sections	Possible score
Target Market Profile	10 points.
Healthy Food Financial Products	10 points.
Projected HFFI–FA Activities	15 points.
HFFI Track Record	20 points.
Management Capacity for Providing Healthy Food Financing.	5 points.
Total HFFI-FA Possible Score.	60 points.

3. Persistent Poverty Counties—Financial Assistance (PPC–FA) Application Scoring, Award Selection, Review, and Selection Process: A CDFI Fund internal reviewer will evaluate the PPC–FA request of each associated Base-FA Application that progresses to Step 4 of the FA Application review process. PPC–FA requests are not scored. PPC–FA award amounts will be determined based on the total number of eligible Applicants and funding availability, the Applicant's requested amount, and on certain factors, including but not limited to, an Applicant's overall portfolio size, historical track record of deployment in PPC, pipeline of projects in PPC, minimum award size, and funding availability. Applicants that fail to receive a Base-FA award will not be considered for a PPC–FA award.

4. Disability Funds-Financial Assistance (DF–FA) Application Scoring, Award Selection, Review, and Selection Process: A CDFI Fund internal reviewer will evaluate each DF–FA Application associated with a Base-FA Application that progresses to Step 4 of the FA Application review process. The reviewer will evaluate the Application and assign a Total DF- FA Score on a scale of one (1) to three (3), with one (1) being the highest score. Applicants are then grouped according to Total DF- FA Score. All Applications will be reviewed in accordance with standard reviewer evaluation materials. Applicants that fail to receive a Base-FA award will not be considered for a DF–FA award. Award amounts will be determined on the basis of the Total DF–FA Score, the Applicant's requested amount, and on certain factors, including but not limited to, an Applicant's deployment track record, minimum award size, and funding availability. Award amounts may be reduced from the requested award amount as a result of this analysis. The CDFI Fund will make awards to the highest scoring Applicants first.

TABLE 16—STEP 3 DF–FA APPLICATION SCORING CRITERIA

Section	Possible scores	High score
DF–FA Narrative Questions	1, 2, or 3	1
Total DF–FA Score	1, 2, or 3	1

5. Technical Assistance (TA) Application Scoring, Award Selection, Review, and Selection Process: The CDFI Fund will evaluate each Application to determine its eligibility pursuant to Section III of this NOFA. If the Application satisfies the eligibility criteria, the CDFI Fund will evaluate the TA Application. Emerging CDFI Applicants must receive a rating of Low Risk or Medium Risk in Section I of the TA Business Plan Review to progress to

Section II of the TA Business Plan Review. Emerging CDFI Applicants that receive a rating of High Risk in Section I of the TA Business Plan Review will not be considered for an award. Section I of the TA Business Plan Review is not applicable for Certified CDFI Applicants. Emerging CDFI and Certified CDFI Applicants must receive a rating of Low Risk or Medium Risk in Section II of the TA Business Plan Review to be considered for an award. Applicants that receive a rating of High Risk in Section II of the TA Business Plan Review will not be considered for an award. An Applicant that is a Certified CDFI will be evaluated on the demonstrated need for TA funding to build the CDFI's capacity, further the Applicant's strategic goals, and achieve impact within the Applicant's Target Market. An Applicant that is an Emerging CDFI will be evaluated on the Applicant's demonstrated capability and plan to achieve CDFI certification within three years, or if a prior Recipient, the certification PG&M stated in its prior Assistance Agreement. An Applicant that is an Emerging CDFI will also be evaluated on its demonstrated need for TA funding to build the CDFI's capacity and further its strategic goals. The CDFI Fund will rate each part of the TA Business Plan Review as indicated in Table 17.

TABLE 17—TA BUSINESS PLAN REVIEW

Business plan review component	Applicant type	Ratings
Section I:		
Primary Mission	Emerging CDFI Applicants	Low Risk, Medium Risk, or High Risk.
Financing Entity	Emerging CDFI Applicants.	
Target Market	Emerging CDFI Applicants.	
Accountability	Emerging CDFI Applicants.	
Development Services	Emerging CDFI Applicants.	
Section II:		
Target Market Needs & Strategy	Emerging and Certified CDFI Applicants	Low Risk, Medium Risk, or High Risk.
Organizational Capacity	Emerging and Certified CDFI Applicants.	
Management Capacity	Emerging and Certified CDFI Applicants.	

Each TA Application will be evaluated by one internal CDFI Fund reviewer. All Applications will be reviewed in accordance with CDFI Fund standard reviewer evaluation materials for the Business Plan Review.

The CDFI Fund conducts additional levels of due diligence for Applications that are under consideration for an award. This due diligence includes an analysis of programmatic and financial risk factors including, but not limited to, financial stability, history of performance in managing Federal awards (including timeliness of reporting and compliance), reports and findings from audits, and the Applicant's ability to effectively implement Federal requirements. The CDFI Fund will also evaluate the compliance risk of each Applicant using information provided in the Application as well as an Applicant's reporting history, reporting capacity, and performance risk with respect to the CDFI Fund's PG&Ms. Each Applicant will receive a Total Compliance Composite Score on a scale of one (1) to five (5), with one (1) being the highest rating. Applicants that receive an initial Total Compliance Composite Score of four (4) or five (5) will be re-evaluated by CDFI Fund staff. If the Applicant is deemed a high compliance risk after CDFI staff review, the Applicant will not be considered for an award. The CDFI Fund will also evaluate the Applicant's ability to meet certification criteria of being a legal entity and a non-government entity. Award amounts may be reduced as a result of the due diligence analysis in addition to consideration of the Applicant's funding request and similar factors. Lastly, the CDFI Fund may consider the geographic diversity of Applicants when making its funding decisions.

6. Regulated Institutions: The CDFI Fund will consider safety and soundness information from the Appropriate Federal or State Banking Agency. If the Applicant is a CDFI Depository Institution Holding Company, the CDFI Fund will consider information provided by the Appropriate Federal or State Banking Agencies about both the CDFI Depository Institution Holding Company and the Certified CDFI Subsidiary Insured Depository Institution that will expend and carry out the award. If the Appropriate Federal or State Banking Agency identifies safety and soundness concerns, the CDFI Fund will assess whether such concerns cause or will cause the Applicant to be incapable of undertaking the activities for which funding has been requested.

7. Non-Regulated Institutions: The CDFI Fund must ensure, to the maximum extent practicable, that Recipients which are non-regulated CDFIs are financially and managerially sound, and maintain appropriate internal controls (12 U.S.C. 4707(f)(1)(A) and 12 CFR 1805.800(b)). Further, the CDFI Fund must determine that an Applicant's capacity to operate as a CDFI and its continued viability will not be dependent upon assistance from the CDFI Fund (12 U.S.C. 4704(b)(2)(A)). If it is determined that the Applicant is incapable of meeting these requirements, the CDFI Fund reserves the right to deem the Applicant ineligible or terminate the award.

B. Anticipated Award Announcement: The CDFI Fund anticipates making CDFI Program award announcement before September 30, 2021. However, the anticipated award Announcement Date is subject to change without notice.

C. Application Rejection: The CDFI Fund reserves the right to reject an Application if information (including administrative errors) comes to the CDFI Fund's attention that: adversely affects an Applicant's eligibility for an award; adversely affects the Recipient's certification as a CDFI (to the extent that the award is conditional upon CDFI certification); adversely affects the CDFI Fund's evaluation or scoring of an Application; or indicates fraud or mismanagement on the Applicant's part. If the CDFI Fund determines any portion of the Application is incorrect in a material respect, the CDFI Fund reserves the right, in its sole discretion, to reject the Application. The CDFI Fund reserves the right to change its eligibility and evaluation criteria and procedures, if the CDFI Fund deems it appropriate. If the changes materially affect the CDFI Fund's award decisions, the CDFI Fund will provide information about the changes through its website. The CDFI Fund's award decisions are

final, and there is no right to appeal decisions.

D. External Non-CDFI Fund Reviewers: All external non-CDFI Fund reviewers are selected based on criteria that includes a professional background in community and economic development finance, and experience reviewing the financial statements of all CDFI institution types. Reviewers must complete the CDFI Fund's conflict of interest process and be approved by the CDFI Fund. The CDFI Fund's Application reader conflict of interest policy is located on the CDFI Fund's website.

VI. Federal Award Administration Information

A. Award Notification: Each successful Applicant will receive an email ''notice of award'' notification from the CDFI Fund stating that its Application has been approved for an award. Each Applicant not selected for an award will receive an email stating that a debriefing notice has been provided in its AMIS account.

B. Assistance Agreement: Each Applicant selected to receive an award must enter into an Assistance Agreement with the CDFI Fund in order to receive a payment(s). The Assistance Agreement will set forth the award's terms and conditions, including but not be limited to the: (i) Award amount; (ii) award type; (iii) award uses; (iv) eligible use of funds; (v) PG&Ms; and (vi) reporting requirements. FA Assistance Agreements have three-year Periods of Performance. TA Assistance Agreements have two-year Period of Performance for Certified CDFIs and three-year Periods of Performance for Emerging CDFIs.

1. Certificate of Good Standing: All FA and TA Recipients that are not Regulated Institutions will be required to provide the CDFI Fund with a certificate of good standing from the secretary of state for the Recipient's jurisdiction of formation prior to closing. This certificate can often be acquired online on the secretary of state website for the Recipient's jurisdiction of formation and must generally be dated within 180 days prior to the date the Recipient executes the Assistance Agreement. Due to potential backlogs in state government offices, Applicants are advised to submit requests for certificates of good standing no later than 60 days after they submit their Applications.

2. Closing: Pursuant to the Assistance Agreement, there will be an initial closing at which point the Assistance Agreement and related documents will be properly executed and delivered, and an initial payment of FA or TA may be made. FA Recipients that are subject to the Matching Funds requirement will not receive a payment until 100% of their Matching Funds are In-Hand. The first payment is the estimated amount of the award that the Recipient states in its Application that it will use for eligible FA or TA activities in the first 12 months after the award announcement. The CDFI Fund reserves the right to increase the first payment amount on any award to ensure that any subsequent payments are at least $25,000 for FA and $5,000 for TA awards.

The CDFI Fund will minimize the time between the Recipient incurring costs for eligible activities and award payment(s) in accordance with the Uniform Requirements. Advanced payments for eligible activities will occur no more than one year in advance of the Recipient incurring costs for the eligible activities. Following the initial closing, there may be subsequent closings involving additional award payments. Any documentation in addition to the Assistance Agreement that is connected with such subsequent closings and payments shall be properly executed and timely delivered by the Recipient to the CDFI Fund.

3. Requirements Prior to Entering into an Assistance Agreement: If, prior to entering into an Assistance Agreement, information (including administrative errors) comes to the CDFI Fund's attention that: Adversely affects the Recipient's eligibility for an award; adversely affects the Recipient's certification as a CDFI (to the extent that the award is conditional upon CDFI certification); adversely affects the CDFI Fund's evaluation of the Application; indicates that the Recipient is not in compliance with any requirement listed in the Uniform Requirements; indicates that the Recipient is not in compliance with a term or condition of a prior CDFI Fund award; indicates the Recipient has failed to execute and return a prior round Assistance Agreement to the CDFI Fund within the CDFI Fund's deadlines; or indicates fraud or mismanagement on the Recipient's part, the CDFI Fund may, in its discretion and without advance notice to the Recipient, terminate the award or take such other actions as it deems appropriate. The CDFI Fund reserves the right, in its sole discretion, to rescind an award if the Recipient fails to return the Assistance Agreement, signed by the Authorized Representative of the Recipient, and/or provide the CDFI Fund with any requested documentation, within the CDFI Fund's deadlines.

In addition, the CDFI Fund reserves the right, in its sole discretion, to terminate and rescind the Assistance Agreement and the award made under this NOFA pending the criteria described in the following table:

TABLE 18—REQUIREMENTS PRIOR TO EXECUTING AN ASSISTANCE AGREEMENT

Requirement	Criteria
Failure to meet reporting requirements	• If a Recipient received a prior award under any CDFI Fund program and is not in compliance with the reporting requirements of the previously executed agreement(s), the CDFI Fund may delay entering into an Assistance Agreement or disbursing an award until such reporting requirements are met. If the Recipient is unable to meet the requirement(s) within the timeframe specified by the CDFI Fund, the CDFI Fund may terminate and rescind the Assistance Agreement and the award made under this NOFA. • The automated systems the CDFI Fund uses only acknowledge a report's receipt and are not a determination of meeting reporting requirements.
Failure to maintain CDFI certification	• An FA Recipient must be a Certified CDFI. • If an FA Recipient fails to maintain CDFI certification, the CDFI Fund will terminate and rescind the Assistance Agreement and the award made under this NOFA. • If a TA Recipient is a Certified CDFI at the time of award announcement, it must maintain CDFI certification. • If a Certified CDFI TA Recipient fails to maintain CDFI certification, the CDFI Fund may terminate and rescind the Assistance Agreement and the award made under this NOFA.

TABLE 18—REQUIREMENTS PRIOR TO EXECUTING AN ASSISTANCE AGREEMENT—Continued

Requirement	Criteria
Pending resolution of noncompliance	• The CDFI Fund will delay entering into an Assistance Agreement with a Recipient that has pending noncompliance issues with any of its previously executed CDFI award agreement(s), if the CDFI Fund has not yet made a final compliance determination. • If the Recipient is unable to satisfactorily resolve the compliance issues, the CDFI Fund may terminate and rescind the Assistance Agreement and the award made under this NOFA.
Noncompliance or default status	• If, at any time prior to entering into an Assistance Agreement, the CDFI Fund determines that a Recipient is noncompliant or found in default with any previously executed award agreement(s), and the CDFI Fund has provided written notification that the Recipient is ineligible to apply for or receive any future awards or allocations for a time period specified by the CDFI Fund in writing, the CDFI Fund may delay entering into an Assistance Agreement until the Recipient has cured the noncompliance by taking actions the CDFI Fund has specified within such specified timeframe. If the Recipient is unable to cure the noncompliance within the specified timeframe, the CDFI Fund may terminate and rescind the Assistance Agreement and the award made under this NOFA.
Compliance with Federal civil rights requirements.	• If, prior to entering into an Assistance Agreement under this NOFA, the Recipient receives a final determination, made within the last three years, in any proceeding instituted against the Recipient in, by, or before any court, governmental, or administrative body or agency, declaring that the Recipient has violated the following laws: Title VI of the Civil Rights Act of 1964, as amended (42 U.S.C. 2000d); Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794); the Age Discrimination Act of 1975, (42 U.S.C. 6101–6107), and Executive Order 13166, Improving Access to Services for Persons with Limited English Proficiency, the CDFI Fund will terminate and rescind the Assistance Agreement and the award made under this NOFA.
Do Not Pay	• The Do Not Pay Business Center was developed to support Federal agencies in their efforts to reduce the number of improper payments made through programs funded by the Federal government. • The CDFI Fund reserves the right, in its sole discretion, to rescind an award if the Recipient (or Affiliate of a Recipient) is determined to be ineligible based on data in the Do Not Pay database.
Safety and soundness	• If it is determined the Recipient is, or will be, incapable of meeting its award obligations, the CDFI Fund will deem the Recipient to be ineligible, or require it to improve its safety and soundness prior to entering into an Assistance Agreement.

C. Reporting

1. Reporting requirements: On an annual basis during the Period of Performance, the CDFI Fund may collect information from each Recipient including, but not limited to, an Annual Report with the following components (Annual Reporting Requirements):

TABLE 19—ANNUAL REPORTING REQUIREMENTS *

Financial Statement Audit Report (Non-profit Recipient including Insured Credit Unions and State-Insured Credit Unions).	A Non-profit Recipient (including Insured Credit Unions and State-Insured Credit Unions) must submit a Financial Statement Audit (FSA) Report in AMIS, along with the Recipient's statement of financial condition audited or reviewed by an independent certified public accountant, if any are prepared. Under no circumstances should this be construed as the CDFI Fund requiring the Recipient to conduct or arrange for additional audits not otherwise required under Uniform Requirements or otherwise prepared at the request of the Recipient or parties other than the CDFI Fund.
Financial Statement Audit Report (For-Profit Recipient).	For-profit Recipients must submit a FSA Report in AMIS, along with the Recipient's statement of financial condition audited or reviewed by an independent certified public accountant.
Financial Statement Audit Report (Depository Institution Holding Company and Insured Depository Institution).	If the Recipient is a Depository Institution Holding Company or an Insured Depository Institution, it must submit a FSA Report in AMIS.
Single Audit Report (Non-Profit Recipients, if applicable).	A non-profit Recipient must complete an annual Single Audit pursuant to the Uniform Requirements (see 2 CFR Subpart F-Audit Requirements) if it expends $750,000 or more in Federal awards in its fiscal year, or such other dollar threshold established by OMB pursuant to 2 CFR 200.501. If a Single Audit is required, it must be submitted electronically to the Federal Audit Clearinghouse (FAC) (see 2 CFR subpart F-Audit Requirements in the Uniform Requirements) and optionally through AMIS.
Transaction Level Report (TLR)	The Recipient must submit a TLR to the CDFI Fund through AMIS. If the Recipient is a Depository Institution Holding Company that deploys all or a portion of its Financial Assistance through its Subsidiary CDFI Insured Depository Institution, that Subsidiary CDFI Insured Depository Institution must also submit a TLR. Furthermore, if the Depository Institution Holding Company itself deploys any portion of the Financial Assistance, the Depository Institution Holding Company must submit a TLR. The TLR is not required for TA Recipients.

TABLE 19—ANNUAL REPORTING REQUIREMENTS *—Continued

Uses of Award Report	The Recipient must submit the Uses of Award Report to the CDFI Fund in AMIS. If the Recipient is a Depository Institution Holding Company that deploys all or a portion of its Financial Assistance through its Subsidiary CDFI Insured Depository Institution, that Subsidiary CDFI Insured Depository Institution must also submit a Uses of Award Report. Furthermore, if the Depository Institution Holding Company itself deploys any portion of the Financial Assistance, the Depository Institution Holding Company must submit a Uses of Award Report.
Shareholders Report	If the Assistance is in the form of an Equity Investment, the Recipient must submit shareholder information to the CDFI Fund showing the class, series, number of shares and valuation of capital stock held or to be held by each shareholder. The Shareholder Report must be submitted for as long as the CDFI Fund is an equity holder. The Shareholders Report is submitted through AMIS.
Performance Progress Report	The Recipient must submit the Performance Progress Report through AMIS.
	If the Recipient is a Depository Institution Holding Company that deploys all or a portion of its Financial Assistance through its Subsidiary CDFI Insured Depository Institution, that Subsidiary CDFI Insured Depository Institution must also submit a Performance Progress Report. Furthermore, if the Depository Institution Holding Company itself deploys any portion of the Financial Assistance, the Depository Institution Holding Company must submit a Performance Progress Report.

* Personally Identifiable Information (PII) is information, which if lost, compromised, or disclosed without authorization, could result in substantial harm, embarrassment, inconvenience, or unfairness to an individual. Although Applicants are required to enter addresses of individual borrowers/residents of Distressed Communities in AMIS, Applicants should *not* include the following PII for the individuals who received the Financial Products or Financial Services in AMIS or in the supporting documentation (*i.e.,* name of the individual, Social Security Number, driver's license or state identification number, passport number, Alien Registration Number, etc.). *This information should be redacted from all supporting documentation.*

Each Recipient is responsible for the timely and complete submission of the Annual Reporting Requirements. The CDFI Fund reserves the right to contact the Recipient and additional entities or signatories to the Assistance Agreement to request additional information and/or documentation. The CDFI Fund will use such information to monitor each Recipient's compliance with the requirements of the Assistance Agreement and to assess the impact of the CDFI Program. The CDFI Fund reserves the right, in its sole discretion, to modify these reporting requirements, including increasing the scope and frequency of reporting, if it determines it to be appropriate and necessary; however, such reporting requirements will be modified only after notice to Recipients.

2. Financial Management and Accounting: The CDFI Fund will require Recipients to maintain financial management and accounting systems that comply with Federal statutes, regulations, and the terms and conditions of the Federal award. These systems must be sufficient to permit the preparation of reports required by the CDFI Fund to ensure compliance with the terms and conditions of the CDFI Program, including the tracing of funds to a level of expenditures adequate to establish that such funds have been used in accordance with Federal statutes, regulations, and the terms and conditions of the Federal award.

The cost principles used by Recipients must be consistent with Federal cost principles and support the accumulation of costs as required by the principles, and must provide for adequate documentation to support costs charged to the CDFI Program award. In addition, the CDFI Fund will require Recipients to: Maintain effective internal controls; comply with applicable statutes, regulations, and the Assistance Agreement; evaluate and monitor compliance; take appropriate action when not in compliance; and safeguard personally identifiable information.

VII. Agency Contacts

A. The CDFI Fund will respond to questions concerning this NOFA and the Application between the hours of 9:00 a.m. and 5:00 p.m. Eastern Time, starting on the date that the NOFA is published through the date listed in Table 1 and Table 12. The CDFI Fund strongly recommends Applicants submit questions to the CDFI Fund via an AMIS Service Request to the CDFI Program, Office of Certification, Compliance Monitoring and Evaluation, or IT Help Desk. The CDFI Fund will post on its website responses to reoccurring questions received about the NOFA and Application. Other information regarding the CDFI Fund and its programs may be obtained from the CDFI Fund's website at *http://www.cdfifund.gov.* Table 20 lists CDFI Fund contact information:

TABLE 20—CONTACT INFORMATION

Type of question	Preferred method	Telephone number (not toll free)	Email addresses
CDFI Program	Service Request via AMIS	202–653–0421, option 1	*cdfihelp@cdfi.treas.gov*
CCME	Service Request via AMIS	202–653–0423	*ccme@cdfi.treas.gov*
AMIS—IT Help Desk	Service Request via AMIS	202–653–0422	*AMIS@cdfi.treas.gov*

B. Information Technology Support: For IT assistance, the preferred method of contact is to submit a Service Request within AMIS. For the Service Request, select ''Technical Issues'' from the Program dropdown menu of the Service Request. People who have visual or mobility impairments that prevent them from using the CDFI Fund's website should call (202) 653–0422 for assistance (this is not a toll free number).

C. Communication with the CDFI Fund: The CDFI Fund will use the contact information in AMIS to communicate with Applicants and Recipients. It is imperative, therefore, that Applicants, Recipients, Subsidiaries, Affiliates, and signatories maintain accurate contact information in their accounts. This includes information such as contact names (especially for the Authorized Representative), email addresses, fax and phone numbers, and office locations.

D. Civil Rights and Diversity: Any person who is eligible to receive benefits or services from the CDFI Fund or Recipients under any of its programs is entitled to those benefits or services without being subject to prohibited discrimination. The Department of the Treasury's Office of Civil Rights and Diversity enforces various Federal statutes and regulations that prohibit discrimination in financially assisted and conducted programs and activities of the CDFI Fund. If a person believes that s/he has been subjected to discrimination and/or reprisal because of membership in a protected group, s/he may file a complaint with: Associate Chief Human Capital Officer, Office of Civil Rights, and Diversity, 1500 Pennsylvania Ave NW, Washington, DC 20220 or (202) 622–1160 (not a toll-free number).

E. Statutory and National Policy Requirements: The CDFI Fund will manage and administer the Federal award in a manner so as to ensure that Federal funding is expended and associated programs are implemented in full accordance with the U.S. Constitution, Federal Law, statutory, and public policy requirements: including but not limited to, those protecting free speech, religious liberty, public welfare, the environment, and prohibiting discrimination.

VIII. Other Information

A. Paperwork Reduction Act: Under the Paperwork Reduction Act (44 U.S.C. chapter 35), an agency may not conduct or sponsor a collection of information, and an individual is not required to respond to a collection of information, unless it displays a valid OMB control number. If applicable, the CDFI Fund may inform Applicants that they do not need to provide certain Application information otherwise required. Pursuant to the Paperwork Reduction Act, the CDFI Program, and NACA Program Application has been assigned the following control number: 1559–0021, inclusive of PPC–FA, DF–FA, and HFFI–FA.

B. Application Information Sessions: The CDFI Fund may conduct webinars or host information sessions for organizations that are considering applying to, or are interested in learning about, the CDFI Fund's programs. For further information, visit the CDFI Fund's website at *http://www.cdfifund.gov.*

Authority: 12 U.S.C. 4701, et seq; 12 CFR parts 1805 and 1815; 2 CFR part 200.

Jodie L. Harris,

Director, Community Development Financial Institutions Fund.

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DEPARTMENT OF THE TREASURY

Community Development Financial Institutions Fund

Notice of Funds Availability Inviting Applications for Financial Assistance Awards or Technical Assistance Grants Under the Native American CDFI Assistance Fiscal Year 2021 Funding Round

Funding Opportunity Title: Notice of Funds Availability (NOFA) inviting Applications for Financial Assistance (FA) awards or Technical Assistance (TA) grants under the Native American CDFI Assistance (NACA Program) fiscal year (FY) 2021 Funding Round.

Announcement Type: Announcement of funding opportunity.

Funding Opportunity Number: CDFI–2021–NACA.

Catalog of Federal Domestic Assistance (CFDA) Number: 21.012.

DATES:

TABLE 1—FY 2021 NACA PROGRAM FUNDING ROUND CRITICAL DEADLINES FOR APPLICANTS

Description	Deadline	Time (eastern time—ET)	Submission method
Last day to create an Awards Management Information Systems (AMIS) Account (all Applicants).	March 22, 2021	11:59 p.m.	AMIS.
Last day to enter EIN and DUNS numbers in AMIS (all Applicants).	March 22, 2021	11:59 p.m.	AMIS.
Last day to submit SF–424 Mandatory (Application for Federal Assistance).	March 22, 2021	11:59 p.m.	Electronically via *Grants.gov.*
Last day to contact NACA Program staff	April 29, 2021	5:00 p.m.	Service Request [1] via AMIS or CDFI Fund Helpdesk: 202–653–0421.
Last day to contact AMIS–IT Help Desk (regarding AMIS technical problems only).	May 3, 2021	5:00 p.m.	Service Request via AMIS or 202–653–0422 or *AMIS@cdfi.treas.gov*
Last day to submit NACA Program Application for Financial Assistance (FA) *or* Technical Assistance (TA).	May 3, 2021	11:59 p.m.	AMIS.

Executive Summary: Through the NACA Program, the Community Development Financial Institutions (CDFI) Fund provides (i) FA awards of up to $1 million to Certified Community Development Financial Institutions (CDFIs) serving Native American, Alaska Native, or Native Hawaiian populations or Native American areas defined as Federally-designated reservations, Hawaiian homelands, Alaska Native Villages and U.S. Census Bureau-designated Tribal Statistical Areas (collectively, ''Native Communities'') to build their financial capacity to lend to Eligible Markets and/or their Target Markets, and (ii) TA grants of up to $150,000 to build Certified, and Emerging CDFIs' organizational capacity to serve Eligible Markets and/or their Target Markets, and Sponsoring Entities ability to create

[1] Service Request shall mean a written inquiry or notification submitted to the CDFI Fund via AMIS.

Certified CDFIs that serve Native Communities. All awards provided through this NOFA are subject to funding availability.

I. Program Description

A. History: The CDFI Fund was established by the Riegle Community Development Banking and Financial Institutions Act of 1994 to promote economic revitalization and community development through investment in and assistance to CDFIs. The Native American CDFI Assistance (NACA) Program made its first awards in 2002, after the CDFI Program began making awards in 1996.

B. Priorities: Through the NACA Program's FA awards and TA grants, the CDFI Fund invests in and builds the capacity of for-profit and non-profit community based lending organizations known as CDFIs. These organizations, certified as CDFIs by the CDFI Fund, serve Native Communities.

C. Authorizing Statutes and Regulations: The CDFI Program is authorized by the Riegle Community Development Banking and Financial Institutions Act of 1994 (Pub. L. 103–325, 12 U.S.C. 4701 *et seq.*) (Authorizing Statute). The regulations governing the NACA Program are found at 12 CFR parts 1805 and 1815 (the Regulations) and are used by the CDFI Fund to govern, in general, the NACA Program, setting forth evaluation criteria and other program requirements. The CDFI Fund encourages Applicants to review the Regulations; this NOFA; the NACA Program Application for Financial Assistance or Technical Assistance (the Application); all related materials and guidance documents found on the CDFI Fund's website (Application materials); and the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (2 CFR part 1000), which is the Department of the Treasury's codification of the Office of Management and Budget (OMB) government-wide framework for grants management at 2 CFR part 200 (the Uniform Requirements) for a complete understanding of the NACA Program. Capitalized terms in this NOFA are defined in the Authorizing Statute, the Regulations, this NOFA, the Application, Application materials, or the Uniform Requirements. Details regarding Application content requirements are found in the Application and Application materials.

D. Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (2 CFR part 1000): The Uniform Requirements codify financial, administrative, procurement, and program management standards that Federal award agencies must follow. When evaluating Applications, awarding agencies must evaluate the risks posed by each Applicant, and each Applicant's merits and eligibility. These requirements are designed to ensure that Applicants for Federal assistance receive a fair and consistent review prior to an award decision. This review will assess items such as the Applicant's financial stability, quality of management systems, the soundness of its business plan, history of performance, ability to achieve measurable impacts through its products and services, and audit findings. In addition, the Uniform Requirements include guidance on audit requirements and other award compliance requirements for Recipients.

E. Funding limitations: The CDFI Fund reserves the right to fund, in whole or in part, any, all, or none of the Applications submitted in response to this NOFA. The CDFI Fund also reserves the right to reallocate funds from the amount that is anticipated to be available through this NOFA to other CDFI Fund initiatives that are designed to benefit Native Communities, particularly if the CDFI Fund determines that the number of awards made through this NOFA is fewer than projected.

II. Federal Award Information

A. Funding Availability:

1. FY 2021 Funding Round: The CDFI Fund expects to award, through this NOFA, approximately $16.5 million as indicated in the following table:

TABLE 2—FY 2021 FUNDING ROUND ANTICIPATED CATEGORY AMOUNTS

Funding categories (see definition in Table 7 for TA or Table 8 for FA)	Estimated total amount to be awarded (millions)	Award Amount		Estimated number of awards for FY 2021	Estimate average amount awarded in FY 2021	Average amount awarded in FY 2020
		Minimum	Maximum			
Base-FA	$11.9	$150,000	$1,000,000	23	$517,000	$615,000
Persistent Poverty Counties—Financial Assistance (PPC–FA)	1.6	100,000	300,000	11	145,000	143,750
TA	3	10,000	$150,000	20	148,000	145,000
Total (Base-FA, PPC–FA, and TA)	16.5			54		
Disability Funds—Financial Assistance (DF–FA) *	3	100,000	500,000	16	187,000	235,000
Healthy Food Financing Initiative—Financial Assistance (HFFI–FA) *	22	500,000	5,000,000	14	1,600,000	1,692,000

* DF–FA and HFFI–FA appropriation will be allocated in one competitive round between the NACA and CDFI Program NOFAs.

The CDFI Fund reserves the right to award more or less than the amounts cited above in each category, based upon available funding and other factors, as appropriate.

2. Funding Availability for the FY 2021 Funding Round: As of the date of this NOFA the CDFI Fund is operating under the Consolidated Appropriations Act, 2021 (Pub. L. 116–260).

3. Anticipated Start Date and Period of Performance: The Period of Performance for TA grants begins with the date of the award announcement and includes either (i) an Emerging CDFI Recipient's three full consecutive fiscal years after the date of the award announcement, or (ii) a Certified CDFI Recipient's two full consecutive fiscal years after the date of the award announcement, or (iii) a Sponsoring Entity Recipient's four full years after the date of the award announcement, during which the Recipient must meet the Performance Goals and Measures (PG&Ms) set forth in the Assistance Agreement. The Period of Performance for FA awards begins with the date of the award announcement and includes a Recipient's three full consecutive fiscal years after the date of the award announcement, during which time the Recipient must meet the PG&Ms set forth in the Assistance Agreement.

B. Types of Awards: Through the NACA Program, the CDFI Fund provides two types of awards: Financial Assistance (FA) and Technical Assistance (TA) awards. *An Applicant may submit an Application for a TA grant or an FA award under the NACA Program, but not both.* FA Awards include the Base Financial Assistance (Base-FA) award and the following awards that are provided as a supplement to the Base-FA award: Healthy Food Financing Initiative-Financial Assistance (HFFI–FA), Persistent Poverty Counties-Financial Assistance (PPC–FA), and Disability Funds-Financial Assistance (DF–FA). The HFFI–FA, PPC–FA, and DF–FA Applications will be evaluated independently from the Base-FA Application, and will not affect the Base-FA Application evaluation or Base-FA award amount.

However, Applicants that qualify for the NACA Program may submit two Applications: *One* Application—either for a TA grant or an FA award, but not both—through the CDFI Program, and *one* Application—either for a TA grant or an FA award, but not both—through the NACA Program. NACA qualified Applicants that choose to apply for awards through both the CDFI Program and the NACA Program may either apply for the same type of award under each Program or for a different type of award under each Program. NACA qualified FA Applicants that choose to apply for an FA award under both the NACA Program and CDFI Program and are selected for an award under both Programs will be provided the FA award under the CDFI Program. NACA qualified TA Applicants that choose to apply for a TA award under both the NACA Program and CDFI Program and are selected for an award under both Programs will be provided the TA award under the NACA Program. NACA qualified Applicants that choose to apply for a TA award and a FA award under separate programs will be provided the larger of the two awards. NACA Applicants cannot receive an award under both Programs within the same funding round.

The Indian Community Economic Enhancement Act of 2020 (Pub. L. 116–261) permanently waived the Matching Funds [2] requirement for Native American CDFIs, [3] and as a result, Native American CDFI FA Applicants are not required to provide Matching Funds. Additionally, TA Applicants are not required to provide Matching Funds.

1. Base-FA Awards: Base-FA awards are provided in the form of a grant. The CDFI Fund reserves the right, in its sole discretion, to provide a Base-FA award in an amount other than that which the Applicant requests; however, the award amount will not exceed the Applicant's award request as stated in its Application.

2. Persistent Poverty Counties—Financial Assistance (PPC–FA) Awards: PPC–FA awards will be provided as a supplement to Base-FA awards; therefore, only those Applicants that are selected to receive a Base-FA award through the NACA Program FY 2021 Funding Round will be eligible to receive a PPC–FA award. PPC–FA awards are provided in the form of a grant. The CDFI Fund reserves the right, in its sole discretion, to provide a PPC–FA award in an amount other than that which the Applicant requests; however, the award amount will not exceed the Applicant's award request as stated in its Application.

3. Disability Funds—Financial Assistance (DF–FA) Awards: DF–FA awards will be provided as a supplement to Base-FA awards; therefore, only those Applicants that have been selected to receive a Base-FA award through the NACA Program FY 2021 Funding Round will be eligible to receive a DF–FA award. DF–FA awards are provided in the form of a grant for Native American CDFIs. The CDFI Fund reserves the right, in its sole discretion, to provide a DF–FA award in an amount other than that which the Applicant requests; however, the award amount will not exceed the Applicant's award request as stated in its Application.

4. Healthy Food Financing Initiative—Financial Assistance (HFFI–FA) Awards: HFFI–FA awards will be provided as a supplement to Base-FA awards; therefore, only those Applicants that have been selected to receive a Base-FA award through the NACA Program FY 2021 Funding Round will be eligible to receive an HFFI–FA award. HFFI–FA awards are provided in the form of a grant for Native American CDFIs. The CDFI Fund reserves the right, in its sole discretion, to provide an HFFI–FA award in an amount other than that which the Applicant requests; however, the award amount will not exceed the Applicant's award request as stated in its Application.

5. TA Grants: TA is provided in the form of grants. The CDFI Fund reserves the right, in its sole discretion, to provide a TA grant in an amount other than that which the Applicant requests; however, the TA grant amount will not exceed the Applicant's request as stated in its Application.

C. Eligible Activities:

1. FA Awards: Base-FA, PPC–FA, DF–FA, and HFFI–FA award funds may be expended for activities serving Commercial Real Estate, Small Business, Microenterprise, Community Facilities, Consumer Financial Products, Consumer Financial Services, Commercial Financial Products, Commercial Financial Services, Affordable Housing, Intermediary Lending to Non-Profits and CDFIs, and other lines of business as deemed appropriate by the CDFI Fund in the following five categories: (i) Financial Products; (ii) Financial Services; (iii) Loan Loss Reserves; (iv) Development Services; and (v) Capital Reserves. The FA Budget is the amount of the award and must be expended in the five eligible activity categories prior to the end of the Budget Period. [4] None of the eligible activity categories will be authorized for Indirect Costs or an associated Indirect Cost Rate. Base-FA Recipients must meet PG&Ms, which will be derived from projections and attestations provided by the Applicant in its Application, to achieve one or more of the following FA Objectives: (i) Increase Volume of Financial Products in an Eligible Market(s) and/or in the Applicant's approved Target Market and/or Increase Volume of Financial Services in an Eligible Market(s) and/or in the Applicant's approved Target Market; (ii) Serve Eligible Market(s) or the Applicant's approved Target Market in New Geographic Area or Areas; (iii) Provide New Financial Products in an Eligible Market(s) and/or in the Applicant's approved Target Market, Provide New Financial Services in an Eligible Market(s) and/or in the Applicant's approved Target Market, or Provide New Development Services in an Eligible Market(s) and/or in the Applicant's approved Target Market; and (iv) Serve New Targeted Population or Populations. At the end of each year of the Period of Performance, 50% or more of the Financial Products closed by NACA Recipients must be in Native Communities. FA awards may only be used for Direct Costs associated with an eligible activity; no indirect expenses

[2] Matching Funds shall mean funds from sources other than the Federal government as defined in accordance with the CDFI Program Regulations at 12 CFR 1805.500.

[3] A Native American CDFI (Native CDFI) is one that Primarily Serves a Native Community. Primarily Serves is defined as 50% or more of an Applicant's activities being directed to a Native Community.

[4] Budget Period means the time interval from the start date of a funded portion of an award to the end date of that funded portion during which Recipients are authorized to expend the funds awarded.

are allowed. Up to 15% of the FA award may be used for Direct Administrative Expenses associated with an eligible FA activity. ''Direct Administrative Expenses'' shall mean Direct Costs, as described in 2 CFR 200.413 of the Uniform Requirements, which are incurred by the Recipient to carry out the Financial Assistance. Direct Costs incurred to provide Development Services or Financial Services do not constitute Direct Administrative Expenses.

The Recipient must comply, as applicable, with the Buy American Act of 1933, 41 U.S.C. 8301–8303 and 2 CFR 200.216 of the Uniform Requirements, [5] with respect to any Direct Costs. For purposes of this NOFA, the five eligible activity categories are defined below:

TABLE 3—BASE-FA, PPC–FA, DF–FA, AND HFFI–FA ELIGIBLE ACTIVITY CATEGORIES

FA eligible activity	FA eligible activity definition *	Eligible CDFI institution types
i. Financial Products	FA expended as loans, Equity Investments and similar financing activities (as determined by the CDFI Fund) including the purchase of loans originated by Certified CDFIs and the provision of loan guarantees. In the case of CDFI Intermediaries, Financial Products may also include loans to CDFIs and/or Emerging CDFIs, and deposits in Insured Credit Union CDFIs, Emerging Insured Credit Union CDFIs, and/or State-Insured Credit Union CDFIs.. For HFFI–FA, however, the purchase of loans originated by Certified CDFIs, loan refinancing, or any type of financing for prepared food outlets are not eligible activities..	All.
ii. Financial Services	FA expended for providing checking, savings accounts, check cashing, money orders, certified checks, automated teller machines, deposit taking, safe deposit box services, and other similar services.	Regulated Institutions [6] only. Not applicable for HFFI-FA Recipients.
iii. Loan Loss Reserves	FA set aside in the form of cash reserves, or through accounting-based accrual reserves, to cover losses on loans, accounts, and notes receivable or for related purposes that the CDFI Fund deems appropriate.	All.
iv. Development Services	FA expended for activities undertaken by a CDFI, its Affiliate or contractor that (i) promote community development and (ii) prepare or assist current or potential borrowers or investees to use the CDFI's Financial Products or Financial Services. For example, such activities include financial or credit counseling;. homeownership counseling; business planning; and management assistance..	All.
v. Capital Reserves	FA set aside as reserves to support the Applicant's ability to leverage other capital, for such purposes as increasing its net assets or providing financing, or for related purposes as the CDFI Fund deems appropriate.	Regulated Institutions only. Not applicable for DF–FA.
vi.		

* All FA eligible activities must be in an Eligible Market or the Applicant's approved Target Market. Eligible Market is defined as (i) a geographic area meeting the requirements set forth in 12 CFR 1805.201(b)(3)(ii), or (ii) individuals that are Low-Income, African American, Hispanic, Native American, Native Hawaiians residing in Hawaii, Alaska Natives residing in Alaska, or Other Pacific Islanders residing in American Samoa, Guam or the Northern Mariana Islands.

2. DF–FA Award: DF–FA award funds may only be expended for eligible FA activities (referenced in Table 3) to directly or indirectly benefit individuals with disabilities. The DF–FA Recipient must close Financial Products for the primary purpose of directly or indirectly benefiting people with disabilities, where the majority of the DF–FA supported loans or investments benefit individuals with disabilities, in an amount equal to or greater than 85% of the total DF–FA provided. Eligible DF–FA financing activities may include, among other activities, loans to develop or purchase affordable, accessible, and safe housing; loans to provide or facilitate employment opportunities; and loans to purchase assistive technology.

For the purposes of DF- FA, a person with a Disability is a person who has a physical or mental impairment that substantially limits one or more major life activities, a person who has a history or record of such an impairment, or a person who is perceived by others as having such an impairment, as defined by the American Disabilities Act (ADA) at *https://www.ada.gov/cguide.htm.*

3. TA Grants: TA grant funds may be expended for the following eight eligible activity categories: (i) Compensation—Personal Services; (ii) Compensation—Fringe Benefits; (iii) Professional Service Costs; (iv) Travel Costs; (v) Training and Education Costs; (vi) Equipment; (vii) Supplies; and (viii) Incorporation Costs. Only Sponsoring Entities may use TA grant funds for Incorporation Costs. The TA Budget is the amount of the award and must be expended in the eight eligible activity categories before the end of the Budget Period. None of the eligible activity categories will be authorized for Indirect Costs or an associated Indirect Cost Rate. Any expenses that are prohibited by the Uniform Requirements are unallowable and are generally found in Subpart E-Cost Principles. The Recipient must comply, as applicable, with the Buy American Act of 1933, 41 U.S.C. 8301–8303 and 2 CFR 200.216 of the Uniform Requirements, with respect to any Direct Costs. For purposes of this

[5] *2 CFR 200.216 prohibits Recipients and Subrecipients from obligating or expending loan or grant funds to procure or obtain, by contract or otherwise, equipment, services, or systems that use ''covered telecommunications equipment''. As used herein, ''covered telecommunications equipment'' is telecommunications equipment produced by Huawei Technologies Company or ZTE Corporation (or any Subsidiary or Affiliate of such entities).*

[6] Regulated Institutions include Insured Credit Unions, Insured Depository Institutions, State-Insured Credit Unions and Depository Institution Holding Companies.

NOFA, the eight eligible activity categories are defined below:

TABLE 4—TA ELIGIBLE ACTIVITY CATEGORIES, SUBJECT TO THE APPLICABLE PROVISIONS OF THE UNIFORM REQUIREMENTS

(i) Compensation—Personal Services.	TA paid to cover all remuneration paid currently or accrued, for services of Applicant's employees rendered during the Period of Performance under the TA grant in accordance with § 200.430 of the Uniform Requirements. Any work performed directly but unrelated to the purposes of the TA grant may not be paid as Compensation through a TA grant. For example, the salaries for building maintenance would not carry out the purpose of a TA grant and would be deemed unallowable.
(ii) Compensation—Fringe Benefits.	TA paid to cover allowances and services provided by the Applicant to its employees as Compensation in addition to regular salaries and wages, in accordance with § 200.431 of the Uniform Requirements. Such expenditures are allowable as long as they are made under formally established and consistently applied organizational policies of the Applicant.
(iii) Professional Service Costs.	TA used to pay for professional and consultant services (e.g., such as strategic and marketing plan development), rendered by persons who are members of a particular profession or possess a special skill (e.g., credit analysis, portfolio management), and who are not officers or employees of the Applicant, in accordance with § 200.459 of the Uniform Requirements. Payment for a consultant's services may not exceed the current maximum of the daily equivalent rate paid to an Executive Schedule Level IV Federal employee. Professional and consultant services must build the capacity of the CDFI. For example, professional services that provide direct Development Services to the customers does not build the capacity of the CDFI to provide those services and would not be eligible. The Applicant must comply, as applicable, with 2 CFR 200.216 of the Uniform Requirements, with respect to payment of Professional Service Costs.
(iv) Travel Costs	TA used to pay costs of transportation, lodging, subsistence, and related items incurred by the Applicant's personnel who are on travel status on business related to the TA award, in accordance with § 200.475 of the Uniform Requirements. Travel Costs do not include costs incurred by the Applicant's consultants who are on travel status. Any payments for travel expenses incurred by the Applicant's personnel but unrelated to carrying out the purpose of the TA grant would be deemed unallowable. As such, documentation must be maintained that justifies the travel as necessary to the TA grant.
(v) Training and Education Costs.	TA used to pay the cost of training and education provided by the Applicant for employees' development in accordance with § 200.473 of the Uniform Requirements. TA can only be used to pay for training costs incurred by the Applicant's employees. Training and Education Costs may not be incurred by the Applicant's consultants.
(vi) Equipment	TA used to pay for tangible personal property, having a useful life of more than one year and a per-unit acquisition cost of at least $5,000, in accordance with § 200.1 of the Uniform Requirements. For example, items such as office furnishings and information technology systems are allowable as Equipment costs. The Applicant must comply, as applicable, with the Buy American Act of 1933, 41 U.S.C. 8301–8303 and 2 CFR 200.216 of the Uniform Requirements, with respect to the purchase of Equipment.
(vii) Supplies	TA used to pay for tangible personal property with a per unit acquisition cost of less than $5,000 in accordance with § 200.1 of the Uniform Requirements. For example, a desktop computer costing $1,000 is allowable as a Supply cost. The Applicant must comply, as applicable, with the Buy American Act of 1933, 41 U.S.C. 8301–8303 and 2 CFR 200.216 of the Uniform Requirements, with respect to the purchase of Supplies.
(viii) Incorporation Costs (*Sponsoring Entities only*).	TA used to pay for incorporation fees in connection with the establishment or reorganization of an organization as a CDFI, in accordance with § 200.455 of the Uniform Requirements. Incorporation Costs are allowable for NACA Program Sponsoring Entity Applicants only.

4. HFFI–FA Award: HFFI–FA award funds may only be expended for eligible FA activities referenced in Table 3. The HFFI–FA investments must comply with the following guidelines:

a. Recipient must close Financial Products for Healthy Food Retail Outlets and Healthy Food Non-Retail Outlets in its approved Target Market in an amount equal to or greater than 100% of the total HFFI Financial Assistance provided. Eligible financing activities to Healthy Food Retail Outlets and Healthy Food Non-Retail Outlets require that the majority of the loan or investment be devoted to offering a range of Healthy Food choices, which may include, among other activities, investments supporting an existing retail store or wholesale operation upgrade to offer an expanded range of Healthy Food choices, or supporting a nonprofit organization that expands the availability of Healthy Foods in underserved areas.

b. Recipient must demonstrate that it has closed Financial Products to Healthy Food Retail Outlets located in Food Deserts in the Recipient's approved Target Market in an amount equal to 75% of the total HFFI Financial Assistance provided.

Definitions:

Healthy Foods: Healthy Foods include unprepared nutrient-dense foods and beverages as set forth in the USDA Dietary Guidelines for Americans 2020–2025 including whole fruits and vegetables, whole grains, fat free or low-fat dairy foods, lean meats and poultry (fresh, refrigerated, frozen or canned). Healthy Foods should have low or no added sugars, and be low-sodium, reduced sodium, or no-salt-added. (See USDA Dietary Guidelines: *http://www.dietaryguidelines.gov*).

Healthy Food Retail Outlets: Commercial sellers of Healthy Foods including, but not limited to, grocery stores, mobile food retailers, farmers markets, retail cooperatives, corner stores, bodegas, stores that sell other food and non-food items along with a range of Healthy Foods.

Healthy Food Non-Retail Outlets: Wholesalers of Healthy Foods including, but not limited to, wholesale food outlets, wholesale cooperatives, or other non-retail food producers that supply for sale a range of Healthy Food options; entities that produce or distribute Healthy Foods for eventual retail sale, and entities that provide consumer education regarding the consumption of Healthy Foods.

Food Deserts: Distressed geographic areas where either a substantial number or share of residents has low access to a supermarket or large grocery store. For the purpose of satisfying this requirement, a Food Desert must either: (1) Be a census tract determined to be a Food Desert by the U.S. Department of Agriculture (USDA), in its USDA Food Access Research Atlas; (2) be a census tract adjacent to a census tract determined to be a Food Desert by the USDA, in its USDA Food Access Research Atlas; which has a median family income less than or equal to 120% of the applicable Area Median Family Income; or (3) be a Geographic Unit as defined in 12 CFR 1805.201(b)(3)(ii)(B), which (i) individually meets at least one of the criteria in 12 CFR 1805.201(b)(3)(ii)(D), and (ii) has been identified as having low access to a supermarket or grocery store through a methodology that has been adopted for use by another governmental or philanthropic healthy food initiative.

5. PPC–FA Award: PPC–FA award funds may only be expended for eligible FA activities referenced in Table 3. The PPC–FA Recipient must close Financial Products in PPC in an Eligible Market or in the Applicant's approved Target Market in an amount equal to or greater than 100% of the total PPC Financial Assistance provided. The specific counties that meet the criteria for ''persistent poverty'' can be found at: *https://www.cdfifund.gov/Documents/CDFIPPCFeb19-2020.xls.*

III. Eligibility Information

A. Eligible Applicants: For the purposes of this NOFA, the following tables set forth the eligibility criteria to receive an award from the CDFI Fund, along with certain definitions of terms. There are four categories of Applicant eligibility criteria: (1) CDFI certification criteria (Table 5); (2) requirements that apply to all Applicants (Table 6); (3) requirements that apply to TA Applicants (Table 7); and (4) requirements that apply to FA Applicants (Table 8).

TABLE 5—CDFI CERTIFICATION CRITERIA DEFINITIONS

Certified CDFI	• An entity that the CDFI Fund has officially notified that it meets all CDFI certification requirements.
Emerging CDFI (TA Applicants)	• A non-Certified entity that demonstrates to the CDFI Fund in its Application that it has an acceptable plan to meet CDFI certification requirements by the end of its Period of Performance, or another date that the CDFI Fund selects. • An Emerging CDFI that has prior award(s) must comply with CDFI certification PG&M(s) stated in its prior Assistance Agreement(s). • An Emerging CDFI selected to receive a TA grant will be required to become a Certified CDFI by a date specified in the Assistance Agreement.
Sponsoring Entity	• Sponsoring Entities include any legal organization that primarily serves a Native Community with ''primary'' meaning, at least 50% of its activities are directed toward the Native Community. • An eligible organization that proposes to create a separate legal organization that will become a Certified CDFI serving Native Communities. • Each Sponsoring Entity selected to receive a TA grant will be required to create a CDFI and ensure that this newly created CDFI becomes certified by the dates specified in the Assistance Agreement.
Definition of Native Other Targeted Population as Target Market.	The CDFI Fund uses the following definitions, set forth in the Office of Management and Budget (OMB) Notice, Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity (October 30, 1997), as amended and supplemented: • American Indian, Native American, or Alaska Native: A person having origins in any of the original peoples of North and South America (including Central America) and who maintains tribal affiliation or community attachment; and • Native Hawaiian (living in Hawaii): A person having origins in any of the original peoples of Hawaii.

TABLE 6—ELIGIBILITY REQUIREMENTS FOR ALL APPLICANTS

Applicant	• Only the entity that will carry out the proposed award activities may apply for an award (other than Depository Institution Holding Companies (DIHC)[7]—see below and Sponsoring Entities). Recipients may not create a new legal entity to carry out the proposed award activities (except for Sponsoring Entities). • The information in the Application should only reflect the activities of the Applicant, including the presentation of financial and portfolio information. Do not include financial or portfolio information from parent companies, Affiliates, or Subsidiaries in the Application unless it relates to the provision of Development Services. • An Applicant that applies on behalf of another organization will be rejected without further consideration, other than Depository Institution Holding Companies (see below).
Application type and submission overview through *Grants.gov* and Awards Management Information System (AMIS).	• Applicants must submit the Required Application Documents listed in Table 10. • The CDFI Fund will only accept Applications that use the official Application templates provided on the *Grants.gov* and AMIS websites. Applications submitted with alternative or altered templates will not be considered. • Applicants undergo a two-step process that requires the submission of Application documents by two separate deadlines in two different locations: (1) The SF–424 in *Grants.gov* and (2) all other Required Application Documents in AMIS. • *Grants.gov* and the SF–424: ○ *Grants.gov:* Applicants must submit the Standard Form (SF) SF–424, Application for Federal Assistance. ○ All Applicants must register in the *Grants.gov* system to successfully submit an Application. The *Grants.gov* registration process can take 30 days or more to complete. The CDFI Fund strongly encourages Applicants to register as early as possible. ○ The CDFI Fund will not extend the SF–424 application deadline for any Applicant that started the *Grants.gov* registration process on, before, or after the date of the publication of this NOFA, but did not complete it by the deadline except in the case of a Federal government administrative or technological error that directly resulted in a late submission of the SF–424.

TABLE 6—ELIGIBILITY REQUIREMENTS FOR ALL APPLICANTS—Continued

	○ The SF–424 must be submitted in *Grants.gov* on or before the deadline listed in Table 1 and Table 12. Applicants are strongly encouraged to submit their SF–424 as early as possible in the *Grants.gov* portal. ○ The deadline for the *Grants.gov* submission is before the AMIS submission deadline. ○ The SF–424 must be submitted under the NACA Program Funding Opportunity Number for the NACA Program Application. *NACA Program Applicants should be careful to not select the CDFI Program Funding Opportunity Number when submitting their SF–424 for the NACA Program.* NACA Program Applicants that submit their SF–424 for the NACA Program Application under the CDFI Program Funding Opportunity Number will be deemed ineligible for the NACA Program Application. ○ If the SF–424 is not accepted by *Grants.gov* by the deadline, the CDFI Fund will not review any material submitted in AMIS and the Application will be deemed ineligible. • AMIS and all other Required Application Documents listed in Table 10: ○ AMIS is an enterprise-wide information technology system. Applicants will use AMIS to submit and store organization and Application information with the CDFI Fund. ○ Applicants are only allowed one NACA Program Application submission in AMIS. ○ Each Application in AMIS must be signed by an Authorized Representative. ○ Applicants must ensure that the Authorized Representative is an employee or officer of the Applicant, authorized to sign legal documents on behalf of the organization. *Consultants working on behalf of the organization may not be designated as Authorized Representatives.* ○ Only the Authorized Representative or Application Point of Contact, included in the Application, may submit the Application in AMIS. ○ All Required Application Documents must be submitted in AMIS on or before the deadline specified in Tables 1 and 12. ○ The CDFI Fund will not extend the deadline for any Applicant except in the case of a Federal government administrative or technological error that directly resulted in the late submission of the Application in AMIS.
Employer Identification Number (EIN).	• Applicants must have a unique EIN assigned by the Internal Revenue Service (IRS). • The CDFI Fund will reject an Application submitted with the EIN of a parent or Affiliate organization. • The EIN in the Applicant's AMIS account must match the EIN in the Applicant's System for Award Management (SAM) account. The CDFI Fund reserves the right to reject an Application if the EIN in the Applicant's AMIS account does not match the EIN in its SAM account. • Applicants must enter their EIN into their AMIS profile on or before the deadline specified in Tables 1 and 12.
Dun & Bradstreet, (DUNS) number	• Pursuant to OMB guidance (68 FR 38402), an Applicant must apply using its unique DUNS number in *Grants.gov*. • The CDFI Fund will reject an Application submitted with the DUNS number of a parent or Affiliate organization. • The DUNS number in the Applicant's AMIS account must match the DUNS number in the Applicant's *Grants.gov* and SAM accounts. The CDFI Fund will reject an Application if the DUNS number in the Applicant's AMIS account does not match the DUNS number in its *Grants.gov* and SAM accounts. • Applicants must enter their DUNS number into their AMIS profile on or before the deadline specified in Tables 1 and 12.
System for Award Management (SAM).	• SAM is a web-based, government-wide application that collects, validates, stores, and disseminates business information about the federal government's trading partners in support of the contract awards, grants, and electronic payment processes. • Applicants must register in SAM as part of the *Grants.gov* registration process. • Applicants must have a DUNS number and an EIN number in order to register in SAM. • Applicants must be registered in SAM in order to submit an SF–424 in *Grants.gov*. • The CDFI Fund reserves the right to deem an Application ineligible if the Applicant's SAM account expires during the Application evaluation period, or is set to expire before September 30, 2021, and the Applicant does not re-activate, or renew, as applicable, the account within the deadlines that the CDFI Fund communicates to affected Applicants during the Application evaluation period.
AMIS Account	• Each Applicant must register as an organization in AMIS and submit all Required Application Documents listed in Table 10 through the AMIS portal. • The Application of any organization that does not properly register in AMIS by the deadline set forth in Table 1—FY 2021 NACA Program Funding Round Critical Deadlines for Applicants—will be rejected without further consideration. • The Authorized Representative and/or Application Point of Contact must be included as "users" in the Applicant's AMIS account. • An Applicant that fails to properly register and update its AMIS account may miss important communication from the CDFI Fund and/or may not be able to successfully submit an Application.
501 (c)(4) status	• Pursuant to 2 U.S.C. 1611, any 501(c)(4) organization that engages in lobbying activities is not eligible to receive a CDFI or NACA Program award.
Compliance with Nondiscrimination and Equal Opportunity Statutes, Regulations, and Executive Orders.	• An Applicant may not be eligible to receive an award if proceedings have been instituted against it in, by, or before any court, governmental agency, or administrative body, and a final determination within the last three years indicates the Applicant has violated any of the following laws, including but not limited to: Title VI of the Civil Rights Act of 1964, as amended (42 U.S.C.2000d); Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794); the Age Discrimination Act of 1975, (42 U.S.C. 6101–6107), and Executive Order 13166, Improving Access to Services for Persons with Limited English Proficiency.
Depository Institution Holding Company Applicant.	• In the case where a CDFI Depository Institution Holding Company Applicant intends to carry out the activities of an award through its Subsidiary CDFI Insured Depository Institution, the Application must be submitted by the CDFI Depository Institution Holding Company and reflect the activities and financial performance of the Subsidiary CDFI Insured Depository Institution.

TABLE 6—ELIGIBILITY REQUIREMENTS FOR ALL APPLICANTS—Continued

	• Authorized Representatives of both the Depository Institution Holding Company and the Subsidiary CDFI Insured Depository Institution must certify that the information included in the Application represents that of the Subsidiary CDFI Insured Depository Institution, and that the award funds will be used to support the Subsidiary CDFI Insured Depository Institution for the eligible activities outlined in the Application.
Use of award	• All awards made through this NOFA must be used to support the Applicant's activities in at least one of the FA or TA Eligible Activity Categories (see Section II. (C)).
	• With the exception of Depository Institution Holding Company Applicants, awards may not be used to support the activities of, or otherwise be passed through, transferred, or co-awarded to, third-party entities, whether Affiliates, Subsidiaries, or others, unless done pursuant to a merger or acquisition or similar transaction, and with the CDFI Fund's prior written consent. The Recipient of any award made through this NOFA must comply, as applicable, with the Buy American Act of 1933, 41 U.S.C. 8301–8303 and 2 CFR 200.216 of the Uniform Requirements, with respect to any Direct Costs.
Requested award amount	• An Applicant must state its requested award amount in the Application in AMIS. An Applicant that does not include this amount will not be allowed to submit an Application.
Pending resolution of noncompliance.	• The CDFI Fund will consider an Application submitted by an Applicant that has pending noncompliance issues on any of its previously executed award agreement(s), if the CDFI Fund has not yet made a final compliance determination.
Noncompliance or default status	• The CDFI Fund will not consider an Application submitted by an Applicant that has a previously executed award agreement(s) if, as of the date of the Application, (i) the CDFI Fund has made a final determination that such entity is noncompliant or found in default with a previously executed agreement, and (ii) the CDFI Fund has provided written notification that such entity is ineligible to apply for or receive any future CDFI Fund awards or allocations. Such entities will be ineligible to submit an Application for such time period as specified by the CDFI Fund in writing.
	• The CDFI Fund will not consider any Applicant that has defaulted on a loan from the CDFI Fund within five years of the Application deadline.
Debarment/Do Not Pay Verification	• The CDFI Fund will conduct a debarment check and will not consider an Application submitted by an Applicant (or Affiliate of an Applicant) if the Applicant is delinquent on any Federal debt.
	• The Do Not Pay Business Center was developed to support Federal agencies in their efforts to reduce the number of improper payments made through programs funded by the Federal government. The Do Not Pay Business Center provides delinquency information to the CDFI Fund to assist with the debarment check.

TABLE 7—ELIGIBILITY REQUIREMENTS FOR TA APPLICANTS

CDFI certification status	Certified CDFIs, Emerging CDFIs, or Sponsoring Entities (see definitions in Table 5).
Matching Funds	• Matching Funds documentation is not required for TA awards.
Limitation on Awards	• An Emerging CDFI serving Native Communities may not receive more than three TA awards as an uncertified CDFI.
	• A Sponsoring Entity is only eligible to apply for an award if (i) it does not have an active prior award or (ii) the certification goal in its active award's Assistance Agreement has been satisfied and it proposes to create another CDFI that will serve one or more Native Communities.
Proposed Activities	• Applicants must propose to directly undertake eligible activities with TA awards. For example, an uncertified CDFI Applicant must propose to become certified as part of its Application and a Certified CDFI Applicant must propose activities that build its capacity to serve its Target Market or an Eligible Market.
	• With the exception of Sponsoring Entities, Applicants may not propose to use a TA award to create a separate legal entity to become a Certified CDFI or otherwise carry out the TA award activities.
Regulated Institution	• Each Regulated Institution TA Applicant must have a CAMELS/CAMEL rating (rating for banks and credit unions, respectively) or equivalent type of rating by its regulator (collectively referred to as "CAMELS/CAMEL rating") of at least "4".
	• TA Applicants with CAMELS/CAMEL ratings of "5" will not be eligible for awards.
	• The CDFI Fund will also evaluate material concerns identified by the Appropriate Federal Banking Agency in determining the eligibility of Regulated Institution Applicants.
Target Market	• TA Applicants must demonstrate that the Certified CDFI, Emerging CDFI, or the CDFI to be created by the Sponsoring Entity will primarily serve one or more Native Communities as its Target Market.

TABLE 8—ELIGIBILITY REQUIREMENTS FOR FA APPLICANTS

CDFI certification status	• Each FA Applicant must be a Certified CDFI prior to the date of the release of this NOFA.
	• The CDFI Fund will consider an Application submitted by an Applicant that has pending noncompliance issues with its Annual Certification Report if the CDFI Fund has not yet made a final compliance determination.
	• If a Certified CDFI loses its certification at any point prior to the award announcement, the Application will no longer be considered by the CDFI Fund.
Activities in Native Communities	• For consideration under this NOFA, each FA Applicant must:

[7] Depository Institution Holding Company or DIHC means a Bank Holding Company or a Savings and Loan Holding Company.

TABLE 8—ELIGIBILITY REQUIREMENTS FOR FA APPLICANTS—Continued

	○ Demonstrate that at least 50% of its past activities were in one or more Native Communities; and ○ Describe how it will target its lending/investing activities to one or more Native Communities.
Target Market	• For consideration under this NOFA, an FA Applicant's certification Target Market must have one or more of the following characteristics: ○ For qualifying with an *Investment Area,* the Applicant must demonstrate that the Investment Area approved for certification is *also* a geographic area of Federally-designated reservations, Hawaiian homelands, Alaska Native Villages and U.S. Census Bureau designated Tribal Statistical Areas; and/or ○ For qualifying with an *Other Targeted Population (OTP),* the applicant's Target Market approved for certification must be an OTP of Native Americans or American Indians, including Alaska Natives living in Alaska and Native Hawaiians living in Hawaii. • Any FA Applicant whose certification Target Market does not meet either of the conditions above will not be eligible for an FA award under this NOFA.
Community Collaboration	• All FA Applicants must demonstrate strong community collaboration with Native Communities.
Matching Funds documentation	• Native American CDFIs are not required to provide Matching Funds.
$5 Million funding cap	• The CDFI Fund is prohibited from obligating more than $5 million in CDFI and NACA Program awards, in the aggregate, to any one organization and its Subsidiaries and Affiliates during any three-year period from the Announcement Date. • For TA Applicants, for purposes of this NOFA and per final FY 2021 appropriations language, the CDFI Fund will include CDFI and NACA Program final awards in the cap calculation that were provided to an Applicant (and/or its Subsidiaries or Affiliates) under the FY 2019, and 2020 funding rounds, as well as the requested FY 2021 award, excluding DF–FA and HFFI–FA awards. • For FA Applicants, for purposes of this NOFA and per final FY 2021 appropriations language, the CDFI Fund will include CDFI and NACA Program final awards in the cap calculation that were provided to an Applicant (and/or its Subsidiaries or Affiliates) under the FY 2019 and 2020 funding rounds, as well as the requested FY 2021 award, excluding DF–FA and HFFI–FA awards.
FA Applicants with Community Partners.	• A NACA Applicant can apply for assistance jointly with a Community Partner. The CDFI Applicant must complete the NACA Program Application and address the Community Partnership in its business plan and other sections of the Application as specified in the Application materials. • The CDFI Applicant must be a Certified CDFI as defined in Table 5. • An Application with a Community Partner must: ○ Describe how the NACA Applicant and Community Partner will each participate in the partnership and how the partnership will enhance eligible activities serving the Investment Area and/or Targeted Population. ○ Demonstrate that the Community Partnership activities are consistent with the strategic plan submitted by the NACA Applicant. • Assistance provided upon approval of an Application with a Community Partner shall only be entrusted to the NACA Applicant and shall not be used to fund any activity carried out directly by the Community Partner or an Affiliate or Subsidiary thereof.
Regulated Institution	• Each Regulated Institution FA Applicant must have a CAMELS/CAMEL rating (rating for banks and credit unions, respectively) or equivalent type of rating by its regulator (collectively referred to as ''CAMELS/CAMEL rating'') of at least ''3''. • FA Applicants with CAMELS/CAMEL ratings of ''4 or 5'' will not be eligible for awards. • The CDFI Fund will also evaluate material concerns identified by the Appropriate Federal Banking Agency in determining the eligibility of Regulated Institution Applicants.
PPC–FA	• All PPC–FA Applicants must: ○ Submit a CDFI or NACA Program FA Application; ○ Meet all NACA FA award eligibility requirements; and ○ Provide a PPC–FA award request amount in AMIS.
DF–FA	• All DF–FA Applicants must: ○ Submit a CDFI or NACA Program FA Application; ○ Meet all NACA FA award eligibility requirements; ○ Submit the DF–FA Application; and ○ Provide a DF–FA award request amount in AMIS.
HFFI–FA	• All HFFI–FA Applicants must: ○ Submit a CDFI or NACA Program FA Application; ○ Meet all NACA FA award eligibility requirements; ○ Submit the HFFI–FA Application; and ○ Provide a HFFI–FA award request amount in AMIS.

B. Matching Funds Requirements:
Native American CDFIs are not required to provide Matching Funds.

TABLE 9—RESERVED

IV. Application and Submission Information

A. Address to Request an Application Package: Application materials can be found on the CDFI Fund's website at *www.cdfifund.gov/programs-training/Programs/native-initiatives.* Applicants may request a paper version of any Application material by contacting the CDFI Fund Help Desk at *cdfihelp@cdfi.treas.gov.* Paper versions of Application materials will only be provided if an Applicant cannot access the CDFI Fund's website.

B. Content and Form of Application Submission: All Applications must be prepared using the English language, and calculations must be computed in U.S. dollars. The following table lists the Required Application Documents for the FY 2021 Funding Round. The CDFI Fund reserves the right to request and review other pertinent or public information that has not been specifically requested in this NOFA or the Application. Information submitted by the Applicant that the CDFI Fund has not specifically requested will not be reviewed or considered as part of the Application. Financial data, portfolio, and activity information provided in the Application should only include the Applicant's activities. Information submitted must accurately reflect the Applicant's activities.

TABLE 10—REQUIRED APPLICATION DOCUMENTS

Application documents	Applicant type	Submission format
Active AMIS Account	All Applicants	AMIS.
SF–424	All Applicants	Fillable PDF in *Grants.gov*.
NACA Program Application Components: • Funding Application Detail. • Data, Charts, and Narrative sections as listed in AMIS and outlined in Application materials.	All Applicants	AMIS.
PPC–FA Application Components: • Funding Application Detail • Narratives • AMIS Charts	PPC–FA Applicants	AMIS.
DF–FA Application Components: • Funding Application Detail. • Narratives. • AMIS Charts.	DF–FA Applicants	AMIS.
HFFI–FA Application Components: • Funding Application Detail. • Narratives. • AMIS charts.	HFFI–FA Applicants	AMIS.
ATTACHMENTS TO THE APPLICATION: Add to "Related Attachments" related list in Application		
Key Staff Resumes	All Applicants	PDF or Word document in AMIS.
Organizational Chart	All Applicants	PDF in AMIS.
Audited financial statements for the Applicant's Three Most Recent Historic Fiscal Years.	FA Applicants: Loan funds, Venture Capital Funds,[8] and other non-Regulated Institutions. TA Applicants, if available: loan funds, Venture Capital Funds, and other non-Regulated Institutions.	PDF in AMIS.
Management Letter for the Applicant's Most Recent Historic Fiscal Year The Management Letter is prepared by the Applicant's auditor and is a communication on internal control over financial reporting, compliance, and other matters. The Management Letter contains the auditor's findings regarding the Applicant's accounting policies and procedures, internal controls, and operating policies, including any material weaknesses, significant deficiencies, and other matters identified during auditing. The Management Letter may include suggestions for improving on identified weaknesses and deficiencies and/or best practice suggestions for items that may not be considered to be weaknesses or deficiencies. The Management Letter may also include items that are not required to be disclosed in the annual audited financial statements. The Management Letter is distinct from the auditor's Opinion Letter, which is required by Generally Accepted Accounting Principles (GAAP). Management Letters are not required by GAAP, and are sometimes provided by the auditor as a separate letter from the audit itself.	FA Applicants: Loan funds, Venture Capital Funds, and other non-Regulated Institutions. TA Applicants, if audited financial statements are available: Loan funds, Venture Capital Funds, and other non-Regulated Institutions.	PDF in AMIS.
Statement(s) in Lieu of Management Letter for Applicant's Most Recent Historic Fiscal Year issued by the Board Treasurer or other Board member using the template provided in the Application materials (required only if Management Letters are not available for audited financial statements).	FA Applicants: Loan funds, Venture Capital Funds, and other non-Regulated Institutions. TA Applicants, if audited financial statements ARE available but the Management Letters are NOT available: Loan funds, Venture Capital Funds, and other non-Regulated Institutions.	AMIS.
Unaudited financial statements for Applicant's Three Most Recent Historic Years (required only if audited financial statements are not available).	TA Applicants: Loan funds, Venture Capital Funds, and other non-Regulated Institutions.	PDF in AMIS.

TABLE 10—REQUIRED APPLICATION DOCUMENTS—Continued

Application documents	Applicant type	Submission format
Current Year to Date—December 31, 2020 Unaudited financial statements	FA and TA Applicants: Loan funds, Venture Capital Funds, and other non-Regulated Institutions.	PDF in AMIS.
Community Partnership Agreement	FA Applicants, if applicable	PDF or Word document in AMIS.

C. Application Submission: The CDFI Fund has a two-step process that requires the submission of Required Application Documents (listed in Table 10) on separate deadlines and locations. The SF–424 must be submitted through *Grants.gov* and all other Required Application Documents through the AMIS portal. The CDFI Fund will not accept Applications via email, mail, facsimile, or other forms of communication, except in extremely rare circumstances that have been pre-approved in writing by the CDFI Fund. The deadline for submitting the SF–424 is listed in Tables 1 and 12.

All Applicants must register in the *Grants.gov* system to successfully submit the SF–424. The *Grants.gov* registration process can take 45 days or longer to complete and the CDFI Fund strongly encourages Applicants to start the *Grants.gov* registration process as early as possible (refer to the following link: *http://www.grants.gov/web/grants/register.html*). Since the *Grants.gov* registration process requires Applicants to have DUNS and EIN numbers, Applicants without these required numbers should allow for additional time to complete the *Grants.gov* registration process. Further, as described in Section IV. (E) of this NOFA, new requirements for registration in the System for Awards Management (SAM), which is required as part of the *Grants.gov* registration process, may take more time than in recent years. The CDFI Fund will not extend the Application deadline for any Applicant that started the *Grants.gov* registration process but did not complete it by the deadline. An Applicant that has previously registered with *Grants.gov* must verify that its registration is current and active. Applicants should contact *Grants.gov* directly with questions related to the registration or submission process as the CDFI Fund does not maintain the *Grants.gov* system.

Each Application must be signed by a designated Authorized Representative in AMIS before it can be submitted. Applicants must ensure that an Authorized Representative is an employee or officer and is authorized to sign legal documents on behalf of the Applicant. Consultants working on behalf of the Applicant may not be designated as Authorized Representatives. Only a designated Authorized Representative or Application Point of Contact, included in the Application, may submit the Application in AMIS. If an Authorized Representative or Application Point of Contact does not submit the Application, the Application will be deemed ineligible.

D. Dun & Bradstreet Universal Numbering System: Pursuant to the Uniform Requirements, each Applicant must provide as part of its Application submission, a Dun and Bradstreet Universal Numbering System (DUNS) number. Applicants without a DUNS number will not be able to register and submit an Application in the *Grants.gov* system. Allow sufficient time for Dun & Bradstreet to respond to inquiries and/or requests for DUNS numbers.

E. System for Award Management (SAM): Any entity applying for Federal grants or other forms of Federal financial assistance through *Grants.gov* must be registered in SAM before submitting its Application. Registration in SAM is required as part of the *Grants.gov* registration process. The SAM registration process may take one month or longer to complete. A signed notarized letter identifying the SAM authorized entity administrator for the entity associated with the DUNS number is required. This requirement is applicable to new entities registering in SAM, as well as to existing entities with registrations being updated or renewed in SAM. Applicants without DUNS and/or EIN numbers should allow for additional time as an Applicant cannot register in SAM without those required numbers. Applicants that have previously completed the SAM registration process must verify that their SAM accounts are current and active. Each Applicant must continue to maintain an active SAM registration with current information at all times during which it has an active Federal award or an Application under consideration by a Federal awarding agency. The CDFI Fund will deem ineligible any Applicant that fails to properly register or activate its SAM account and, as a result, is unable to submit the SF–424 in *Grants.gov* or Application in AMIS by the applicable Application deadlines. These restrictions also apply to organizations that have not yet received a DUNS or EIN number. Applicants must contact SAM directly with questions related to registration or SAM account changes as the CDFI Fund does not maintain this system and has no ability to make changes or correct errors of any kind. For more information about SAM, visit *https://www.sam.gov.*

TABLE 11—Grants.gov REGISTRATION TIMELINE SUMMARY

Step	Agency	Estimated minimum time to complete
Obtain a DUNS number	Dun & Bradstreet	One (1) Week.*
Obtain an EIN Number	Internal Revenue Service (IRS)	Two (2) Weeks.*
Register in *SAM.gov*	System for Award Management (*SAM.gov*)	Four (4) Weeks.*

[8] A Venture Capital Fund is an organization that predominantly invests funds in businesses, typically in the form of either Equity Investments or subordinated debt with equity features such as revenue participation or warrants, and generally seeks to participate in the upside returns of such businesses in an effort to at least partially offset the risk of its investments.

TABLE 11—Grants.gov REGISTRATION TIMELINE SUMMARY—Continued

Step	Agency	Estimated minimum time to complete
Register in *Grants.gov*	*Grants.gov*	One (1) Week.**

*Applicants are advised that the stated durations are estimates only and represent minimum timeframes. Actual timeframes may take longer. The CDFI Fund will deem ineligible any Applicant that fails to properly register or activate its SAM account, has not yet received a DUNS or EIN number, and/or fails to properly register in *Grants.gov*.

**This estimate assumes an Applicant has a DUNS number, an EIN number, and is already registered in *SAM.gov*.

F. Submission Dates and Times:

1. Submission Deadlines: The following table provides the critical deadlines for the FY 2021 Funding Round.

TABLE 12—FY 2021 NACA PROGRAM FUNDING ROUND CRITICAL DEADLINES FOR APPLICANTS

Description	Deadline	Time (eastern time—ET)	Submission method
Last day to create an Awards Management Information Systems (AMIS) Account (all Applicants).	March 22, 2021	11:59 p.m.	AMIS.
Last day to enter EIN and DUNS numbers in AMIS (all Applicants).	March 22, 2021	11:59 p.m.	AMIS.
Last day to submit SF–424 (Application for Federal Assistance).	March 22, 2021	11:59 p.m.	Electronically via *Grants.gov.*
Last day to contact NACA Program staff	April 29, 2021	5:00 p.m.	Service Request via AMIS Or CDFI Fund Helpdesk: 202–653–0421.
Last day to contact AMIS–IT Help Desk (regarding AMIS technical problems only).	May 3, 2021	5:00 p.m.	Service Request via AMIS Or 202–653–0422 Or *AMIS@cdfi.treas.gov*
Last day to submit NACA Program Application for Financial Assistance (FA) *or* Technical Assistance (TA).	May 3, 2021	11:59 p.m.	AMIS.

2. Confirmation of Application Submission in Grants.gov and AMIS: Applicants are required to submit the SF–424, Application for Federal Assistance through the *Grants.gov* system, under the NACA Program Funding Opportunity Number by the applicable deadline. All other Required Application Documents (listed in Table 10) must be submitted through the AMIS website by the applicable deadline. Applicants must submit the SF–424 prior to submitting the Application in AMIS. If the SF–424 is not successfully accepted by *Grants.gov* by the deadline, the CDFI Fund will not review the Application submitted in AMIS, and the Application will be deemed ineligible.

a. *Grants.gov* Submission Information: Each Applicant will receive an email from *Grants.gov* immediately after submitting the SF–424 confirming that the submission has entered the *Grants.gov* system. This email will contain a tracking number for the submitted SF–424. Within 48 hours, the Applicant will receive a second email, which will indicate if the submitted SF–424 was either successfully validated or rejected with errors. However, Applicants should not rely on the email notification from *Grants.gov* to confirm that their SF–424 was validated. Applicants are strongly encouraged to use the tracking number provided in the first email to closely monitor the status of their SF–424 by contacting the helpdesk at *Grants.gov* directly. The Application material submitted in AMIS is not officially accepted by the CDFI Fund until *Grants.gov* has validated the SF–424.

b. AMIS Submission Information: AMIS is a web-based portal where Applicants will directly enter their Application information and add the required attachments listed in Table 10. AMIS will verify that the Applicant provided the minimum information required to submit an Application. Applicants are responsible for the quality and accuracy of the information and attachments included in the Application submitted in AMIS. The CDFI Fund strongly encourages Applicants to allow for sufficient time to review and complete all Required Application Documents listed in Table 10, and remedy any issues prior to the Application deadline. Each Application must be signed by an Authorized Representative in AMIS before it can be submitted. Applicants must ensure that the Authorized Representative is an employee or officer and is authorized to sign legal documents on behalf of the Applicant. Consultants working on behalf of the Applicant may not be designated as Authorized Representatives. Only an Authorized Representative or an Application Point of Contact may submit an Application. If an Authorized Representative or Application Point of Contact does not submit the Application, the Application will be deemed ineligible. Applicants may only submit one Base-FA or TA Application under the NACA Program. Upon submission, the Application will be locked and cannot be resubmitted, edited, or modified in any way. The CDFI Fund will not unlock or allow multiple Application submissions.

3. Late Submission: The CDFI Fund will not accept an Application if the SF–424 is not submitted and accepted by *Grants.gov* by the SF–424 deadline. Additionally, the CDFI Fund will not accept an Application if it is not signed by an Authorized Representative and submitted in AMIS by the Application deadline. In either case, the CDFI Fund will not review any material submitted, and the Application will be deemed ineligible.

However, in cases where a Federal government administrative or technological error directly resulted in a

late submission of the SF–424 or the Application, Applicants are provided two opportunities to submit a written request for acceptance of late submissions. The CDFI Fund will not consider the late submission of the SF–424 or the Application that was a direct result of a delay in a Federal Government process, unless such delay was the result of a Federal government administrative or technological error.

a. SF–424 Late Submission: In cases where a Federal government administrative or technological error directly resulted in the late submission of the SF–424, the Applicant must submit a written request for acceptance of the late SF–424 submission and include documentation of the error no later than two business days after the SF–424 deadline. The CDFI Fund will not respond to requests for acceptance of late SF–424 submissions after that time period. Applicants must submit late SF–424 submission requests to the CDFI Fund via an AMIS Service Request to the NACA Program with a subject line of ''Late SF–424 Submission Request.''

b. *Application Late Submission:* In cases where a Federal government administrative or technological error directly resulted in a late submission of the Application in AMIS, the Applicant must submit a written request for acceptance of the late Application submission and include documentation of the error no later than two business days after the Application deadline. The CDFI Fund will not respond to requests for acceptance of late Application submissions after that time period. Applicants must submit late Application submission requests to the CDFI Fund via an AMIS Service Request to the NACA Program with a subject line of ''Late Application Submission Request.''

G. Funding Restrictions: Base-FA, PPC–FA, DF–FA, HFFI–FA and TA awards are limited by the following:

1. Base-FA Awards:

a. A Recipient shall use Base-FA funds only for the eligible activities described in Section II. (C)(1) of this NOFA and its Assistance Agreement.

b. With the exception of Depository Institution Holding Company Applicants, Base-FA awards may not be used to support the activities of, or otherwise be passed through, transferred, or co-awarded to, third-party entities, whether Affiliates, Subsidiaries, or others, unless done pursuant to a merger or acquisition or similar transaction, and with the CDFI Fund's prior written consent.

c. Base-FA funds shall only be paid to the Recipient.

d. The CDFI Fund, in its sole discretion, may pay Base-FA funds in amounts, or under terms and conditions, which are different from those requested by an Applicant.

e. The Recipient must comply, as applicable, with the Buy American Act of 1933, 41 U.S.C. 8301–8303 and 2 CFR 200.216 of the Uniform Requirements, with respect to any Direct Costs.

2. PPC–FA Awards:

a. A Recipient shall use PPC–FA funds only for the eligible activities described in Section II. (C)(5) of this NOFA and its Assistance Agreement.

b. With the exception of Depository Institution Holding Company Applicants, PPC–FA awards may not be used to support the activities of, or otherwise be passed through, transferred, or co-awarded to, third-party entities, whether Affiliates, Subsidiaries, or others, unless done pursuant to a merger or acquisition or similar transaction, and with the CDFI Fund's prior written consent.

c. PPC–FA funds shall only be paid to the Recipient.

d. The CDFI Fund, in its sole discretion, may pay PPC–FA funds in amounts, or under terms and conditions, which are different from those requested by an Applicant.

e. The Recipient must comply, as applicable, with the Buy American Act of 1933, 41 U.S.C. 8301–8303 and 2 CFR 200.216 of the Uniform Requirements, with respect to any Direct Costs.

3. DF–FA Awards:

a. A Recipient shall use DF–FA funds only for the eligible activities described in Section II. (C)(2) of this NOFA and its Assistance Agreement.

b. With the exception of Depository Institution Holding Company Applicants, DF–FA awards may not be used to support the activities of, or otherwise be passed through, transferred, or co-awarded to, third-party entities, whether Affiliates, Subsidiaries, or others, unless done pursuant to a merger or acquisition or similar transaction, and with the CDFI Fund's prior written consent.

c. DF–FA funds shall only be paid to the Recipient.

d. The CDFI Fund, in its sole discretion, may pay DF–FA funds in amounts, or under terms and conditions, which are different from those requested by an Applicant.

e. The Recipient must comply, as applicable, with the Buy American Act of 1933, 41 U.S.C. 8301–8303 and 2 CFR 200.216 of the Uniform Requirements, with respect to any Direct Costs.

2. HFFI–FA Awards:

a. A Recipient shall use HFFI–FA funds only for the eligible activities described in Section II. (C)(4) of this NOFA and its Assistance Agreement.

b. With the exception of Depository Institution Holding Company Applicants, HFFI–FA awards may not be used to support the activities of, or otherwise be passed through, transferred, or co-awarded to, third-party entities, whether Affiliates, Subsidiaries, or others, unless done pursuant to a merger or acquisition or similar transaction, and with the CDFI Fund's prior written consent.

c. HFFI–FA funds shall only be paid to the Recipient.

d. The CDFI Fund, in its sole discretion, may pay HFFI–FA funds in amounts, or under terms and conditions, which are different from those requested by an Applicant.

e. The Recipient must comply, as applicable, with the Buy American Act of 1933, 41 U.S.C. 8301–8303 and 2 CFR 200.216 of the Uniform Requirements, with respect to any Direct Costs.

3. TA Grants:

a. A Recipient shall use TA funds only for the eligible activities described in Section II. (C) (3) of this NOFA and its Assistance Agreement.

b. A Sponsoring Entity Recipient must create the Emerging CDFI as a legal entity no later than the end of the first year of the Period of Performance. Upon creation of the Emerging CDFI, the Sponsoring Entity must request the CDFI Fund to amend the Assistance Agreement to add the Emerging CDFI as a co-Recipient. The Sponsoring Entity must add the Emerging CDFI as a co-Recipient within 90 days the end of the first year of the Period of Performance. The Sponsoring Entity must then transfer any remaining balances and/or assets derived from the TA award to the Emerging CDFI.

c. With the exception of Depository Institution Holding Company Applicants, TA awards may not be used to support the activities of, or otherwise be passed through, transferred, or co-awarded to, third-party entities, whether Affiliates, Subsidiaries, or others, unless done pursuant to a merger or acquisition or similar transaction, and with the CDFI Fund's prior written consent.

d. TA funds shall only be paid to the Recipient.

e. The CDFI Fund, in its sole discretion, may pay TA funds in amounts, or under terms and conditions, which are different from those requested by an Applicant.

f. The Recipient must comply, as applicable, with the Buy American Act of 1933, 41 U.S.C. 8301–8303 and 2 CFR 200.216 of the Uniform Requirements, with respect to any Direct Costs.

V. Application Review Information

A. Criteria: If the Applicant has submitted an eligible Application, the CDFI Fund will conduct a substantive review in accordance with the criteria and procedures described in the Regulations, this NOFA, the Application guidance, and the Uniform Requirements. The CDFI Fund reserves the right to contact the Applicant by telephone, email, or mail for the purpose of clarifying or confirming Application information. If contacted, the Applicant must respond within the time period communicated by the CDFI Fund or risk that its Application will be rejected. The CDFI Fund will review the Base-FA, DF–FA, PPC–FA, HFFI–FA, and TA Applications in accordance with the process below. All internal and external reviewers will complete the CDFI Fund's conflict of interest process. The CDFI Fund's Application conflict of interest policy is located on the CDFI Fund's website.

1. Base-FA Application Scoring, Award Selection, Review, and Selection Process: The CDFI Fund will evaluate each Application using a five-step review process illustrated in the sections below. Applicants that meet the minimum criteria will advance to the next step in the review process. Applicants applying as a Community Partnership must describe the partnership in the Application pursuant to the requirements set forth in Table 8, and will be evaluated in accordance with the review process described below.

a. *Step 1: Eligibility Review:* The CDFI Fund will evaluate each Application to determine its eligibility status pursuant to Section III of this NOFA.

b. *Step 2:* Financial Analysis and Compliance Risk Evaluation:

i. *Step 2: Financial Analysis:* For Regulated Institutions, the CDFI Fund will consider financial safety and soundness information from the Appropriate Federal or State Banking Agency. As detailed in Table 8, each Regulated Institution FA Applicant must have a CAMELS/CAMEL rating of at least ''3'' and/or no significant materials concerns from its regulator. For non-regulated Applicants, the CDFI Fund will evaluate the financial health and viability of each non-regulated Applicant using financial information provided by the Applicant. For the Financial Analysis, each non-regulated Applicant will receive a Total Financial Composite Score on a scale of one (1) to five (5), with one (1) being the highest rating. The Total Financial Composite Score is based on the analysis of twenty-three (23) financial indicators. Applications will be grouped based on the Total Financial Composite Score. Applicants must receive a Total Financial Composite Score of one (1), two (2), or three (3) to advance to Step 3. Applicants that receive an initial Total Financial Composite Score of four (4) or five (5) will be re-evaluated and re-scored by CDFI Fund staff. If the Total Financial Composite Score remains four (4) or five (5) after CDFI Fund staff review, the Applicant will not advance to Step 3.

ii. *Step 2: Compliance Risk Evaluation:* For the compliance analysis, the CDFI Fund will evaluate the compliance risk of each Applicant using information provided in the Application as well as an Applicant's reporting history, reporting capacity, and performance risk with respect to the CDFI Fund's PG&Ms. Each Applicant will receive a Total Compliance Composite Score on a scale of one (1) to five (5), with one (1) being the highest rating. Applicants that receive an initial Total Compliance Composite Score of four (4) or five (5) will be re-evaluated by CDFI Fund staff. If the Applicant is deemed a high compliance risk after CDFI Fund staff review, the Applicant will not advance to Step 3.

c. *Step 3: Business Plan Review:* Applicants that proceed to Step 3 will be evaluated on the soundness of their comprehensive business plan. Two external non-CDFI Fund Reviewers will conduct the Step 3 evaluation. Reviewers will evaluate the Application sections listed in Table 13. All Applications will be reviewed in accordance with standard reviewer evaluation materials. Applications will be ranked based on Total Business Plan Scores, in descending order. In order to advance to Step 4, Applicants must receive a Total Business Plan Score that is either (1) equal to receiving a point score equivalent to a ''Good'' out of a ranking scale in descending order of Excellent, Good, Fair, Limited or Poor, in each section listed in Table 13, or (2) within the top 70% of the NACA FA Applicant pool, whichever is greater. In the case of tied Total Business Plan Scores that would prevent an Applicant from moving to Step 4, all Applicants with the same score will progress to Step 4. Lastly, the CDFI Fund may consider the geographic diversity of Applicants when determining the Step 4 Applicant pool.

TABLE 13—STEP 3: BASE-FA BUSINESS PLAN REVIEW SCORING CRITERIA

Base-FA application sections	Possible score	Score needed to advance
Executive Summary	Not Scored	N/A.
Business Strategy	12	N/A.
Market and Competitive Analysis	7	N/A.
Products and Services	12	N/A.
Management and Track Record	12	N/A.
Growth and Projections	7	N/A.
Total Business Plan Score	50	NACA Applicants: Top 70% of all NACA Applicant Step 3 Scores.

d. *Step 4: Policy Objective Review:* The CDFI Fund internal reviewers will evaluate each Application to determine its ability to meet policy objectives of the CDFI Fund. Each Applicant will be evaluated in each of the categories listed in Table 14 below, and will receive a Total Policy Objective Review Composite Score on a scale of one (1) to five (5), with one (1) being the highest score. Applicants are then grouped according to Total Policy Objective Review Scores.

The CDFI Fund also conducts a due diligence review for Applications that includes an analysis of programmatic risk factors including, but not limited to: history of performance in managing Federal awards (including timeliness of reporting and compliance); ability to meet FA Objective(s) selected by Base-FA Applicants in their Applications; reports and findings from audits; and the Applicant's ability to effectively implement Federal requirements, each of which could impact the Total Policy Objective Review Score.

TABLE 14—STEP 4: BASE-FA POLICY REVIEW SCORING CRITERIA

Section	Possible scores	High score	Score needed o advance
Economic Distress	1, 2, 3, 4, or 5	1	N/A.
Economic Opportunities	1, 2, 3, 4, or 5	1	N/A.
Community Collaboration	1, 2, 3, 4, or 5	1	N/A.
Total Policy Objective Review Composite Score	1, 2, 3, 4, or 5	1	All Scores Advance.

e. *Step 5: Award Amount Determination:* The CDFI Fund determines an award amount for each Application based on the Step 4 Total Policy Objective Review Score, the Applicant's request amount, and on certain other factors, including but not limited to, an Applicant's deployment track record, minimum award size, and funding availability. Award amounts may be reduced from the requested award amount as a result of this analysis. For NACA FA Applicants, the award cannot exceed 100% of the Applicant's total portfolio outstanding as of the Applicant's most recent historic fiscal year end. [9]

2. Healthy Food Financing Initiative-FA (HFFI–FA) Application Scoring, Award Selection, Review, and Selection Process: A CDFI Fund internal reviewer will evaluate each HFFI–FA Application associated with a Base-FA Application that progresses to Step 4 of the FA Application review process. The reviewer will evaluate the Application sections listed in Table 15 and assign a Total HFFI- FA Score up to 60 points. The CDFI Fund will make awards to the highest scoring Applicants first. All Applications will be reviewed in accordance with standard reviewer evaluation materials. Applicants that fail to receive a Base-FA award will not be considered for a HFFI–FA award.

The CDFI Fund conducts additional levels of due diligence for Applications that are under consideration for an HFFI–FA award. Award amounts may be reduced from the requested award amount as a result of this analysis. The CDFI Fund may reduce awards sizes from requested amounts based on certain variables, including but not limited to, an Applicant's loan disbursement activity, total portfolio outstanding, or compliance with prior HFFI–FA awards. Lastly, the CDFI Fund may consider the geographic diversity of Applicants when making its funding decisions.

TABLE 15—STEP 4 HFFI–FA APPLICATION SCORING CRITERIA

Sections	Possible score (points)
Target Market Profile	10
Healthy Food Financial Products	10
Projected HFFI–FA Activities	15
HFFI Track Record	20
Management Capacity for Providing Healthy Food Financing	5
Total HFFI–FA Possible Score	60

3. Persistent Poverty Counties—Financial Assistance (PPC–FA) Application Scoring, Award Selection, Review, and Selection Process: A CDFI Fund internal reviewer will evaluate the PPC–FA request of each associated Base-FA Application that progresses to Step 4 of the FA Application review process. PPC–FA requests are not scored. PPC–FA award amounts will be determined based on the total number of eligible Applicants and funding availability, the Applicant's requested amount, and on certain factors, including but not limited to, an Applicant's overall portfolio size, historical track record of deployment in PPC, pipeline of projects in PPC, minimum award size, and funding availability. Applicants that fail to receive a Base-FA award will not be considered for a PPC–FA award.

4. Disability Funds-Financial Assistance (DF–FA) Application Scoring, Award Selection, Review, and Selection Process: A CDFI Fund internal reviewer will evaluate each DF–FA Application associated with a Base-FA Application that progresses to Step 4 of the FA Application review process. The reviewer will evaluate the Application and assign a Total DF- FA Score on a scale of one (1) to three (3), with one (1) being the highest score. Applicants are then grouped according to Total DF- FA Score. All Applications will be reviewed in accordance with standard reviewer evaluation materials. Applicants that fail to receive a Base-FA award will not be considered for a DF–FA award. Award amounts will be determined on the basis of the Total DF–FA Score, the Applicant's requested amount, and on certain factors, including but not limited to, an Applicant's deployment track record, minimum award size, and funding availability. Award amounts may be reduced from the requested award amount as a result of this analysis. The

[9] For the purposes of this NOFA, an Applicant's most recent historic fiscal year end is determined as follows.

(A) Applicants with a 3/31 fiscal year end date will treat FY 2020 as their most recent historic fiscal year and FY 2021 as their current year.

(B) Applicants with a 6/30 fiscal year end date will treat FY 2020 as their most recent historic fiscal year and FY 2021 as their current year.

(C) Applicants with a 9/30 fiscal year end date and a completed FY 2020 audit will treat FY 2020 as their most recent historic fiscal year and FY 2021 as their current year.

(D) Applicants with a 9/30 fiscal year end date but without a completed FY 2020 audit will treat FY 2019 as their most recent historic fiscal year and FY 2020 as their current year.

(E) Applicants with a 12/31 fiscal year end date, with or without a completed FY 2020 audit, will treat FY 2019 as their most recent historic fiscal year and FY 2020 as their current year.

CDFI Fund will make awards to the highest scoring Applicants first.

TABLE 16—STEP 3 DF–FA APPLICATION SCORING CRITERIA

Section	Possible scores	High score
DF–FA Narrative Questions	1, 2, or 3	1
Total DF–FA Score	1, 2, or 3	1

5. Technical Assistance (TA) Application Scoring, Award Selection, Review, and Selection Process: The CDFI Fund will evaluate each Application to determine its eligibility pursuant to Section III of this NOFA. If the Application satisfies the eligibility criteria, the CDFI Fund will evaluate the TA Application. Sponsoring Entity or Emerging CDFI Applicants must receive a rating of Low Risk or Medium Risk in Section I of the TA Business Plan Review to progress to Section II of the TA Business Plan Review. Sponsoring Entity, or Emerging CDFI Applicants that receive a rating of High Risk in Section I of the TA Business Plan Review will not be considered for an award. Section I of the TA Business Plan Review is not applicable for Certified CDFI Applicants. Sponsoring Entity, Emerging CDFI, and Certified CDFI Applicants must receive a rating of Low Risk or Medium Risk in Section II of the TA Business Plan Review to be considered for an award. Applicants that receive a rating of High Risk in Section II of the TA Business Plan Review will not be considered for an award.

An Applicant that is a Certified CDFI will be evaluated on the demonstrated need for TA funding to build the CDFI's capacity, further the Applicant's strategic goals, and achieve impact within the Applicant's Target Market. An Applicant that is an Emerging CDFI will be evaluated on the Applicant's demonstrated capability and plan to achieve CDFI certification within three years, or if a prior Recipient, the certification PG&M stated in its prior Assistance Agreement. An Applicant that is an Emerging CDFI will also be evaluated on its demonstrated need for TA funding to build the CDFI's capacity and further its strategic goals. An Applicant that is a Sponsoring Entity will be rated on its demonstrated capability to create a separate legal entity within one year that will achieve CDFI certification within four years. An Applicant that is a Sponsoring Entity will also be rated on its demonstrated need for TA funding to build the CDFI's capacity and further its strategic goals.

The CDFI Fund will rate each part of the TA Business Plan Review as indicated in Table 17.

TABLE 17—TA BUSINESS PLAN REVIEW

Business plan review component	Applicant type	Ratings
Section I:		
Primary Mission	Sponsoring Entity and Emerging CDFI Applicants	
Financing Entity	Sponsoring Entity and Emerging CDFI Applicants	
Target Market	Sponsoring Entity and Emerging CDFI Applicants	Low Risk, Medium Risk, or High Risk.
Accountability	Sponsoring Entity and Emerging CDFI Applicants	
Development Services	Sponsoring Entity and Emerging CDFI Applicants	
Section II:		
Target Market Needs & Strategy.	Sponsoring Entity, Emerging CDFI, and Certified Applicants	Low Risk, Medium Risk, or High Risk.
Organizational Capacity	Sponsoring Entity, Emerging CDFI, and Certified Applicants.	
Management Capacity	Sponsoring Entity, Emerging CDFI, and Certified Applicants.	

Each TA Application will be evaluated by one internal CDFI Fund reviewer. All Applications will be reviewed in accordance with CDFI Fund standard reviewer evaluation materials for the Business Plan Review.

The CDFI Fund conducts additional levels of due diligence for Applications that are under consideration for an award. This due diligence includes an analysis of programmatic and financial risk factors including, but not limited to, financial stability, history of performance in managing Federal awards (including timeliness of reporting and compliance), reports and findings from audits, and the Applicant's ability to effectively implement Federal requirements. The CDFI Fund will also evaluate the compliance risk of each Applicant using information provided in the Application as well as an Applicant's reporting history, reporting capacity, and performance risk with respect to the CDFI Fund's PG&Ms. Each Applicant will receive a Total Compliance Composite Score on a scale of one (1) to five (5), with one (1) being the highest rating. Applicants that receive an initial Total Compliance Composite Score of four (4) or five (5) will be re-evaluated by CDFI Fund staff. If the Applicant is deemed a high compliance risk after CDFI staff review, the Applicant will not be considered for an award. The CDFI Fund will also evaluate the Applicant's ability to meet certification criteria of being a legal entity and a non-government entity. Award amounts may be reduced as a result of the due diligence analysis in addition to consideration of the Applicant's funding request and similar factors. Lastly, the CDFI Fund may consider the geographic diversity of Applicants when making its funding decisions.

6. Regulated Institutions: The CDFI Fund will consider safety and soundness information from the Appropriate Federal or State Banking Agency. If the Applicant is a CDFI Depository Institution Holding Company, the CDFI Fund will consider

information provided by the Appropriate Federal or State Banking Agencies about both the CDFI Depository Institution Holding Company and the Certified CDFI Subsidiary Insured Depository Institution that will expend and carry out the award. If the Appropriate Federal or State Banking Agency identifies safety and soundness concerns, the CDFI Fund will assess whether such concerns cause or will cause the Applicant to be incapable of undertaking the activities for which funding has been requested.

7. Non-Regulated Institutions:

The CDFI Fund must ensure, to the maximum extent practicable, that Recipients which are non-regulated CDFIs are financially and managerially sound, and maintain appropriate internal controls (12 U.S.C. 4707(f)(1)(A) and 12 CFR 1805.800(b)). Further, the CDFI Fund must determine that an Applicant's capacity to operate as a CDFI and its continued viability will not be dependent upon assistance from the CDFI Fund (12 U.S.C. 4704(b)(2)(A)). If it is determined that the Applicant is incapable of meeting these requirements, the CDFI Fund reserves the right to deem the Applicant ineligible or terminate the award.

B. Anticipated Award Announcement: The CDFI Fund anticipates making NACA Program award announcement before September 30, 2021. However, the anticipated award Announcement Date is subject to change without notice.

C. Application Rejection: The CDFI Fund reserves the right to reject an Application if information (including administrative errors) comes to the CDFI Fund's attention that: Adversely affects an Applicant's eligibility for an award; Adversely affects the Recipient's certification as a CDFI (to the extent that the award is conditional upon CDFI certification); adversely affects the CDFI Fund's evaluation or scoring of an Application; or indicates fraud or mismanagement on the Applicant's part. If the CDFI Fund determines any portion of the Application is incorrect in a material respect, the CDFI Fund reserves the right, in its sole discretion, to reject the Application. The CDFI Fund reserves the right to change its eligibility and evaluation criteria and procedures, if the CDFI Fund deems it appropriate. If the changes materially affect the CDFI Fund's award decisions, the CDFI Fund will provide information about the changes through its website. The CDFI Fund's award decisions are final, and there is no right to appeal decisions.

D. External Non-CDFI Fund Reviewers: All external non-CDFI Fund reviewers are selected based on criteria that includes a professional background in community and economic development finance, and experience reviewing the financial statements of all CDFI institution types. Reviewers must complete the CDFI Fund's conflict of interest process and be approved by the CDFI Fund. The CDFI Fund's Application reader conflict of interest policy is located on the CDFI Fund's website.

VI. Federal Award Administration Information

A. Award Notification: Each successful Applicant will receive an email ''notice of award'' notification from the CDFI Fund stating that its Application has been approved for an award. Each Applicant not selected for an award will receive an email stating that a debriefing notice has been provided in its AMIS account.

B. Assistance Agreement: Each Applicant selected to receive an award must enter into an Assistance Agreement with the CDFI Fund in order to receive a payment(s). The Assistance Agreement will set forth the award's terms and conditions, including but not be limited to the: (i) Award amount; (ii) award type; (iii) award uses; (iv) eligible use of funds; (v) PG&Ms; and (vi) reporting requirements. FA Assistance Agreements have three-year Periods of Performance. TA Assistance Agreements have two-year Periods of Performance for Certified CDFIs, three-year Periods of Performance for Emerging CDFIs, and four-year Periods of Performance for Sponsoring Entity Recipients. Upon creation of the Emerging CDFI, the Sponsoring Entity must request the CDFI Fund to amend the Assistance Agreement and add the Emerging CDFI as a party thereto. The Emerging CDFI, as co-Recipient, will be subject to all of the terms and conditions of the Assistance Agreement, including all PG&Ms.

1. Certificate of Good Standing: All FA and TA Recipients that are not Regulated Institutions will be required to provide the CDFI Fund with a certificate of good standing from the secretary of state for the Recipient's jurisdiction of formation prior to closing. This certificate can often be acquired online on the secretary of state website for the Recipient's jurisdiction of formation and must generally be dated within 180 days prior to the date the Recipient executes the Assistance Agreement. Due to potential backlogs in state government offices, Applicants are advised to submit requests for certificates of good standing no later than 60 days after they submit their Applications.

2. Closing: Pursuant to the Assistance Agreement, there will be an initial closing at which point the Assistance Agreement and related documents will be properly executed and delivered, and an initial payment of FA or TA may be made. The first payment is the estimated amount of the award that the Recipient states in its Application that it will use for eligible FA or TA activities in the first 12 months after the award announcement. The CDFI Fund reserves the right to increase the first payment amount on any award to ensure that any subsequent payments are at least $25,000 for FA and $5,000 for TA awards.

The CDFI Fund will minimize the time between the Recipient incurring costs for eligible activities and award payment(s) in accordance with the Uniform Requirements. Advanced payments for eligible activities will occur no more than one year in advance of the Recipient incurring costs for the eligible activities. Following the initial closing, there may be subsequent closings involving additional award payments. Any documentation in addition to the Assistance Agreement that is connected with such subsequent closings and payments shall be properly executed and timely delivered by the Recipient to the CDFI Fund.

3. Requirements Prior to Entering into an Assistance Agreement: If, prior to entering into an Assistance Agreement, information (including administrative errors) comes to the CDFI Fund's attention that: Adversely affects the Recipient's eligibility for an award; adversely affects the Recipient's certification as a CDFI (to the extent that the award is conditional upon CDFI certification); adversely affects the CDFI Fund's evaluation of the Application; indicates that the Recipient is not in compliance with any requirement listed in the Uniform Requirements; indicates that the Recipient is not in compliance with a term or condition of a prior CDFI Fund award; indicates the Recipient has failed to execute and return a prior round Assistance Agreement to the CDFI Fund within the CDFI Fund's deadlines; or indicates fraud or mismanagement on the Recipient's part, the CDFI Fund may, in its discretion and without advance notice to the Recipient, terminate the award or take such other actions as it deems appropriate. The CDFI Fund reserves the right, in its sole discretion, to rescind an award if the Recipient fails to return the Assistance Agreement, signed by the Authorized Representative of the Recipient, and/or provide the

CDFI Fund with any requested documentation, within the CDFI Fund's deadlines.

In addition, the CDFI Fund reserves the right, in its sole discretion, to terminate and rescind the Assistance Agreement and the award made under this NOFA pending the criteria described in the following table:

TABLE 18—REQUIREMENTS PRIOR TO EXECUTING AN ASSISTANCE AGREEMENT

Requirement	Criteria
Failure to meet reporting requirements.	• If a Recipient received a prior award under any CDFI Fund program and is not in compliance with the reporting requirements of the previously executed agreement(s), the CDFI Fund may delay entering into an Assistance Agreement or disbursing an award until such reporting requirements are met. If the Recipient is unable to meet the requirement(s) within the timeframe specified by the CDFI Fund, the CDFI Fund may terminate and rescind the Assistance Agreement and the award made under this NOFA. • The automated systems the CDFI Fund uses only acknowledge a report's receipt and are not a determination of meeting reporting requirements.
Failure to maintain CDFI certification.	• An FA Recipient must be a Certified CDFI. • If an FA Recipient fails to maintain CDFI certification, the CDFI Fund will terminate and rescind the Assistance Agreement and the award made under this NOFA. • If a TA Recipient is a Certified CDFI at the time of award announcement, it must maintain CDFI certification. • If a Certified CDFI TA Recipient fails to maintain CDFI certification, the CDFI Fund may terminate and rescind the Assistance Agreement and the award made under this NOFA.
Pending resolution of noncompliance.	• The CDFI Fund will delay entering into an Assistance Agreement with a Recipient that has pending noncompliance issues with any of its previously executed CDFI award agreement(s), if the CDFI Fund has not yet made a final compliance determination. • If the Recipient is unable to satisfactorily resolve the compliance issues, the CDFI Fund may terminate and rescind the Assistance Agreement and the award made under this NOFA.
Noncompliance or default status.	• If, at any time prior to entering into an Assistance Agreement, the CDFI Fund determines that a Recipient is noncompliant or found in default with any previously executed award agreement(s), and the CDFI Fund has provided written notification that the Recipient is ineligible to apply for or receive any future awards or allocations for a time period specified by the CDFI Fund in writing, the CDFI Fund may delay entering into an Assistance Agreement until the Recipient has cured the noncompliance by taking actions the CDFI Fund has specified within such specified timeframe. If the Recipient is unable to cure the noncompliance within the specified timeframe, the CDFI Fund may terminate and rescind the Assistance Agreement and the award made under this NOFA.
Compliance with Federal civil rights requirements.	• If prior to entering into an Assistance Agreement under this NOFA, the Recipient receives a final determination, made within the last three years, in any proceeding instituted against the Recipient in, by, or before any court, governmental, or administrative body or agency, declaring that the Recipient has violated the following laws: Title VI of the Civil Rights Act of 1964, as amended (42 U.S.C. 2000d); Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794); the Age Discrimination Act of 1975, (42 U.S.C. 6101–6107), and Executive Order 13166, Improving Access to Services for Persons with Limited English Proficiency, the CDFI Fund will terminate and rescind the Assistance Agreement and the award made under this NOFA.
Do Not Pay	• The Do Not Pay Business Center was developed to support Federal agencies in their efforts to reduce the number of improper payments made through programs funded by the Federal government. • The CDFI Fund reserves the right, in its sole discretion, to rescind an award if the Recipient (or Affiliate of a Recipient) determined to be ineligible based on data in the Do Not Pay database.
Safety and soundness	• If it is determined the Recipient is, or will be, incapable of meeting its award obligations, the CDFI Fund will deem the Recipient to be ineligible, or require it to improve its safety and soundness prior to entering into an Assistance Agreement.

C. Reporting:

1. Reporting requirements: On an annual basis during the Period of Performance, the CDFI Fund may collect information from each Recipient including, but not limited to, an Annual Report with the following components (Annual Reporting Requirements):

TABLE 19—ANNUAL REPORTING REQUIREMENTS *

Financial Statement Audit Report (Non-profit Recipient including Insured Credit Unions and State-Insured Credit Unions).	A Non-profit Recipient (including Insured Credit Unions and State-Insured Credit Unions) must submit a Financial Statement Audit (FSA) Report in AMIS, along with the Recipient's statement of financial condition audited or reviewed by an independent certified public accountant, if any are prepared. Under no circumstances should this be construed as the CDFI Fund requiring the Recipient to conduct or arrange for additional audits not otherwise required under Uniform Requirements or otherwise prepared at the request of the Recipient or parties other than the CDFI Fund.
Financial Statement Audit Report (For-Profit Recipient).	For-profit Recipients must submit an FSA Report in AMIS, along with the Recipient's statement of financial condition audited or reviewed by an independent certified public accountant.
Financial Statement Audit Report (Depository Institution Holding Company and Insured Depository Institution).	If the Recipient is a Depository Institution Holding Company or an Insured Depository Institution, it must submit a FSA Report in AMIS.

TABLE 19—ANNUAL REPORTING REQUIREMENTS *—Continued

Financial Statement Audit Report (Sponsoring Entities).	A Sponsoring Entity must submit a FSA Report in AMIS, along with a statement of financial condition audited or reviewed by an independent certified public accountant, if any are prepared. Under no circumstances should this be construed as the CDFI Fund requiring the Sponsoring Entity to conduct or arrange for additional audits not otherwise required under Uniform Requirements or otherwise prepared at the request of the Sponsoring Entity or parties other than the CDFI Fund.
Single Audit Report (Non-Profit Recipients, if applicable).	A non-profit Recipient must complete an annual Single Audit pursuant to the Uniform Requirements (see 2 CFR Subpart F-Audit Requirements) if it expends $750,000 or more in Federal awards in its fiscal year, or such other dollar threshold established by OMB pursuant to 2 CFR 200.501. If a Single Audit is required, it must be submitted electronically to the Federal Audit Clearinghouse (FAC) (see 2 CFR Subpart F-Audit Requirements in the Uniform Requirements) and optionally through AMIS.
Transaction Level Report (TLR)	The Recipient must submit a TLR to the CDFI Fund through AMIS. If the Recipient is a Depository Institution Holding Company that deploys all or a portion of its Financial Assistance through its Subsidiary CDFI Insured Depository Institution, that Subsidiary CDFI Insured Depository Institution must also submit a TLR. Furthermore, if the Depository Institution Holding Company itself deploys any portion of the Financial Assistance, the Depository Institution Holding Company must submit a TLR. The TLR is not required for TA Recipients.
Uses of Award Report	The Recipient must submit the Uses of Award Report to the CDFI Fund in AMIS. If the Recipient is a Depository Institution Holding Company that deploys all or a portion of its Financial Assistance through its Subsidiary CDFI Insured Depository Institution, that Subsidiary CDFI Insured Depository Institution must also submit a Uses of Award Report. Furthermore, if the Depository Institution Holding Company itself deploys any portion of the Financial Assistance, the Depository Institution Holding Company must submit a Uses of Award Report.
Performance Progress Report	The Recipient must submit the Performance Progress Report through AMIS. If the Recipient is a Depository Institution Holding Company that deploys all or a portion of its Financial Assistance through its Subsidiary CDFI Insured Depository Institution, that Subsidiary CDFI Insured Depository Institution must also submit a Performance Progress Report. Furthermore, if the Depository Institution Holding Company itself deploys any portion of the Financial Assistance, the Depository Institution Holding Company must submit a Performance Progress Report.

* Personally Identifiable Information (PII) is information, which if lost, compromised, or disclosed without authorization, could result in substantial harm, embarrassment, inconvenience, or unfairness to an individual. Although Applicants are required to enter addresses of individual borrowers/residents of Distressed Communities in AMIS, Applicants should *not* include the following PII for the individuals who received the Financial Products or Financial Services in AMIS or in the supporting documentation (*i.e.,* name of the individual, Social Security Number, driver's license or state identification number, passport number, Alien Registration Number, etc.). *This information should be redacted from all supporting documentation.*

Each Recipient is responsible for the timely and complete submission of the Annual Reporting Requirements. Sponsoring Entities with co-Recipients will be informed of any changes to reporting obligations at the time the Emerging CDFI is joined to the Assistance Agreement. The CDFI Fund reserves the right to contact the Recipient and additional entities or signatories to the Assistance Agreement to request additional information and/or documentation. The CDFI Fund will use such information to monitor each Recipient's compliance with the requirements of the Assistance Agreement and to assess the impact of the NACA Program. The CDFI Fund reserves the right, in its sole discretion, to modify these reporting requirements, including increasing the scope and frequency of reporting, if it determines it to be appropriate and necessary; however, such reporting requirements will be modified only after notice to Recipients.

2. Financial Management and Accounting: The CDFI Fund will require Recipients to maintain financial management and accounting systems that comply with Federal statutes, regulations, and the terms and conditions of the Federal award. These systems must be sufficient to permit the preparation of reports required by the CDFI Fund to ensure compliance with the terms and conditions of the NACA Program, including the tracing of funds to a level of expenditures adequate to establish that such funds have been used in accordance with Federal statutes, regulations, and the terms and conditions of the Federal award.

The cost principles used by Recipients must be consistent with Federal cost principles and support the accumulation of costs as required by the principles, and must provide for adequate documentation to support costs charged to the NACA Program award. In addition, the CDFI Fund will require Recipients to: Maintain effective internal controls; comply with applicable statutes, regulations, and the Assistance Agreement; evaluate and monitor compliance; take appropriate action when not in compliance; and safeguard personally identifiable information.

VII. Agency Contacts

A. The CDFI Fund will respond to questions concerning this NOFA and the Application between the hours of 9:00 a.m. and 5:00 p.m. Eastern Time, starting on the date that the NOFA is published through the date listed in Table 1 and Table 12. The CDFI Fund strongly recommends Applicants submit questions to the CDFI Fund via an AMIS Service Request to the NACA Program, Office of Certification, Compliance Monitoring and Evaluation, or IT Help Desk. The CDFI Fund will post on its website responses to reoccurring questions received about the NOFA and Application. Other information regarding the CDFI Fund and its programs may be obtained from the CDFI Fund's website at *http://www.cdfifund.gov.* Table 20 lists CDFI Fund contact information:

TABLE 20—CONTACT INFORMATION

Type of question	Preferred method	Telephone number (not toll free)	Email addresses
NACA Program	Service Request via AMIS	202–653–0421, option 1	*cdfihelp@cdfi.treas.gov*
CCME	Service Request via AMIS	202–653–0423	*ccme@cdfi.treas.gov*
AMIS—IT Help Desk	Service Request via AMIS	202–653–0422	*AMIS@cdfi.treas.gov*

B. Information Technology Support: For IT assistance, the preferred method of contact is to submit a Service Request within AMIS. For the Service Request, select ''Technical Issues'' from the Program dropdown menu of the Service Request. People who have visual or mobility impairments that prevent them from using the CDFI Fund's website should call (202) 653–0422 for assistance (this is not a toll free number).

C. Communication with the CDFI Fund: The CDFI Fund will use the contact information in AMIS to communicate with Applicants and Recipients. It is imperative, therefore, that Applicants, Recipients, Subsidiaries, Affiliates, and signatories maintain accurate contact information in their accounts. This includes information such as contact names (especially for the Authorized Representative), email addresses, fax and phone numbers, and office locations.

D. Civil Rights and Diversity: Any person who is eligible to receive benefits or services from the CDFI Fund or Recipients under any of its programs is entitled to those benefits or services without being subject to prohibited discrimination. The Department of the Treasury's Office of Civil Rights and Diversity enforces various Federal statutes and regulations that prohibit discrimination in financially assisted and conducted programs and activities of the CDFI Fund. If a person believes that s/he has been subjected to discrimination and/or reprisal because of membership in a protected group, s/he may file a complaint with: Associate Chief Human Capital Officer, Office of Civil Rights, and Diversity, 1500 Pennsylvania Ave NW, Washington, DC 20220 or (202) 622–1160 (not a toll-free number).

E. Statutory and National Policy Requirements: The CDFI Fund will manage and administer the Federal award in a manner so as to ensure that Federal funding is expended and associated programs are implemented in full accordance with the U.S. Constitution, Federal Law, statutory, and public policy requirements: Including but not limited to, those protecting free speech, religious liberty, public welfare, the environment, and prohibiting discrimination.

VIII. Other Information

A. Paperwork Reduction Act: Under the Paperwork Reduction Act (44 U.S.C. chapter 35), an agency may not conduct or sponsor a collection of information, and an individual is not required to respond to a collection of information, unless it displays a valid OMB control number. If applicable, the CDFI Fund may inform Applicants that they do not need to provide certain Application information otherwise required. Pursuant to the Paperwork Reduction Act, the CDFI Program, and NACA Program Application has been assigned the following control number: 1559–0021 inclusive of PPC–FA, DF–FA, and HFFI–FA.

B. Application Information Sessions: The CDFI Fund may conduct webinars or host information sessions for organizations that are considering applying to, or are interested in learning about, the CDFI Fund's programs. For further information, visit the CDFI Fund's website at *http://www.cdfifund.gov.*

Authority: 12 U.S.C. 4701, *et seq.;* 12 CFR parts 1805 and 1815; 2 CFR part 200.

Jodie L. Harris,

Director, Community Development Financial Institutions Fund.

[FR Doc. 2021–03354 Filed 2–18–21; 8:45 am]

BILLING CODE 4810–70–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Forms 1040–PR and 1040–SS

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service (IRS), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning Planilla para la Declaración de la Contribución Federal sobre el Trabajo por Cuenta Propia (Incluyendo el Crédito Tributario Adicional por Hijos para Residentes Bona Fide de Puerto Rico) and U.S. Self-Employment Tax Return (Including the Additional Child Tax Credit for Bona Fide Residents of Puerto Rico).

DATES: Written comments should be received on or before April 20, 2021 to be assured of consideration.

ADDRESSES: Direct all written comments to Kinna Brewington, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the forms and instructions should be directed to Martha R. Brinson, at (202) 317–5753, or at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at *Martha.R.Brinson@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Planilla para la Declaración de la Contribución Federal sobre el Trabajo por Cuenta Propia (Incluyendo el Crédito Tributario Adicional por Hijos para Residentes Bona Fide de Puerto Rico).

OMB Number: 1545–0090.

Form Number: 1040–PR.

Abstract: Form 1040–PR is used by self-employed individuals to figure and report self-employment tax under IRC chapter 2 of Subtitle A, and provide credit to the taxpayer's social security account. Anejo H–PR is used to compute household employment taxes and the Form 1040–PR burden calculation includes this burden of 2,400 responses with 5,376 hours.

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals or households, Businesses and other for-profit organizations, Farms.

Estimated Number of Respondents: 154,860.

Estimated Time per Respondent: 11 hours, 34 minutes.

Estimated Total Annual Burden Hours: 1,792,208.

Title: U.S. Self-Employment Tax Return (Including the Additional Child Tax Credit for Bona Fide Residents of Puerto Rico).

OMB Number: 1545–0090.

Form Number: 1040–SS.

Abstract: Form 1040–SS is used by self-employed individuals to figure and report self-employment tax under IRC chapter 2 of Subtitle A, and provide credit to the taxpayer's social security account. Both of these forms are also used by bona-fide residents of Puerto Rico to claim the additional child tax credit.

Current Actions:

(1) Part I: A new line 11 was added, which will be used to enter the deferral of self-employment and household employment taxes as permitted by Section 2302 of the CARES Act (Pub. L. 116–136).

(2) A new Part VII was added, which will be used by filers to figure the maximum amount of self-employment tax that can be deferred. The entire amount of self-employment tax will still be reported on Part V, line 12, and carried to Part I, line 3. The deferral figured in new Part VII will be used in the worksheet in the 2020 Instructions for Form 1040–SS to figure the total amount of self-employment and household employment taxes (from Schedule H (Form 1040)) that can be deferred for 2020.

Type of Review: Revision of a currently approved collection.

Affected Public: Individuals or households, Businesses and other for-profit organizations, Farms.

Estimated Number of Respondents: 92,000.

Estimated Time per Respondent: 11 hours, 57 minutes.

Estimated Total Annual Burden Hours: 1,099,400.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. Comments will be of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: January 25, 2021.

Martha R. Brinson,

Tax Analyst.

[FR Doc. 2021–03376 Filed 2–18–21; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 5309

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service (IRS), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning Application for Determination of Employee Stock Ownership Plan.

DATES: Written comments should be received on or before April 20, 2021 to be assured of consideration.

ADDRESSES: Direct all written comments to Kinna Brewington, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Martha R. Brinson, at (202) 317–5753, or at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at *Martha.R.Brinson@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Application for Determination of Employee Stock Ownership Plan.

OMB Number: 1545–0284.

Form Number: 5309.

Abstract: Internal Revenue Code section 404(a) allows employers an income tax deduction for contributions to their qualified deferred compensation plans. Form 5309 is used to request an IRS determination letter about whether the plan is qualified under Code section 409 or 4975(e)(7).

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses or other for-profit organizations.

Estimated Number of Responses: 2,500.

Estimated Time per Response: 10 hrs., 47 mins.

Estimated Total Annual Burden Hours: 26,975.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number.

Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. Comments will be of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: January 25, 2021.

Martha R. Brinson,

Tax Analyst.

[FR Doc. 2021–03375 Filed 2–18–21; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Forms 3921 and 3922 and TD 9470

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service (IRS), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning Exercise of an Incentive Stock Option, Information Reporting Requirements Under Internal Revenue Service Code Section 6039, and Transfer of Stock Acquired Through an Employee Stock Purchase Plan.

DATES: Written comments should be received on or before April 20, 2021 to be assured of consideration.

ADDRESSES: Direct all written comments to Kinna Brewington, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the forms and instructions should be directed to Martha R. Brinson, at (202) 317–5753, or at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at *Martha.R.Brinson@irs.gov*.

SUPPLEMENTARY INFORMATION:

Title: Form 3921, Exercise of an Incentive Stock Option Under Section 422(b), Information Reporting Requirements Under Internal Revenue Service Code Section 6039, and Form 3922, Transfer of Stock Acquired Through an Employee Stock Purchase Plan Under Section 423(c).

OMB Number: 1545–2129.

Form Numbers: 3921 and 3922 and TD 9470.

Abstract: Form 3921 is a copy of the information return filed with the Internal Revenue Service by the corporation which transferred shares of stock to a recipient. Form 3922 is used by the corporation to record a transfer of the legal title of a share of stock acquired by the employee where the stock was acquired pursuant to the exercise of an option described in Internal Revenue Code section 423(c). These forms are required to be filed for stock transfers occurring after 2008. Treasury Decision 9470 contains the final regulations relating to the return and information statement requirements under Internal Revenue Code section 6039. These regulations reflect changes to section 6039 made by section 403 of the Tax Relief and Health Care Act of 2006. These regulations affect corporations that issue statutory stock options and provide guidance to assist corporations in complying with the return and information statement requirements under section 6039.

Current Actions: There is no change in the paperwork burden previously approved by OMB.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals and Households, Businesses and other for-profit organizations.

Estimated Number of Respondents: 51,000.

Estimated Time per Response: 29 mins.

Estimated Total Burden Hours: 25,205.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number.

Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. Comments will be of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: January 25, 2021.

Martha R. Brinson,

Tax Analyst.

[FR Doc. 2021–03127 Filed 2–18–21; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Multiple Alcohol and Tobacco Tax and Trade Bureau Information Collection Requests

AGENCY: Departmental Offices, U.S. Department of the Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury will submit the following information collection requests to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. The public is invited to submit comments on these requests.

DATES: Comments must be received on or before March 22, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Copies of the submissions may be obtained from Molly Stasko by emailing *PRA@treasury.gov,* calling (202) 622–8922, or viewing the entire information collection request at *www.reginfo.gov.*

SUPPLEMENTARY INFORMATION:

Alcohol and Tobacco Tax and Trade Bureau (TTB)

1. Title: Application for Amended Basic Permit Under the Federal Alcohol Administration Act.

OMB Control Number: 1513–0019.

Type of Review: Extension of a currently approved collection.

Description: The Federal Alcohol Administration Act (FAA Act), at 27 U.S.C. 203, requires that a person apply for and receive a permit, known as a ''basic permit,'' to: (1) Import distilled spirits, wine, or malt beverages into the United States; (2) distill spirits or produce wine, rectify or blend distilled spirits or wine, or bottle and/or warehouse distilled spirits; or (3) purchase distilled spirits, wine, or malt

beverages for resale at wholesale. The FAA Act, at 27 U.S.C. 204, also imposes certain requirements for basic permits and authorizes the Secretary of the Treasury (the Secretary) to prescribe the manner and form of all applications for basic permits. The TTB regulations in 27 CFR part 1 provide for the amendment of a basic permit using form TTB F 5100.18 when changes occur to the name, trade name, address, ownership, management, or control of the business. The collected information assists TTB in maintaining accurate information identifying the business and its location; and determining whether an applicant for an amended basic permit meets the statutory criteria for holding such a permit under the FAA Act.

Form: TTB F 5100.18.

Affected Public: Business or other for-profits.

Estimated Number of Respondents: 8,550.

Frequency of Response: Once.

Estimated Total Number of Annual Responses: 8,550.

Estimated Time per Response: 23 minutes.

Estimated Total Annual Burden Hours: 3,278 hours.

2. Title: Application for an Industrial Alcohol User Permit.

OMB Control Number: 1513–0028.

Type of Review: Extension of a currently approved collection.

Description: The Internal Revenue Code (IRC) at 26 U.S.C. 5271 authorizes the Secretary to prescribe regulations requiring persons using tax-free alcohol for certain non-beverage purposes (hospitals, laboratories, research centers, etc.) and persons using or dealing in specially denatured spirits (alcohol and/or rum) to apply for and receive a permit to do so prior to commencing business. Under that authority, the TTB regulations specify the use of TTB F 5150.22 as the application form for permits to deal in or use specially denatured spirits (alcohol/rum) (see 27 CFR 20.41), or to use tax-free alcohol for non-beverage purposes (see 27 CFR 22.41). TTB uses the collected information to identify the applicant and the location of their business or entity, and to determine if the applicant is eligible to deal in or use specially denatured or use tax-free alcohol, and if the proposed operations conform to Federal laws and regulations.

Form: TTB F 5150.22.

Affected Public: Business or other for-profits.

Estimated Number of Respondents: 2,710.

Frequency of Response: Once.

Estimated Total Number of Annual Responses: 2,710.

Estimated Time per Response: 0.7 hour.

Estimated Total Annual Burden Hours: 2,168 hours.

3. Title: Report—Manufacturer of Tobacco Products or Cigarette Papers and Tubes; Report—Manufacturer of Processed Tobacco.

OMB Control Number: 1513–0033.

Type of Review: Extension of a currently approved collection.

Description: The IRC at 26 U.S.C. 5722 requires manufacturers of tobacco products, cigarette papers and tubes, or processed tobacco to make reports containing such information, in such form, at such times, and for such periods as the Secretary prescribes by regulation. The TTB regulations at 27 CFR 40.202, 40.422, and 40.522 prescribe the use of TTB F 5210.5 to report information about tobacco products and cigarette papers and tubes manufactured, received, and removed per month, and the use of TTB F 5250.1 to report information about processed tobacco manufactured, received, and removed per month. TTB uses the collected information to ensure that manufacturers have properly paid Federal excise taxes and are in compliance with applicable Federal law and regulations.

Form: TTB F 5210.5 and TTB F 5250.1.

Affected Public: Business or other for-profits.

Estimated Number of Respondents: 235.

Frequency of Response: Monthly.

Estimated Total Number of Annual Responses: 2,820.

Estimated Time per Response: 1 hour.

Estimated Total Annual Burden Hours: 2,820 hours.

4. Title: Schedule of Tobacco Products, Cigarette Papers or Tubes Withdrawn From the Market.

OMB Control Number: 1513–0034.

Type of Review: Extension of a currently approved collection.

Description: The IRC at 26 U.S.C. 5705 provides that a manufacturer or importer may receive credit for or refund of the Federal excise taxes paid on tobacco products, cigarette papers, or cigarette tubes withdrawn from the market if the Secretary is provided with satisfactory proof of the withdrawal. Under that IRC authority, the TTB regulations provide for the use of TTB F 5200.7 to identify tobacco products, cigarette papers, or cigarette tubes to be withdrawn from the market and the location of those articles. The form also documents the taxpayer's planned disposition of the articles (destroyed, reduced to materials, or returned to bond), and TTB's decision to witness or not witness that disposition. Taxpayers then file the completed TTB F 5200.7 to support their subsequent claim for credit or refund of the excise taxes paid on the withdrawn articles. The collected information is necessary to protect the revenue as it allows TTB to determine if such a claim is valid.

Form: TTB F 5200.7.

Affected Public: Business or other for-profits.

Estimated Number of Respondents: 50.

Frequency of Response: 5 times per year.

Estimated Total Number of Annual Responses: 250.

Estimated Time per Response: 0.75 hour.

Estimated Total Annual Burden Hours: 188 hours.

5. Title: Tobacco Products Manufacturers—Supporting Records for Removals for the Use of the United States.

OMB Control Number: 1513–0069.

Type of Review: Extension of a currently approved collection.

Description: Under the IRC at 26 U.S.C. 5701, tobacco products and cigarette papers and tubes manufactured in or imported into the United States are subject to a Federal excise tax, and, under 26 U.S.C. 5741, all such manufacturers and importers must keep the records the Secretary prescribes by regulation. The IRC at 26 U.S.C. 5704(b) provides that manufacturers may remove such articles, without payment of tax, ''for use of the United States'' under regulations issued by the Secretary. Under those IRC authorities, the TTB regulations at 27 CFR 45.51 requires manufacturers to keep records that include information regarding the date of removal, the name and address of the receiving Federal agency, the kind and quantity of products removed, and, for large cigars, the sale price. The required records also must detail any such items that the agency returns to the manufacturer. The required records are necessary to ensure that products removed without payment of tax are delivered to a Federal agency for the authorized tax-exempt use.

Form: None.

Affected Public: Business or other for-profits.

Estimated Number of Respondents: 205.

Frequency of Response: Once.

Estimated Total Number of Annual Responses: 205.

Estimated Time per Response: 1 hour.

Estimated Total Annual Burden Hours: 205 hours.

6. Title: Manufacturers of Non-beverage Products—Records To Support Claims for Drawback (TTB REC 5530/2).

OMB Control Number: 1513–0073.

Type of Review: Extension of a currently approved collection.

Description: The IRC at 26 U.S.C.5001 imposes Federal excise tax on distilled spirits produced or imported into the United States. The IRC at 26 U.S.C. 5111–5114, allows manufacturers of certain ''non-beverage'' products that are unfit for beverage use—medicines, medicinal preparations, food products, flavors, flavoring extracts, or perfume—to claim drawback (refund) of all but $1.00 per proof gallon of the excise tax paid on the distilled spirits used in the production of such products. Under these IRC authorities, TTB has issued regulations governing non-beverage product drawback claims, contained in 27 CFR part 17, which includes a requirement to keep source records supporting such claims. The required records document the distilled spirits received, taxes paid, date used, the quantity and kind used in each product, other ingredients received and used (to validate formula compliance), amount of alcohol recovered, quantity of intermediate products transferred to other plants, and the disposition or purchaser of the products. The collected information helps prevent fraudulent claims and the diversion to beverage use of distilled spirits on which respondents claim non-beverage drawback.

TTB Recordkeeping Number: TTB REC 5530/2.

Affected Public: Business or other for-profits.

Estimated Number of Respondents: 615.

Frequency of Response: Once.

Estimated Total Number of Annual Responses: 615.

Estimated Time per Response: 1 hour.

Estimated Total Annual Burden Hours: 615 hours.

7. Title: Proprietors or Claimants Exporting Liquors (TTB REC 5900/1).

OMB Control Number: 1513–0075.

Type of Review: Extension of a currently approved collection.

Description: Under the IRC at 26 U.S.C. 5053, 5214, and 5362, distilled spirits, wine, and beer may be exported without payment of Federal excise tax. Under the IRC at 26 U.S.C. 5055 and 5062, taxpaid distilled spirits, wine, and beer may be exported and the exporter may claim drawback (refund) of the taxes paid. To prevent payment of fraudulent or incorrect drawback claims, the TTB regulations in 27 CFR part 28 require exporters to keep and make available records of pertinent Customs and TTB forms and commercial records documenting the export of taxpaid alcohol beverages for which they will claim drawback.

TTB Recordkeeping Number: TTB REC 5900/1.

Affected Public: Business or other for-profits.

Estimated Number of Respondents: 750.

Frequency of Response: Once.

Estimated Total Number of Annual Responses: 750.

Estimated Time per Response: 1 hour.

Estimated Total Annual Burden Hours: 750 hours.

8. Title: Administrative Remedies—Requests for Closing Agreements.

OMB Control Number: 1513–0099.

Type of Review: Extension of a currently approved collection.

Description: The IRC at 26 U.S.C. 7121 authorizes the Secretary to enter into a written agreement with any person, or their agent, relating to the liability of that person for any internal revenue tax for any taxable period. Under that authority, TTB has issued regulations at 27 CFR 70.485 pertaining to such ''closing agreements.'' Specific to this information collection, that regulation requires a taxpayer or their agent to submit a written request to TTB to enter into a closing agreement to resolve excise tax matters. TTB uses the information collected in the request and any attached supporting documentation to determine whether the Bureau should pursue a closing agreement with the taxpayer. Closing agreements allow TTB and a taxpayer to resolve tax liability matters prior to any adversarial legal or administrative proceedings.

Form: None.

Affected Public: Business or other for-profits.

Estimated Number of Respondents: 10.

Frequency of Response: Once.

Estimated Total Number of Annual Responses: 10.

Estimated Time per Response: 1 hour.

Estimated Total Annual Burden Hours: 10 hours.

9. Title: Marks and Notices on Packages of Tobacco Products (TTB REC 5210/13).

OMB Control Number: 1513–0101.

Type of Review: Revision of a currently approved collection.

Description: The IRC at 26 U.S.C. 5723(b) requires packages of tobacco products, processed tobacco, and cigarette paper or tubes to bear the marks, labels, and notices required by regulation. Under that authority, the TTB tobacco regulations in 27 CFR parts 40, 41, 44, and 45 require packages of domestic and imported tobacco products to bear certain marks identifying the product sufficient to determine its excise tax class, and the product's quantity or weight, depending on the basis of the tax. The regulations also require certain notices on the packages (or shipping containers) of tobacco products intended for export or use of the United States, as those products may be removed without tax payment or with benefit of tax drawback. The disclosed information identifies tobacco products, and the appearance of the notices on the packages helps to identify the products if diverted into the domestic market after withdrawal without payment of tax or with benefit of tax drawback into the domestic market.

TTB Recordkeeping Number: TTB REC 5210/3.

Affected Public: Business or other for-profits.

Estimated Number of Respondents: 724.

Frequency of Response: Once.

Estimated Total Number of Annual Responses: 724.

Estimated Time per Response: 1 hour.

Estimated Total Annual Burden Hours: 724 hours.

10. Title: Labeling of Major Food Allergens and Petitions for Exemption.

OMB Control Number: 1513–0121.

Type of Review: Extension of a currently approved collection.

Description: The FAA Act at 27 U.S.C. 205(e) authorizes the Secretary to issue regulations regarding the labeling of wine, distilled spirits, and malt beverages in order to, among other things, prohibit consumer deception and ensure that labels provide consumers with adequate information as to the identity and quality of such products. Under this authority, the TTB regulations provide for the voluntary labeling of major food allergens used in the production of alcohol beverages. (As defined in the Food Allergen Labeling and Consumer Protection Act of 2004 (118 Stat. 905)), the major food allergens are milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, and soybeans.) Under the TTB regulations, if the bottler declares any one major food allergen, then all major food allergens used in the product must be declared on the label, except when TTB has approved a petition for exemption from such labeling. This information collection includes the labeling of allergens and petitions for exemption.

Form: None.

Affected Public: Business or other for-profits.

Estimated Number of Respondents: 700.

Frequency of Response: Once.

Estimated Total Number of Annual Responses: 700.

Estimated Time per Response: 49 minutes.

Estimated Total Annual Burden Hours: 572 hours.

(Authority: 44 U.S.C. 3501 *et seq.*)

Dated: February 16, 2021.

Molly Stasko,

Treasury PRA Clearance Officer.

[FR Doc. 2021–03423 Filed 2–18–21; 8:45 am]

BILLING CODE 4810–31–P

DEPARTMENT OF THE TREASURY

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Multiple Internal Revenue Service Information Collection Requests

AGENCY: Departmental Offices, U.S. Department of the Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury will submit the following information collection requests to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. The public is invited to submit comments on these requests.

DATES: Comments must be received on or before March 22, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Copies of the submissions may be obtained from Molly Stasko by emailing *PRA@treasury.gov,* calling (202) 622–8922, or viewing the entire information collection request at *www.reginfo.gov.*

SUPPLEMENTARY INFORMATION:

Internal Revenue Service (IRS)

1. Title: Forms 945, 945–A, 945–X and TD 8672.

OMB Control Number: 1545–1430.

Type of Review: Extension of a currently approved collection.

Description: Form 945 is used to report income tax withholding on non-payroll payments including backup withholding and withholding on pensions, annuities, IRAs, military retirement, and gambling winnings. Form 945–A is used by employers who deposit non-payroll income tax withheld (such as from pensions and gambling) on a semiweekly schedule, or whose tax liability on any day is $100,000 or more, use Form 945–A with Form 945 or CT–1 to report their tax liability. Form 945–X is used to correct errors made on Form 945, Annual Return of Withheld Federal Income Tax. TD 8672 relates to the reporting of non-payroll withheld income taxes under section 6011 of the Internal Revenue Code. The regulations require a person to file Form 945, Annual Return of Withheld Federal Income Tax, only for a calendar year in which the person is required to withhold Federal income tax from nonpayroll payments.

Form: IRS Form 945, IRS Form 945–A, IRS Form 945–X, and TD 8672.

Affected Public: Individuals or Households; Businesses or other for-profit organizations; Not-for-profit institutions; and Federal, State, Local, and Tribal governments.

Estimated Number of Respondents: 59,318.

Frequency of Response: Annually.

Estimated Total Number of Annual Responses: 59,318.

Estimated Time per Response: 6 hour, 56 minutes.

Estimated Total Annual Burden Hours: 411,278 hours.

2. Title: Master and Prototype and Volume Submitter Plans, Revenue Procedure 2017–41.

OMB Control Number: 1545–1674.

Type of Review: Extension of a currently approved collection.

Description: This revenue procedure modifies Rev. Proc. 2015–36 and sets forth the procedures for the merger of the master and prototype (M&P) program with the volume submitter (VS) plan. This revenue procedure requires employers adopting pre-approved plans to complete and sign new signature pages or new adoption agreements, as applicable, to restate their plans for recent changes in the law. This revenue procedure requires sponsors of pre-approved plans to furnish copies of their plans to the Service's Employee Plans Determinations office; to maintain records of employers that have adopted their plans; to prepare and communicate any necessary interim amendments to adopting employers; to make reasonable and diligent efforts to ensure that employers restate their plans when necessary; to notify employers if the sponsor concludes that employers' plans are no longer qualified; and to provide that mass submitters must keep records of their user fees. This allows mass submitters to certify to the number of other practitioners seeking approval of the identical pre-approved plan.

Regulation Project Number: Revenue Procedure 2017– 41.

Affected Public: Individuals or Households; Businesses or other for-profit organizations; Not-for-profit institutions; and Federal, State, Local, and Tribal governments.

Estimated Number of Respondents: 321,500.

Frequency of Response: On Occasion.

Estimated Total Number of Annual Responses: 321,500.

Estimated Time per Response: 3 hours, 45 minutes.

Estimated Total Annual Burden Hours: 1,108,225 hours.

3. Title: Election Out of Generation-Skipping Transfer Tax (GST) Deemed Allocations.

OMB Control Number: 1545–1892.

Type of Review: Extension of a currently approved collection.

Description: This information is required by the IRS for taxpayers who elect to have the automatic allocation rules not apply to the current transfer and/or to future transfers to the trust or to terminate such election. This information is also required by the IRS for taxpayers who elect to treat trusts described in section 2632(c)(3)(B)(i) through (vi) as GST trusts or to terminate such election. This information will be used to identify the trusts to which the election or termination of election will apply.

Affected Public: Individuals or Households.

Estimated Number of Respondents: 25,000.

Frequency of Response: On Occasion.

Estimated Total Number of Annual Responses: 25,000.

Estimated Time per Response: 30 minutes.

Estimated Total Annual Burden Hours: 12,500 hours.

4. Title: Longevity Annuity Contracts.

OMB Control Number: 1545–2234.

Type of Review: Extension of a currently approved collection.

Description: This collection covers final regulations relating to the use of longevity annuity contracts in tax qualified defined contribution plans under section 401(a) of the Internal Revenue Code (Code), section 403(b) plans, individual retirement annuities and accounts (IRAs) under section 408, and eligible governmental plans under section 457(b).

Form 1098–Q is used to comply with the reporting requirements under TD 9673. Any person who issues a contract intended to be a QLAC that is purchased or held under any plan, annuity, or account described in section 401(a), 403(a), 403(b), 408 (other than a Roth IRA) or eligible governmental plan under section 457(b), must file Form 1098–Q.

Form Number: IRS Form 1098–Q and TD 9673.

Affected Public: Individuals or Households; Businesses or other for-profit organizations; and Not-for-profit institutions.

Estimated Number of Respondents: 150.

Frequency of Response: Annually.

Estimated Total Number of Annual Responses: 213,966.

Estimated Time per Response: 8 minutes.

Estimated Total Annual Burden Hours: 28,529 hours.

5. Title: Notice of Intent to Operate Under Section 501(c)(4), Form 8976.

OMB Control Number: 1545–2268.

Type of Review: Extension of a currently approved collection.

Description: The Protecting Americans from Tax Hikes Act of 2015 (the PATH Act) section 506 to the Internal Revenue Code (Code) requires an organization described in section 501(c)(4), no later than 60 days after the organization is established, to notify the Secretary that it is operating as a section 501(c)(4) organization (the notification). Section 506(b) provides that the notification must include: (1) The name, address, and taxpayer identification number of the organization; (2) the date on which, and the State under the laws of which, the organization was organized; and (3) a statement of the purpose of the organization.

Form Number: IRS Form 8976.

Affected Public: Businesses or other for-profit organizations.

Estimated Number of Respondents: 2,500.

Frequency of Response: Once.

Estimated Total Number of Annual Responses: 2,500.

Estimated Time per Response: 45 minutes.

Estimated Total Annual Burden Hours: 1,875 hours.

Authority: 44 U.S.C. 3501 *et seq.*

Dated: February 16, 2021.

Molly Stasko,

Treasury PRA Clearance Officer.

[FR Doc. 2021–03413 Filed 2–18–21; 8:45 am]

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Friday, February 19, 2021

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