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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 317 and 381

[Docket Number FSIS–2018–0012]

RIN 0583–AD71

Rescission of Dual Labeling Requirements for Certain Packages of Meat and Poultry

AGENCY: Food Safety and Inspection Service, Department of Agriculture (USDA).

ACTION: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending its labeling regulations to remove provisions that require packages of meat or poultry products that contain at least one pound or one pint, but less than four pounds or one gallon, to express the net weight or net contents in two different units of measurement on the product label. FSIS is taking this action in response to a petition submitted on behalf of a small meat processing establishment. After reviewing the regulatory provisions and the comments on the proposed rule to remove them, FSIS has determined that it is not necessary for labels of any meat or poultry products to bear dual statements of weight or content using more than one unit of measurement to convey the accurate weight or amount of the product to consumers.

DATES: Effective October 17, 2022.

FOR FURTHER INFORMATION CONTACT: Rosalyn Murphy-Jenkins, Director, Labeling and Program Delivery Staff (LPDS), Office of Policy and Program Development; Telephone: (301) 504–0878, Fax: (202) 245–4795.

SUPPLEMENTARY INFORMATION:

Executive Summary

On April 17, 2019, FSIS proposed (84 FR 15989) to amend its labeling regulations to remove provisions that require packages of meat or poultry products that contain at least one pound or pint, but less than four pounds or one gallon, to express the net weight or net content in two different units of measurement on the product label. Specifically, under the regulations at 9 CFR 317.2(h)(5) and 381.121(c)(5), dual declaration is required to express the net weight in ounces and immediately thereafter in parentheses in pounds, with any remainder in terms of ounces or common or decimal fraction of the pound (*e.g.,* ''Net Wt. 24 oz. (1 lb. 8 oz.), ''Net Wt. 24 oz. (1.5 lbs.)'' or ''Net Wt. 24 oz. (1½ lb.)''). For liquid measure, dual declaration is required to be expressed as the net content in fluid ounces and immediately thereafter in parentheses the largest whole U.S. customary unit (*e.g.,* pints or, quarts, with any remainder expressed in terms of fluid ounces or common or decimal fraction of the pint or quart (*e.g.,* ''Net contents 32 fl oz. (1 QT)'' or ''Net contents 30 fl oz. (1 pint 14 fl oz.)''). Packages of products that contain less than one pound or pint or that contain four pounds or one gallon or more are not subject to the ''dual declaration'' and may express the product's net weight or net content as a single, accurate statement.

FSIS published the proposed rule in response to a petition submitted on behalf of a small meat processing establishment. The petitioner contended that the dual weight labeling requirements were unnecessary and imposed disparate cost on small businesses. After reviewing the existing regulations, FSIS determined that it is not necessary for labels of any meat or poultry products to bear dual statements of weight or content, using more than one unit of measurement to convey the accurate weight or amount of the product to consumers.

This final rule adopts the requirements in its April 17, 2019 proposed rule, but for a few non-substantive changes to the proposed regulatory language. Specifically, FSIS is revising the proposed regulatory language at 9 CFR 317.2(h)(4) and 9 CFR 381.121(c)(5), and revising, instead of removing, the language at 9 CFR 317.2(h)(5), to update the net weight statement examples and to preserve specific unrelated requirements associated with the labeling of random weight packages of meat and poultry that were inadvertently proposed for deletion. Otherwise, FSIS has reviewed the comments on the proposed rule and is finalizing it without changes related to the comments.

Responses to Comments

FSIS received 22 comments on the proposed rule submitted by a small business advocacy group; a meat and poultry trade association; individuals, including students; a State association of agricultural commissioners; and a nonprofit weights and measures organization.

Comment: FSIS received comments from individuals, including students, opposed to the proposal. According to these commenters, having to convert weight measurements from one unit of measurement to another would be inconvenient. The commenters supported dual weight labeling because of its convenience in calculating weights for recipes and in determining nutritional values and because, according to them, the dual weight requirement is helpful for people from other cultures. These commenters also questioned FSIS' analysis that found that the change would result in benefits for small businesses.

Response: FSIS believes there are various options available to consumers today that allow for the conversion of weight measurements with minimal inconvenience or cost to consumers. Requiring two different units of measurement on the same product, for limited products, is unlikely to significantly help inform consumers of different cultural backgrounds about the weights of their purchases. As discussed elsewhere in this document, industry, including small businesses, should benefit from the flexibility offered by this change to the labeling regulations.

Comment: FSIS received comments from a nonprofit and a State association that supported the proposal, noting that it makes FSIS' regulations more consistent with the Fair Packaging and Labeling Act (the FPLA, from which meat and poultry are exempt), which was amended in 1992 to eliminate the requirement for product weight labeling in pounds and ounces on consumer commodities. To further promote FPLA consistency, these comments recommended that FSIS:

- Require all meat and poultry weights be declared in largest whole units;

• Remove the requirement to include the words ''Net Weight'' or ''Net Wt.'' from avoirdupois [1] net weight statements and remove ''Net Contents'' and ''Net'' from liquid net weight statements, or as an alternative, allow the use of ''Net'' and ''Net Mass'' for avoirdupois net weight statements; and

• Require that all meat and poultry weights be declared in both imperial [2] and metric units,[3] or, as an alternative, allow metric units instead of imperial units.

One commenter also proposed that the net weight statement be allowed in any order, regardless of the use of imperial or metric units.

Response: In general, FSIS believes that the costs to industry from the additional requirements proposed by these commenters cannot be justified. Further, since 1966, meat and poultry product labeling are expressly exempted from the FPLA and the regulations issued thereunder. Thus, consistency between the FSIS labeling regulations and the FPLA is not required. Specifically, FSIS' net weight regulations already require that the ''largest whole unit'' be used for liquid weights to promote consistency on labeling due to the high number of volume measurements, for example, fluid ounce, cups, pints, quarts, and gallons, and will remain in use pursuant to 9 CFR 317.2(h)(5) and 381.121(c)(5).

FSIS is removing the dual declaration requirement for avoirdupois weight on packages weighing one pound to less than four pounds to allow for the use of either ounces or pounds alone or in a voluntary dual declaration format that allows for ounces and pounds to be listed in any order. Requiring the use of the ''largest whole unit'' for these packages would require that all such packages be declared in pounds first; therefore, that requirement would remove the compliance flexibility that FSIS is providing by removing the dual declaration requirement.

Regarding the comments on net weight declaration, FSIS' position is that the terms ''Net Weight'', ''Net Wt.'', ''Net Contents'', and ''Net'' are an integral part of the net weight statement that clarifies for consumers the weight of the product separate from its package, as well as from other voluntary weights that may be included on a label, such as the weight per piece. FSIS' net weight regulations do not require metric units. However, FSIS allows metric weights and measures in the net weight statement as voluntary information after the net weight information required by the regulations is declared. Changing the regulations to include metric weights and measurements and the term ''Net Mass'' is outside the scope of this rule.

Executive Orders 12866 and 13563, and the Regulatory Flexibility Act

E.O.s 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety benefits, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This final rule has been designated as a ''non-significant'' regulatory action under section 3(f) of E.O. 12866. Accordingly, the rule has not been reviewed by the Office of Management and Budget (OMB) under E.O. 12866.

Economic Impact Analysis

FSIS has updated the final qualitative analysis to incorporate more recent data. The changes include: Updated estimates in the ''Baseline'' section with 2019 Information Resources, Inc (IRI) scanner data; and updated estimates in the ''Expected Benefits Associated with the Final Rule'' section with 2020 Label Submission and Approval System (LSAS) data.

Baseline

Prior to the effective date of this final rule, FSIS' regulations required labeling on packages of meat or poultry products that contain at least one pound or one pint, but less than four pounds or one gallon, to express the net weight or content as a ''dual declaration'' (*i.e.,* in both ounces and pounds or fluid ounces and pints, or quarts) on the product label, unless an exemption [4] applied. According to 2019 IRI scanner data,[5] about 30,758 FSIS regulated products in the retail market have a dual net weight or content statement on the label. About 55 percent (2,620/4,725) of FSIS regulated companies manufacture at least one product with a dual net weight or content statement, and about 31 percent (1,459/4,725) of FSIS regulated companies manufacture products with both a dual and single net weight or content statement.

Expected Benefits Associated With the Final Rule

The final regulatory amendments to 9 CFR 317.2(h)(5) and 9 CFR 381.121(c)(5) remove the requirements for dual net weight or content statements on labels of meat and poultry products that contain at least one pound or one pint, but less than four pounds or one gallon. Under the final rule, all FSIS meat and poultry products will need to include only one unit of measurement in the net weight or content statement. Industry will benefit from more flexible net weight and content statement regulations across all FSIS meat and poultry products, especially start-up companies and companies currently with products having both single and dual net weight or content statements. Companies will no longer have to keep track of which products need to include a dual or single net weight or content declaration.

The final rule also clarifies the net weight and content requirements for the industry and FSIS inspectors. When FSIS analyzed historical askFSIS [6] data, it showed confusion surrounding the dual declaration net weight and content requirements. Industry often incorrectly interpreted the dual declaration net weight and content requirements as needing to include both the avoirdupois measure (ounces or pounds) and the metric measure (grams or kilograms) in the net weight or content statement. FSIS also received askFSIS questions about exemptions. For example, industry wanted to know if random weight packages, packages under one pound, and products sold for further processing were exempt from the dual declaration net weight and content requirements. The remaining questions sought formatting clarification on the order of the measurements and about the line spacing. Questions regarding the order sought clarification on which measurements should be listed first: pounds or ounces, fluid ounces or pints or quarts. Industry also asked if the second net weight or content declaration could be listed on a separate line to better fit on labels. Under the final rule, FSIS expects that the new net weight and content requirements will be

[1] Avoirdupois is a system of weights and measures that includes pounds and ounces.

[2] The imperial system is a system of weights and measures that includes pounds, ounces, feet, yards, and miles.

[3] The metric system is a system of weights and measures that includes meters, liters, and grams.

[4] See 9 CFR 317.2(h)(9) and 381.121(h)(9) for the list of exemptions.

[5] The analysis, findings, and conclusions expressed in this report should not be attributed to IRI. IRI gathers data by scanners in supermarkets, drugstores, and mass merchandisers and maintains a panel of consumer households that record purchases at outlets by scanning UPC codes on the products purchased.

[6] askFSIS is a web-based computer application, designed to help answer technical and policy-related questions from inspection program personnel, industry, consumer groups, other stakeholders, and the public.

clearer for industry and FSIS inspectors and that there will be fewer askFSIS questions and less misunderstanding of the net weight and content requirements.

Further, the likelihood of misprinted labels should decrease under the final rule. FSIS' Labeling and Program Delivery Staff (LPDS) evaluates sketches of labels [7] through the LSAS prior to the associated labels entering the marketplace. According to 2020 LSAS data, LPDS requested corrections of errors in the dual net weight statement for 48 labels from 27 firms. These labels would not have needed modifications to their net weight statement under this final rule.

In addition, removing the dual declaration requirements will free-up a small amount of space on the principal display panel of labels. Switching from dual declarations to single declarations could also marginally decrease ink consumption for companies.

FSIS did not find a price difference in capital printing equipment for complying with the dual declaration net weight or content statement. However, there is a price difference in scale-printing systems for printing a dual net weight or content statement versus a single statement. Companies typically use scale-printing systems to print net weight information on random weight packages (*e.g.,* sliced turkey from a deli counter). Random weight packages with varying weight and with no fixed weight pattern are currently exempt from the dual declaration net weight and content statement requirement. Therefore, the scale-printer cost discrepancies were not included in the cost analysis. The Agency sought, but did not receive, comment on capital costs for printing equipment for the dual declaration net weight and content statement.

Expected Costs Associated With the Final Rule

There are no expected costs associated with this final rule. Companies that already have products labeled with the two measurements in the net weight or content statement are not required to update their labels to a single net weight or content statement.

[7] LPDS evaluates four types of FSIS labels: (1) Labels for religious exempt products, (2) Labels for export with deviations from domestic requirements, (3) Labels with special statements and claims, and (4) Labels for temporary approval. All other labels can be generically approved. Additional information on generically approved labels is available here: *https://www.fsis.usda.gov/wps/wcm/connect/bf170761-33e3-4a2d-8f86-940c2698e2c5/Label-Approval-Guide.pdf?MOD=AJPERES/.*

Regulatory Flexibility Act Assessment

The FSIS Administrator has made a determination that this final rule will not have a significant economic impact on a substantial number of small entities, as defined by the Regulatory Flexibility Act (5 U.S.C. 601). The final rule is not expected to increase costs to the industry.

Paperwork Reduction Act

There are no new paperwork or recordkeeping requirements associated with this final rule under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Executive Order 12988, Civil Justice Reform

This rule has been reviewed under E.O. 12988, Civil Justice Reform. Under this rule: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) no administrative proceedings will be required before parties may file suit in court challenging this rule.

E-Government Act

FSIS and USDA are committed to achieving the purposes of the E-Government Act (44 U.S.C. 3601, *et seq.*) by, among other things, promoting the use of the internet and other information technologies and providing increased opportunities for citizen access to Government information and services, and for other purposes.

Executive Order 13175

This rule has been reviewed in accordance with the requirements of E.O. 13175, ''Consultation and Coordination with Indian Tribal Governments.'' E.O. 13175 requires Federal agencies to consult and coordinate with tribes on a government-to-government basis on policies that have tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

FSIS has assessed the impact of this rule on Indian tribes and determined that this rule does not, to our knowledge, have tribal implications that require tribal consultation under E.O. 13175. If a Tribe requests consultation, FSIS will work with the Office of Tribal Relations to ensure meaningful consultation is provided where changes, additions and modifications identified herein are not expressly mandated by Congress.

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List of Subjects

9 CFR Part 317

Food labeling, Food packaging, Meat inspection, Nutrition, Reporting and recordkeeping requirements.

9 CFR Part 381

Administrative practice and procedure, Animal diseases, Crime, Exports, Food grades and standards, Food labeling, Food packaging, Government employees, Grant programs-agriculture, Intergovernmental relations, Laboratories, Meat inspection, Nutrition, Polychlorinated biphenyls (PCB's), Poultry and poultry products, Reporting and recordkeeping requirements, Seizures and forfeitures, Signs and symbols, Technical assistance, Transportation.

For the reasons set out in the preamble, FSIS amends 9 CFR parts 317 and 381 as follows:

PART 317—LABELING, MARKING DEVICES, AND CONTAINERS

■ 1. The authority citation for part 317 continues to read as follows:

Authority: 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

§ 317.2 [Amended]

■ 2. Amend § 317.2 as follows:
■ a. In paragraph (h)(4), remove the phrase ''a declaration of 1½ pounds avoirdupois weight shall be expressed as ''Net Wt. 24 oz. (1 lb. 8 oz.),'' ''Net Wt. 24 oz. (1½ lb.),'' or ''Net Wt. 24 oz. (1.5 lbs.).'''' and add in its place ''a declaration of 1 ½ pounds avoirdupois weight shall be expressed as ''Net Wt. 24 oz.,'' ''Net Wt. 1 lb. 8 oz.,'' ''Net Wt. 1½ lb.,'' or ''Net Wt. 1.5 lbs.''.''.
■ b. In paragraph (h)(5), remove ''the statement shall be expressed as a dual declaration both in ounces and (immediately thereafter in parentheses) in pounds'' and add in its place ''the statement shall be expressed in ounces or in pounds''.
■ c. In paragraph (h)(9)(i), remove the phrase '', dual declaration,'' from the second and fourth sentences;
■ d. In paragraph (h)(9)(iii), remove the phrase '', dual declaration,'';
■ e. In paragraph (h)(9)(iv), remove ''paragraphs (h) (3) and (5)'' and add in its place ''paragraph (h)(3)'';
■ f. In paragraph (h)(9)(v), remove ''paragraphs (h)(3) and (h)(5)'' and add in its place ''paragraph (h)(3)'' and remove the phrase '', and that the statement be expressed both in ounces and in pounds,'';
■ g. In paragraph (h)(12), remove the phrase '', except that such declaration of total quantity need not be followed by an additional parenthetical declaration in terms of the largest whole units and subdivisions thereof, as required by paragraph (h)(5) of this section''.

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

■ 3. The authority citation for part 381 is revised to read as follows:

Authority: 7 U.S.C. 138f, 1633; 21 U.S.C. 451–472; 7 CFR 2.7, 2.18, 2.53.

■ 4. Amend § 381.121 as follows:
■ a. Paragraph (c)(5) is revised.
■ b. In paragraph (c)(8), remove '', except that such declaration of total quantity need not be followed by an additional parenthetical declaration in terms of the largest whole units and subdivisions thereof, as otherwise required by this paragraph (c)'' from the first sentence;
■ c. In paragraph (c)(9)(i), remove the phrase '', dual declaration,'' from the second and fourth sentences; and
■ d. In paragraph (c)(9)(iii), remove the phrase '', dual declaration,''.

The revision reads as follows:

§ 381.121 Quantity of contents.

* * * * *

(c) * * *

(5) The terms ''net weight'' or ''net wt.'' shall be used when stating the net quantity of contents in terms of weight, and the term ''net contents'' or ''contents'' when stating the net quantity of contents in terms of fluid measure. Except as provided in § 381.128, the statement shall be expressed in terms of avoirdupois weight or liquid measure. Where no general consumer usage to the contrary exists, the statement shall be in terms of liquid measure, if the product is liquid, or in terms of weight if the product is solid, semi-solid, viscous, or a mixture of solid and liquid. On packages containing less than 1 pound or 1 pint, the statement shall be expressed in ounces or fractions of a pint, respectively. On packages containing 1 pound or 1 pint or more, and less than 4 pounds or 1 gallon, the statement shall be expressed in ounces or in pounds with any remainder in terms of ounces or common or decimal fraction of the pound, or in the case of liquid measure, in the largest whole units with any remainder in terms of fluid ounces or common or decimal fraction of the pint or quart. For example, a declaration of three-fourths pound avoirdupois weight shall be expressed as ''Net Wt. 12 oz.''; a declaration of 1½ pounds avoirdupois weight shall be expressed as ''Net Wt. 24 oz.,'' ''Net Wt. 1 lb. 8 oz.,'' ''Net Wt. 1½ lb.,'' or ''Net Wt. 1.5 lbs.''. However, on random weight packages the statement shall be expressed in terms of pounds and decimal fractions of the pound, for packages over 1 pound, and for packages which do not exceed 1 pound the statement may be in decimal fractions of the pound in lieu of ounces. The numbers may be written in provided the unit designation is printed. Paragraphs (c)(8) and (9) of this section permit certain exceptions to this paragraph (c)(5) for multi-unit packages, and random weight consumer size and small packages (less than ½ ounce), respectively.

* * * * *

Done in Washington, DC.

Paul Kiecker,

Administrator.

[FR Doc. 2022–17498 Filed 8–16–22; 8:45 am]

BILLING CODE 3410–DM–P

CONSUMER FINANCIAL PROTECTION BUREAU

12 CFR Chapter X

Limited Applicability of Consumer Financial Protection Act's ''Time or Space'' Exception With Respect to Digital Marketing Providers

AGENCY: Consumer Financial Protection Bureau.

ACTION: Interpretive rule.

SUMMARY: Section 1002 of the Consumer Financial Protection Act of 2010 (CFPA) defines the term ''service provider'' and sets forth two exceptions to that definition. Under one of those exceptions, a person is not a service provider solely by virtue of such person offering or providing to a covered

person time or space for an advertisement for a consumer financial product or service through print, newspaper, or electronic media. The Consumer Financial Protection Bureau (Bureau or CFPB) is issuing this interpretive rule to address digital marketing providers that commingle the targeting and delivery of advertisements to consumers, such as by using algorithmic models or other analytics, with the provision of advertising ''time or space.'' Digital marketing providers that are materially involved in the development of content strategy would not fall within the ''time or space'' exception as interpreted by the Bureau. Accordingly, digital marketing providers that are involved in the identification or selection of prospective customers or the selection or placement of content to affect consumer engagement, including purchase or adoption behavior, are typically service providers under the CFPA.

DATES: This interpretive rule is effective on August 17, 2022.

FOR FURTHER INFORMATION CONTACT: Christopher Davis, Attorney-Advisor; Office of Fair Lending and Equal Opportunity, at *CFPB_FairLending@cfpb.gov,* or Brad Lipton, Senior Counsel, Legal Division, at 202–435–7000. If you require this document in an alternative electronic format, please contact *CFPB_Accessibility@cfpb.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Financial services companies rely on digital marketing providers to target and deliver advertisements across various platforms to consumers on their behalf. By doing so, financial services companies may be able to engage with audiences in ways that they were previously unable to with traditional advertising methods. Many modern digital marketing providers (or ''digital marketers'') play a dramatically different role in consumer advertising than did traditional media sources like print newspapers or radio stations. Many digital marketers target and deliver ads to specific consumers [1] using sophisticated analytical techniques, including machine learning and behavioral analytics, to process large amounts of consumer data.[2] In other words, many digital marketers aggregate and analyze immense amounts of granular consumer data, and then use that data to determine what advertisements to provide to specific consumers at what times. Accordingly, digital marketing providers commingle the service of targeting and delivering advertisements with the activities of traditional media sources in providing airtime or physical space.

Digital marketing providers obtain data from a variety of sources, including but not limited to data collected directly from consumers, for example when registering for an account or when conducting a search query into a search bar. Further, digital marketers may harvest a wide variety of consumer data by monitoring and tracking a consumer's web activity, including for example, their browsing history, their activity while online, and their geolocation.[3] (This is sometimes called ''surveillance advertising.'' [4]) Digital marketers may also obtain data from third-party data brokers or ''second-party'' partnerships with other companies.[5] Using these tools and others, digital marketers collect granular consumer data that they analyze to develop insights about consumers' behavior more broadly.[6]

The insights that digital marketing providers develop enable them to offer financial services companies targeted advertising services. For example, collected data from individual consumers can be analyzed by these marketers and used to segment consumers across various groupings, such as by age, location, or specific interests (*e.g.,* ''concert goers''). After these categories have been developed, firms that use digital marketing providers to acquire customers can select (or exclude) certain types of customers.[7]

In contrast, digital marketers may also target advertisements at specific times based on context, *i.e.,* the content that a user is currently viewing. Such contextual advertisements more closely resemble traditional ads users might find in other spaces—such as an ad for a sporting goods store aired during a televised basketball match or a print clothing ad placed in a fashion magazine—as they are based on the contents of what is being displayed, not consumer-specific data.

Digital marketers engaged in ad targeting and delivery may operate the websites or platforms on which ads appear, or they may not. In either case, digital marketers serve as an intermediary between the financial services company and consumers.

The ways in which digital marketing providers specifically target ads are varied and evolve over time. Ultimately, the digital marketer may decide which group(s) the consumer belongs in and which financial services companies desire to advertise to that group, and may select the specific ad to display to that consumer and/or when to display the ad based on other factors (*e.g.,* the amount a firm is willing to pay to display the ad). Accordingly, many digital marketing providers are materially involved in the development of ''content strategy'' [8] by identifying or selecting prospective customers and/or selecting or placing content to affect consumer engagement, including purchasing or adoption behavior. These activities go well beyond the activities of traditional media sources, such as print newspapers or radio, that solely passively provided airtime or physical space for advertisements.

II. Analysis

Service Providers

A person is a ''covered person'' under the CFPA, and thus subject to that law, including its prohibition on unfair, deceptive, or abusive acts or practices (UDAAPs), if it offers or provides a financial product or service for use by consumers primarily for personal, family, or household purposes.[9] ''Service provider[s]'' to covered persons are also subject to the CFPA, including its UDAAP prohibition.[10]

The CFPA defines a service provider as ''any person that provides a material service to a covered person in connection with the offering or provision by such covered person of a consumer financial product or

[1] The targeting and delivery of advertisements includes both the targeting and delivery of certain ads to consumers generally at specific times to increase or maximize engagement and the targeting and delivery of ads to specific consumers at specific times. For instance, a digital marketer may select certain ads to show late at night to consumers generally. Or a digital marketer may select certain ads to show late at night to certain consumers.

[2] *See* C.A. Summers, R.W. Smith, and R.W. Reczek, ''An audience of one: Behaviorally targeted ads as implied social labels,'' Journal of Consumer Research, vol. 43, no. 1, pp. 156–178 (June 2016).

[3] *See* Paige M. Boshell, *The Power of Place: Geolocation Tracking and Privacy,* Bus. Law Today (Mar. 2019).

[4] *See* Shoshana Zuboff, The Age of Surveillance Capitalism: The Fight for a Human Future at the New Frontier of Power (2019).

[5] *See supra* note 3.

[6] *See supra* note 2.

[7] *See id.*

[8] Content strategy is ''the strategy for the distribution of th[e] content'' as well as ''the set of methods and guidelines for the development and curation of content.'' Christen Geiler, *Information Architecture vs Content Strategy—and Why YOU Need Both, Digital.gov* (July 18, 2016), *https://digital.gov/2016/07/18/information-architecture-vs-content-strategy-and-why-you-need-both/.*

[9] *See* 12 U.S.C. 5481(5), (6), (15)(A); 5531; 5536.

[10] *See* 12 U.S.C. 5481(26); 5531; 5536. As the CFPB has explained, discrimination may constitute an unfair act or practice that violates the CFPA's UDAAP prohibition. *See* CFPB UDAAP Exam Manual (updated Apr. 11, 2022).

service.'' [11] The term ''service provider'' includes, but is not limited to, a person that ''participates in designing, operating, or maintaining the consumer financial product or service'' or ''processes transactions relating to the consumer financial product or service.'' [12] The term ''service provider,'' however, ''does not include a person solely by virtue of such person offering or providing to a covered person'' either ''a support service of a type provided to businesses generally or a similar ministerial service,'' or ''time or space for an advertisement for a consumer financial product or service through print, newspaper, or electronic media.'' [13]

Material Service

When digital marketing providers are materially involved in the development of content strategy, they typically provide a material service. Unlike most traditional media sources, digital marketing providers engaged in ad targeting and delivery are not solely providing airtime or physical space for ads. Rather, digital marketers commingle the targeting and delivery of advertisements with the provision of ''time or space.''

A ''material'' service is a service that is significant or important.[14] When digital marketers identify or select prospective customers and/or select or place content to affect consumer engagement, including purchasing or adoption behavior, they are providing a significant—and thus ''material''—service provided to covered persons. In particular, identifying prospective customers and then attempting to acquire those customers is a significant component of the ''offering'' of a consumer financial product or service, which is part of the legally relevant test for determining that a firm is a ''covered person.'' [15]

Indeed, modern digital ad targeting and content delivery typically consists of many functions—such as lead generation,[16] customer acquisition, or marketing analysis or strategy—that would often be performed by covered persons. For example, a covered person may measure the effectiveness of certain marketing efforts by calculating a ''customer acquisition rate.'' [17] Similarly, a covered person's marketing group may analyze where to purchase advertising across multiple channels to maximize impact.[18] The involvement in the development of content strategy by digital marketing providers increasingly resembles these functions and others often performed by covered persons themselves (although the services are often carried out in a more sophisticated way, based on the digital marketers' data and technology). Accordingly, digital marketers that are materially involved in the development of content strategy by identifying or selecting prospective customers and/or selecting or placing content to affect consumer engagement, including purchasing or adoption behavior, typically provide a material service.

''Time or Space'' Exception

As noted above, the CFPA provides that the term service provider ''does not include a person solely by virtue of such person offering or providing to a covered person'' either ''a support service of a type provided to businesses generally or a similar ministerial service,'' or ''time or space for an advertisement for a consumer financial product or service through print, newspaper, or electronic media.'' [19] The reference to ''solely'' providing ''time or space for an advertisement'' means that digital marketers that provide additional services beyond ''time or space''—*i.e.,* beyond airtime or physical space for the ad—do not qualify for the exception. Accordingly, when digital marketers are materially involved in the development of content strategy in addition to providing airtime or physical space, they fall outside the exception for ''solely'' providing ''time or space.''

The ''service provider'' definition should be interpreted as a cohesive whole.[20] Thus, the ''time or space'' exception should be interpreted alongside its inclusion with the exception for ''a support service of a type provided to businesses generally or a similar ministerial service.'' [21] Firms that provide a ''ministerial'' service to financial institutions are not materially involved in the marketing or distribution of the consumer financial product or service; they are not typically involved in the identification or selection of prospective customers, nor do they select or place content to affect consumer engagement. For example, a firm that furnishes broadband access to a financial institution is not involved in the strategic marketing and distribution of the consumer financial product or service and is generally not providing a material service.

Additionally, the ''time or space'' exception refers to ''electronic media'' within the phrase ''print, newspaper, or electronic media.'' [22] This phrasing—especially alongside the other exemption for ''a support service of a type provided to businesses generally or a similar ministerial service''—indicates that the ''time or space'' exception should be interpreted to refer to the offering of advertising in a manner similar to that was generally performed by traditional media sources, such as ''print'' or ''newspaper.'' [23] A traditional media source typically provided ''time or space''—*i.e.,* the airtime or physical space for the ad—with relatively little (*i.e.,* largely ''ministerial'') involvement in the development of content strategy.[24]

To be sure, some traditional media sources may have been involved in the selection of the audience for or content of ads to some degree (such as by allowing businesses to select advertising space in a geographic-specific section of a newspaper to businesses operating in that geographic area or putting advertisements for financial services in the financial section of the newspaper). But traditional media sources were typically not materially involved in the development of content strategy; in the main, their function was solely to provide ''time or space'' by operating as

[11] 12 U.S.C. 5481(26)(A).

[12] 12 U.S.C. 5481(26)(B)(i), (ii). Of course, nothing in this interpretive rule precludes a digital marketing provider from being considered a covered person based on its acts and practices. Indeed, by engaging in consumer data collection, tracking, analysis, and maintenance activities, digital marketing providers may be covered persons. *See* 12 U.S.C. 5481(15)(A)(ix).

[13] 12 U.S.C. 5481(26)(B)(i), (ii).

[14] *See* Merriam Webster's Dictionary (online ed.) (defining ''material'' as ''having real importance or great consequences''); Black's Law Dictionary (11th ed. online) (defining ''material'' as ''significant; essential'').

[15] *See* 12 U.S.C. 5481(6).

[16] *See, e.g.,* Complaint for Violations of the Consumer Financial Protection Act of 2010, *Consumer Fin. Prot. Bureau* v. *D and D Marketing, Inc.,* No. 2:15–cv–9692 (filed Dec. 17, 2015), *https://files.consumerfinance.gov/f/201512_cfpb_complaint-v-d-and-d-marketing-inc-et-al.pdf* (alleging that a lead aggregator is a ''service provider'' because it sold consumer loan applications as ''leads'' to payday and installment lenders who are ''covered persons'').

[17] *See, e.g.,* Jacquelyn S. Thomas, Werner Reinartz, and V. Kumar, ''Getting the Most out of All Your Customers,'' *Harvard Business Review* (July–August 2004) (noting that ''most companies still use the customer acquisition rate'').

[18] *See, e.g.,* Wes Nichols, ''Advertising Analytics 2.0,'' *Harvard Business Review* (March 2013) (noting that ''most businesses still . . . measured how [their] TV, print, radio, and online ads each functioned independently to drive sales'').

[19] 12 U.S.C. 5481(26)(B)(i), (ii).

[20] *See, e.g., Gustafson* v. *Alloyd Co., Inc.,* 513 U.S. 561, 569 (1995) (noting that ''the Act is to be interpreted as a symmetrical and coherent regulatory scheme'').

[21] 12 U.S.C. 5481(26)(B)(i), (ii).

[22] 12 U.S.C. 5481(26)(B)(i).

[23] *Cf. Gustafson,* 513 U.S. at 576 (''[T]he term 'written communication' must be read in context to refer to writings that, from a functional standpoint, are similar to the terms 'notice, circular, and advertisement.' '').

[24] 12 U.S.C. 5481(26)(B)(i), (ii).

passive conduits of information provided by their customers.

Indeed, when digital marketers are materially involved in the development of content strategy, the marketers perform functions that would often traditionally be undertaken by the covered person itself, rather than by a traditional media outlet. For example, as noted above, a covered person's marketing group may analyze where or when to purchase advertising across multiple channels to maximize impact.[25] Of course, covered persons may sometimes engage third-party vendors for these activities. For example, they may engage an advertising or consulting firm to perform marketing analysis. But this would *not* typically be a service that was performed by a traditional media source, such as a newspaper or radio station. The enterprises or firms providing these services may be ''service providers'' under the CFPA, but a media source that merely provided airtime or physical space would fall into the ''time or space'' exception and would not be a service provider.

Specific Circumstances

The conduct of digital marketers that provide services to covered persons varies widely and, depending on the conduct, may or may not fall within the ''time or space'' exception. Under the interpretation of the definition of ''service provider'' described above, the role played by the digital marketing provider—*i.e.,* whether the digital marketing provider is materially involved in the development of content strategy by identifying or selecting prospective customers and/or selecting or placing content to affect consumer engagement—will determine whether the advertiser falls within the ''time or space'' exception. Increasingly, the role typically played by digital marketers fall outside the exception and the digital marketers are typically service providers under the CFPA.

In certain circumstances, the digital marketing provider is only minimally involved in identifying or selecting prospective customers or selecting or placing content to affect consumer engagement. For instance, digital marketers may offer covered persons the ability to choose to run an advertisement on a particular web page or application of the covered person's choosing, with advertisements seen by any user of that page or application. In these circumstances, the digital marketer would typically fall within the ''time or space'' exception. The digital marketer in this situation is ''solely'' providing ''time or space'' for the ad, in the sense of airtime or physical space for the ad, without commingling targeting or delivery of the advertisements. Moreover, the digital marketer's conduct in these circumstances is similar to a traditional media source (such as a newspaper or radio station) that offered advertisements directed at a particular market of the covered person's choosing, rather than a function traditionally performed by a covered person itself.

Digital marketing providers may also target and deliver the advertisements to users with certain characteristics (such as demographics, geography, online behavior (such as particular keyword searches), or offline behavior). In some circumstances, the covered person may provide an audience of existing users and specify that advertisements be provided to similar consumers. While the covered person may specify certain parameters of the intended audience for a specific consumer financial product or service, it is the digital marketers' ad targeting and delivery algorithms that identify the audience with the desired characteristics and determine whether and/or when specific consumers see an advertisement.[26]

Digital marketing providers do not fall within the ''time or space'' exception if they target and deliver advertisements to users with certain characteristics, even if those characteristics are specified by the covered person. In these circumstances, although the covered person also plays a role, the digital marketer selects, including through its algorithms and data, the specific audience that sees the advertisement for the covered person's consumer financial product or service. The selection of specific consumers to see specific ads goes beyond solely selling airtime or physical space as performed by traditional media sources such as newspapers or radio. When digital marketers target and deliver advertisements to users with certain characteristics, the digital marketer is materially involved in the development of content strategy and is not covered by the ''time or space'' exception.

Moreover, when digital marketers target and deliver advertisements to users with certain characteristics, the selection of the audience through algorithms and data is akin to a customer acquisition function that would traditionally be performed in-house by a covered person (or a vendor other than a traditional media source, such as a consulting firm). Accordingly, digital marketers that target and deliver advertisements to users with certain characteristics specified by the covered person are typically service providers under the CFPA.

Similarly, digital marketing providers do not fall into the ''time or space'' exception if a covered person identifies particular users by name and the digital marketer targets and delivers the advertisements to those users at specific times to increase or maximize engagement. The provision of the service of analyzing when advertisements should appear goes beyond ''solely'' selling airtime or physical space as performed by traditional media sources such as newspapers or radio. To be sure, a traditional media source might have provided some basic information to firms about when to air particular advertisements, but the business purchasing the ad was generally the entity that made the decision about when and where to place the ad. Here, the use of algorithms and business-specific data to determine when to display a specific business' ads to specific consumers to affect consumer engagement extends well beyond the activities performed by a traditional media source.

There are also circumstances in which the digital marketing provider plays an even more significant role in determining which specific consumers see digital advertisements, such as by determining or suggesting to the covered person which users are the most appropriate audience for the covered person's advertisements (rather than receiving such direction from the covered person). Digital marketers may determine who is the appropriate audience to receive ads based on, for instance, the content of the particular ad, the type of businesses being advertised, the marketer's own knowledge of a particular user's characteristics and behavior (including offline behavior), the behavior of other users, and past user engagement with similar types of ads.[27]

In circumstances such as these in which a digital marketing provider plays an even more significant role in

[25] *See, e.g.,* Wes Nichols, ''Advertising Analytics 2.0,'' *Harvard Business Review* (March 2013) (noting that ''most businesses still . . . measured how [their] TV, print, radio, and online ads each functioned independently to drive sales'').

[26] *See, e.g.,* Charge of Discrimination at 5 ¶ 17, *Facebook, Inc.,* No. 01–18–0323–8 (Dep't of Hous. & Urban Dev. Mar. 28, 2019), *https://www.hud.gov/sites/dfiles/Main/documents/HUD_v_Facebook.pdf.*

[27] *See, e.g.,* Charge of Discrimination at 4 ¶ 16, *Facebook, Inc.,* No. 01–18–0323–8 (Dep't of Hous. & Urban Dev. Mar. 28, 2019), *https://www.hud.gov/sites/dfiles/Main/documents/HUD_v_Facebook.pdf.*

determining which specific users see digital advertisements, such as by determining or suggesting which users are the appropriate audience for advertisements, the digital marketer does not fall within the ''time or space'' exception and is typically a service provider under the CFPA. Determining which users are the appropriate audience for a particular covered person's advertisement is well beyond providing airtime or physical space. To the contrary, determining the appropriate audience is much more similar to the function traditionally performed by a covered person's own customer acquisition or marketing group than by a traditional media source. Indeed, identifying or selecting prospective customers for a covered person's business is similar to the function of a ''lead generator'' that would be considered a service provider under the CFPA. Accordingly, digital marketers that, for example, determine or suggest which users are the appropriate audience for advertisements are materially involved in the development of content strategy, do not fall under the ''time or space'' exception, and are typically service providers under the CFPA.

III. Regulatory Matters

This is an interpretive rule issued under the Bureau's authority to interpret the CFPA, including under section 1022(b)(1) of the CFPA, which authorizes guidance as may be necessary or appropriate to enable the Bureau to administer and carry out the purposes and objectives of Federal consumer financial laws, such as the CFPA.[28]

As an interpretive rule, this rule is exempt from the notice-and-comment rulemaking requirements of the Administrative Procedure Act.[29] Because no notice of proposed rulemaking is required, the Regulatory Flexibility Act does not require an initial or final regulatory flexibility analysis.[30] The Bureau also has determined that this interpretive rule does not impose any new or revise any existing recordkeeping, reporting, or disclosure requirements on covered entities or members of the public that would be collections of information requiring approval by the Office of Management and Budget under the Paperwork Reduction Act.[31]

Pursuant to the Congressional Review Act,[32] the Bureau will submit a report containing this interpretive 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 the rule's published effective date. The Office of Information and Regulatory Affairs has designated this interpretive rule as not a ''major rule'' as defined by 5 U.S.C. 804(2).

Rohit Chopra,

Director, Consumer Financial Protection Bureau.

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–0990; Project Identifier MCAI–2022–00372–T; Amendment 39–22137; AD 2022–16–08]

RIN 2120–AA64

Airworthiness Directives; Airbus Canada Limited Partnership (Type Certificate Previously Held by C Series Aircraft Limited Partnership (CSALP); Bombardier, Inc.) 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 Airbus Canada Limited Partnership Model BD–500–1A10 and BD–500–1A11 airplanes. This AD was prompted by a dual-engine automatic shutdown on landing. This AD requires revising the existing airplane flight manual (AFM) to incorporate a new normal procedure and revised non-normal procedures, as specified in a Transport Canada Civil Aviation (TCCA) AD, which is incorporated by reference. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD becomes effective September 1, 2022.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of September 1, 2022.

The FAA must receive comments on this AD by October 3, 2022.

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

For material incorporated by reference (IBR) in this AD, contact TCCA, Transport Canada National Aircraft Certification, 159 Cleopatra Drive, Nepean, Ontario K1A 0N5, Canada; telephone 888–663–3639; email *AD-CN@tc.gc.ca;* internet *tc.canada.ca/en/aviation.* You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available in the AD docket at *www.regulations.gov* by searching for and locating Docket No. FAA–2022–0990.

Examining the AD Docket

You may examine the AD docket at *www.regulations.gov* by searching for and locating Docket No. FAA–2022–0990; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Jiwan Karunatilake, Aerospace Engineer, Airframe and Propulsion Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; email *9-avs-nyaco-cos@faa.gov.*

SUPPLEMENTARY INFORMATION:

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 ''Docket No. FAA–2022–0990; Project Identifier MCAI–2022–00372–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.

[28] 12 U.S.C. 5512(b)(1).

[29] 5 U.S.C. 553(b).

[30] 5 U.S.C. 603(a), 604(a).

[31] 44 U.S.C. 3501–3521.

[32] 5 U.S.C. 801 *et seq.*

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 *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 Jiwan Karunatilake, Aerospace Engineer, Airframe and Propulsion Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; email *9-avs-nyaco-cos@faa.gov.* Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

TCCA, which is the aviation authority for Canada, has issued TCCA AD CF–2022–11, dated March 17, 2022 (TCCA AD CF–2022–11) (also referred to as the MCAI), to correct an unsafe condition for certain Airbus Canada Limited Partnership Model BD–500–1A10 and BD–500–1A11 airplanes. TCCA AD CF–2022–11 supersedes TCCA AD CF–2021–44, dated December 2, 2021.

This AD was prompted by a dual-engine automatic shutdown on landing experienced by a Model BD–500–1A11 airplane. The crew successfully stopped the airplane with degraded systems and functions. An investigation is ongoing to determine the root cause, but preliminary findings of this event indicate that erroneous uncontrolled high thrust (UHT) detection can occur above 16,000 feet when the thrust lever is manually and abruptly [1] moved towards the idle position. Based on the preliminary findings from the ongoing investigation, and as a result of extensive subsequent communication with TCCA and Airbus Canada to determine the extent and urgency of the identified unsafe condition, the FAA is issuing this AD, which corresponds to TCCA AD CF–2022–11. TCCA AD CF–2022–11 is an interim action that includes revising the existing AFM by incorporating new AFM operating procedures to mitigate any UHT event—which can result in, for example, stall on the runway or loss of braking on landing—that may occur until the investigation is complete. The FAA is issuing this AD to address an erroneous UHT detection in flight, which would result in engine shutdown on landing with or without indications or crew alerting system messages displayed before landing, and, in the case of an automatic dual-engine shutdown upon landing, could result in loss of braking, loss of control of the airplane, and a runway excursion. See the MCAI for additional background information.

Related Service Information Under 1 CFR Part 51

TCCA AD CF–2022–11 specifies procedures for revising the existing AFM to incorporate a new normal procedure for low-altitude descent check (below 16,000 feet) and revised non-normal procedures for ''L THROTTLE FAIL'' and ''R THROTTLE FAIL.'' These procedures, which are specified in paragraph D of TCCA AD CF–2022–11, replace the interim procedures introduced by TCCA AD CF–2021–44; those interim procedures are specified in paragraphs A and B of TCCA AD CF–2022–11. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination

These products have been approved by the aviation authority of another country and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI described above. The FAA is issuing this AD after determining that the unsafe condition described previously is likely to exist or develop on other products of these same type designs.

Requirements of This AD

This AD requires accomplishing actions specified in paragraph D of TCCA AD CF–2022–11 described previously.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, TCCA AD CF–2022–11 is incorporated by reference in this AD. This AD requires compliance with certain actions in TCCA AD CF–2022–11 through that incorporation. Service information required by TCCA AD CF–2022–11 for compliance will be available at *www.regulations.gov* by searching for and locating Docket No. FAA–2022–0990 after this AD is published.

FAA's Justification and Determination of the Effective Date

Section 553(b)(3)(B) of the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*) authorizes agencies to dispense with notice and comment procedures for rules when the agency, for ''good cause,'' finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under this section, an agency, upon finding good cause, may issue a final rule without providing notice and seeking comment prior to issuance. Further, section 553(d) of the APA authorizes agencies to make rules effective in less than thirty days, upon a finding of good cause.

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 forgoing notice and comment prior to adoption of this rule because an erroneous UHT detection in flight would result in engine shutdown on landing with or without indications or CAS messages displayed before landing. An automatic dual-engine shutdown upon landing could result in loss of braking, loss of control of the airplane, and a runway excursion. Accordingly, notice and opportunity for prior public comment are impracticable and contrary to the

[1] See definition of abrupt throttle movement in Figure 1 of TCCA AD CF–2022–11.

public interest pursuant to 5 U.S.C. 553(b)(3)(B).

In addition, the FAA finds that good cause exists pursuant to 5 U.S.C. 553(d) for making this amendment effective in less than 30 days, for the same reasons the FAA found good cause to forgo notice and comment.

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

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
1 work-hour × $85 per hour = $85	$0	$85	$5,865

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.

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:

2022–16–08 Airbus Canada Limited Partnership (Type Certificate Previously Held by C Series Aircraft Limited Partnership (CSALP); Bombardier, Inc.): Amendment 39–22137; Docket No. FAA–2022–0990; Project Identifier MCAI–2022–00372–T.

(a) Effective Date

This airworthiness directive (AD) is effective September 1, 2022.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Airbus Canada Limited Partnership (Type Certificate previously held by C Series Aircraft Limited Partnership (CSALP); Bombardier, Inc.) Model BD–500–1A10 and BD–500–1A11 airplanes, certificated in any category, as identified in Transport Canada Civil Aviation (TCCA) AD CF–2022–11, dated March 17, 2022 (TCCA AD CF–2022–11).

(d) Subject

Air Transport Association (ATA) of America Code 72, Turbine/turboprop engine.

(e) Unsafe Condition

This AD was prompted by a report of a dual-engine automatic shutdown on landing. The FAA is issuing this AD to address an erroneous uncontrolled high thrust detection in flight, which would result in engine shutdown on landing with or without indications or crew alerting system messages displayed before landing, and, in the case of an automatic dual-engine shutdown upon landing, could result in loss of braking, loss of control of the airplane, and a runway excursion.

(f) Compliance

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

(g) Requirements

Within 120 days from the effective date of this AD, revise the existing airplane flight manual (AFM) in accordance with paragraph D of TCCA AD CF–2022–11.

(h) Additional AD Provisions

The following provisions also apply to this AD:

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

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

(i) Related Information

For more information about this AD, contact Jiwan Karunatilake, Aerospace Engineer, Airframe and Propulsion Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; email *9-avs-nyaco-cos@faa.gov*.

(j) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference of the service information listed in this

paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

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

(i) Transport Canada Civil Aviation (TCCA) AD CF–2022–11, dated March 17, 2022.

(ii) [Reserved]

(3) For TCCA AD CF–2022–11, contact TCCA, Transport Canada National Aircraft Certification, 159 Cleopatra Drive, Nepean, Ontario K1A 0N5, Canada; telephone 888–663–3639; email *AD-CN@tc.gc.ca;* internet *tc.canada.ca/en/aviation.*

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

(5) You may view this material that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fr.inspection@nara.gov,* or go to *www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on July 29, 2022.

Christina Underwood,

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

[FR Doc. 2022–17789 Filed 8–15–22; 4:15 pm]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–1043; Airspace Docket No. 21–ACE–4]

RIN 2120–AA66

Amendment of Jet Routes J–82 and J–94; Extension of Area Navigation (RNAV) Route Q–122; Amendment of VOR Federal Airways V–100, V–138, V–456, and V–505; Removal of VOR Federal Airway V–462; and Removal of the Fort Dodge, IA, Domestic Low Altitude Reporting Point; in the Vicinity of Fort Dodge, IA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends Jet Routes J–82 and J–94, RNAV route Q–122, and VOR Federal airways V–100, V–138, V–456, and V–505; and removes VOR Federal airway V–462 and the Fort Dodge, IA, Domestic Low Altitude Reporting Point. This action is necessary due to the planned decommissioning of the VOR portion of the Fort Dodge, IA, VOR/Tactical Air Navigation (VORTAC), which provides navigation guidance to portions of the affected Air Traffic Service (ATS) routes. The Fort Dodge VOR is being decommissioned as part of the FAA's VOR Minimum Operational Network (VOR MON) program.

DATES: Effective date 0901 UTC, November 3, 2022. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order JO 7400.11F, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *www.faa.gov/air_traffic/publications/.* For further information, you can contact the Rules and Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

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

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

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

History

The FAA published a notice of proposed rulemaking for Docket No. FAA–2021–1043, in the **Federal Register** (86 FR 70780; December 13, 2021) amending Jet Routes J–82 and J–94, RNAV route Q–122, and VOR Federal airways V–100, V–138, V–456, and V–505; and removing VOR Federal airway V–462 and the Fort Dodge, IA, Domestic Low Altitude Reporting Point, due to the planned decommissioning of the VOR portion of the Fort Dodge, IA, VORTAC. The FAA invited interested parties to participate in this rulemaking effort by submitting written comments on the proposal. No comments were received.

United States Jet Routes, RNAV Q-routes, VOR Federal airways, and Domestic Low Altitude Reporting points are published in paragraphs 2004, 2006, 6010(a), and 7001, respectively, of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which are incorporated by reference in 14 CFR 71.1. The ATS routes listed in this document will be published subsequently in FAA Order JO 7400.11.

Differences From the NPRM

In the NPRM, the FAA proposed to remove the BEARR, UT, Fix and the O'Neil, NE (ONL), VORTAC from the Q–122 legal description, indicating the route points were on straight segments of the existing route and were not necessary to be included in the route description. However, although the BEARR, UT, Fix and the O'Neill, NE, VORTAC route points were proposed to be removed from the Q–122 legal description, both were being retained within the NAS and would continue to be charted.

Subsequent to the NPRM, the FAA has determined that the route points do in fact represent turn points of one degree or more on the route and are required in the Q–122 route description to retain the existing route structure. Therefore, the FAA is keeping the BEARR, UT, Fix and the O'Neill, NE, VORTAC route points in the Q–122 route description.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This action amends 14 CFR part 71 by amending Jet Routes J–82 and J–94, RNAV route Q–122, and VOR Federal airways V–100, V–138, V–456, and V–505; and removes VOR Federal Airway V–462 and the Fort Dodge, IA, reporting point.

The ATS route and reporting point amendments are described below.

J–82: J–82 extends between the Battle Ground, WA, VORTAC and the Goshen, IN, VORTAC. The route segment between the Sioux Falls, SD, VORTAC and the Dubuque, IA, VORTAC is

removed. The unaffected portions of the existing route remain as charted.

J–94: J–94 extends between the Mustang, NV, VORTAC and the Flint, MI, VORTAC. The route segment between the O'Neill, NE, VORTAC and Dubuque, IA, VORTAC is removed. The unaffected portions of the existing route remain as charted.

Q–122: Q–122 extends between the MOGEE, CA, waypoint (WP) and the Fort Dodge, IA, VORTAC. The Fort Dodge, IA, VORTAC route point is removed from the route description and replaced by the VIRGN, IA, WP located 3.08 NM south of the Fort Dodge, IA, VORTAC site. From the VIRGN, IA, WP, the route is extended 52 miles eastward to the VIGGR, IA, Fix. Lastly, the KATES, NE, Fix is changed to a WP. The unaffected portions of the existing route remain as charted.

V–100: V–100 extends between the Medicine Bow, WY, VOR/Distance Measuring Equipment (VOR/DME) and the O'Neil, NE, VORTAC; between the Fort Dodge, IA, VORTAC and the Dubuque, IA, VORTAC; and between the Northbrook, IL, VOR/DME and the Litchfield, MI, VOR/DME. The airway segment between the Fort Dodge, IA, VORTAC and the Waterloo, IA, VOR/DME is removed. The unaffected portions of the existing airway remain as charted.

V–138: V–138 extends between the Riverton, WY, VOR/DME and the Sidney, NE, VOR/DME; and between the Grand Island, NE, VOR/DME and the Mason City, IA, VOR/DME. The airway segment between the Omaha, IA, VORTAC and the Mason City, IA, VOR/DME is removed. The unaffected portions of the existing airway remain as charted.

V–456: V–456 extends between the Fort Dodge, IA, VORTAC and the Flying Cloud, MN, VOR/DME. The airway segment between the Fort Dodge, IA, VORTAC and the Mankato, MN, VOR/DME is removed. The unaffected portions of the existing airway remain as charted.

V–462: V–462 extends between the Fort Dodge, IA, VORTAC and the Sioux Falls, SD, VORTAC. The airway is removed in its entirety.

V–505: V–505 extends between the Des Moines, IA, VORTAC and the Gopher, MN, VORTAC; and between the Duluth, MN, VORTAC and the International Falls, MN, VOR/DME. The airway segment between the Des Moines, IA, VORTAC and the Mason City, IA, VOR/DME is removed. The unaffected portions of the existing airway remain as charted.

Fort Dodge, IA, Reporting Point: The Fort Dodge, IA, Domestic Low Altitude Reporting Point is removed.

All of the navigational aid radials in the ATS route descriptions below are unchanged and stated in True degrees.

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

Regulatory Notices and Analyses

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

Environmental Review

The FAA has determined that this action of amending Jet Routes J–82 and J–94, RNAV route Q–122, and VOR Federal airways V–100, V–138, V–456, and V–505; and removing VOR Federal airway V–462 and the Fort Dodge, IA, Domestic Low Altitude Reporting Point, due to the planned decommissioning of the VOR portion of the Fort Dodge, IA, VORTAC navigational aid, qualifies for categorical exclusion under the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) and its implementing regulations at 40 CFR part 1500, and in accordance with FAA Order 1050.1F, Environmental Impacts: Policies and Procedures, paragraph 5–6.5a, which categorically excludes from further environmental impact review rulemaking actions that designate or modify classes of airspace areas, airways, routes, and reporting points (see 14 CFR part 71, Designation of Class A, B, C, D, and E Airspace Areas; Air Traffic Service Routes; and Reporting Points). As such, this action is not expected to result in any potentially significant environmental impacts. In accordance with FAA Order 1050.1F, paragraph 5–2 regarding Extraordinary Circumstances, the FAA reviewed this action for factors and circumstances in which a normally categorically excluded action may have a significant environmental impact requiring further analysis. Accordingly, the FAA determined that no extraordinary circumstances exist that warrant preparation of an environmental assessment or environmental impact study.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Amendment

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

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

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA JO Order 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 2004 Jet Routes.

* * * * *

J–82 [Amended]

From Battle Ground, WA; Donnelly, ID; Dubois, ID; Crazy Woman, WY; Rapid City, SD; to Sioux Falls, SD. From Dubuque, IA; INT Dubuque 095° and Joliet, IL, 317° radials; Joliet; to Goshen, IN.

* * * * *

J–94 [Amended]

From Mustang, NV; Lovelock, NV; Battle Mountain, NV; Lucin, UT; Rock Springs, WY; Scottsbluff, NE; to O'Neill, NE. From Dubuque, IA; Northbrook, IL; Pullman, MI; to Flint, MI.

* * * * *

Paragraph 2006 United States Area Navigation Routes.

* * * * *

Q–122 MOGEE, CA to VIGGR, IA [Amended]

MOGEE, CA	WP	(Lat. 38°20′10.00″ N, long. 121°23′23.00″ W)
MACUS, NV	WP	(Lat. 39°53′00.00″ N, long. 118°48′00.00″ W)

MCORD, NV	WP	(Lat. 40°12′00.00″ N, long. 118°01′00.00″ W)
Lucin, UT (LCU)	VORTAC	(Lat. 41°21′46.63″ N, long. 113°50′26.23″ W)
BEARR, UT	FIX	(Lat. 41°31′50.85″ N, long. 112°29′18.40″ W)
KURSE, WY	WP	(Lat. 42°04′29.66″ N, long. 105°09′36.16″ W)
O'Neill, NE (ONL)	VORTAC	(Lat. 42°28′13.80″ N, long. 098°41′12.94″ W)
KATES, NE	WP	(Lat. 42°32′27.71″ N, long. 096°46′26.52″ W)
VIRGN, IA	WP	(Lat. 42°33′47.92″ N, long. 094°17′39.35″ W)
VIGGR, IA	FIX	(Lat. 42°33′18.67″ N, long. 093°07′26.83″ W)

* * * * *

Paragraph 6010(a) Domestic VOR Federal Airways.

* * * * *

V–100 [Amended]

From Medicine Bow, WY; Scottsbluff, NE; Alliance, NE; Ainsworth, NE; to O'Neill, NE. From Waterloo, IA; to Dubuque, IA. From Northbrook, IL; INT Northbrook 095° and Keeler, MI, 271° radials; Keeler; to Litchfield, MI.

* * * * *

V–138 [Amended]

From Riverton, WY; 35 miles, 80 miles 107 MSL, 16 miles 85 MSL, Medicine Bow, WY; Cheyenne, WY; to Sidney, NE. From Grand Island, NE; INT of Grand Island 099° and Lincoln, NE, 267° radials; Lincoln; to Omaha, IA.

* * * * *

V–456 [Amended]

From Mankato, MN; to Flying Cloud, MN.

* * * * *

V–462 [Removed]

* * * * *

V–505 [Amended]

From Mason City, IA; INT Mason City 349° and Gopher, MN, 188° radials; to Gopher. From Duluth, MN; INT Duluth 331° and Hibbing, MN, 120° radials; Hibbing; INT Hibbing 319° and International Falls, MN, 182° radials; to International Falls.

* * * * *

Paragraph 7001 Domestic Low Altitude Reporting Points.

* * * * *

Fort Dodge, IA [Removed]

* * * * *

Issued in Washington, DC, on August 10, 2022.

Scott M. Rosenbloom,

Manager, Airspace Rules and Regulations.

[FR Doc. 2022–17511 Filed 8–16–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–1097; Airspace Docket No. 19–AAL–64]

RIN 2120–AA66

Amendment of United States Area Navigation (RNAV) Route T-233; Kotzebue, AK

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends United States Area Navigation (RNAV) route T-233 in the vicinity of Kotzebue, AK, in support of a large and comprehensive T-route modernization project for the state of Alaska.

DATES: Effective date 0901 UTC, November 3, 2022. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order JO 7400.11F, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *www.faa.gov/air__traffic/publications/*. For further information, you can contact the Rules and ReguLat.ons Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

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

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing reguLat.ons to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This reguLat.on is within the scope of that authority as it expands the availability of RNAV routes in the state of Alaska and improve the efficient flow of air traffic within the National Airspace System by lessening the dependency on ground based navigation.

History

The FAA published a notice of proposed rulemaking for Docket No. FAA–2021–1097 in the **Federal Register** (86 FR 70785; December 13, 2021), amending RNAV route T–233 in the vicinity of Kotzebue, AK, in support of a large and comprehensive T-route modernization project for the state of Alaska. Interested parties were invited to participate in this rulemaking effort by submitting comments on the proposal. No comments were received.

United States Area Navigation Routes are published in paragraph 6011 of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The RNAV route listed in this document will be published subsequently in FAA Order JO 7400.11.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This actions amends 14 CFR part 71 by amending RNAV route T-233 in the vicinity of Kotzebue, AK, in support of a large and comprehensive T-route modernization project for the state of Alaska. The route amendment is described below.

T–233: T–233 is amended by replacing the Evansville, AK (EAV), Non-Directional Beacon (NDB) with the Bettles, AK (BTT), VHF Omnidirectional

Range/Distance Measuring Equipment (VOR/DME); replacing the Ambler, AK (AMF), NDB with the new TOMPY, AK, waypoint (WP); removing the KORKY, AK, WP as it is no longer a turn point; extending the route westward from the TOMPY WP to the Kotzebue, AK (OTZ), VOR/DME; and adding the new CIBDU, AK, WP between the TOMPY WP and the Kotzebue, AK, VOR/DME to enable a lower minimum enroute altitude between the two route points. Lastly, the route is described in a West to East orientation.

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

Regulatory Notices and Analyses

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

Environmental Review

The FAA has determined that this airspace action of amending RNAV route T–233 in the vicinity of Kotzebue, AK, qualifies for categorical exclusion under the National Environmental Policy Act (42 U.S.C. 4321 et seq.) and its implementing reguLat.ons at 40 CFR part 1500, and in accordance with FAA Order 1050.1F, Environmental Impacts: Policies and Procedures, paragraph 5–6.5a, which categorically excludes from further environmental impact review rulemaking actions that designate or modify classes of airspace areas, airways, routes, and reporting points (see 14 CFR part 71, Designation of Class A, B, C, D, and E Airspace Areas; Air Traffic Service Routes; and Reporting Points), and paragraph 5–6.5i, which categorically excludes from further environmental review the establishment of new or revised air traffic control procedures conducted at 3,000 feet or more above ground level (AGL); procedures conducted below 3,000 feet AGL that do not cause traffic to be routinely routed over noise sensitive areas; modifications to currently approved procedures conducted below 3,000 feet AGL that do not significantly increase noise over noise sensitive areas; and increases in minimum altitudes and landing minima. As such, this action is not expected to result in any potentially significant environmental impacts. In accordance with FAA Order 1050.1F, paragraph 5–2 regarding Extraordinary Circumstances, the FAA has reviewed this action for factors and circumstances in which a normally categorically excluded action may have a significant environmental impact requiring further analysis. Accordingly, the FAA has determined that no extraordinary circumstances exist that warrant preparation of an environmental assessment or environmental impact study.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Amendment

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

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

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 6011 United States Area Navigation Routes.

* * * * *

T–233 Kotzebue, AK (OTZ) to Bettles, AK (BTT) [Amended]

Kotzebue, AK (OTZ)	VOR/DME	(Lat. 66°53′08.46″ N, long. 162°32′23.77″ W)
CIBDU, AK	WP	(Lat. 66°52′57.45″ N, long. 161°03′44.52″ W)
TOMPY, AK	WP	(Lat. 67°06′18.81″ N, long. 157°51′52.03″ W)
ENCOR, AK	WP	(Lat. 66°55′58.35″ N, long. 152°19′54.35″ W)
Bettles, AK (BTT)	VOR/DME	(Lat. 66°54′18.03″ N, long. 151°32′09.18″ W)

* * * * *

Issued in Washington, DC, on August 10, 2022.

Scott M. Rosenbloom,

Manager, Airspace Rules and ReguLat.ons.

[FR Doc. 2022–17512 Filed 8–16–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–1083; Airspace Docket No. 19–AAL–62]

RIN 2120–AA66

Amendment of United States Area Navigation (RNAV) Route T–229; Point Hope, AK

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends United States Area Navigation (RNAV) route T–229 in the vicinity of Point Hope, AK, in support of a large and comprehensive T-route modernization project for the state of Alaska.

DATES: Effective date 0901 UTC, November 3, 2022. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order JO 7400.11F, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *www.faa.gov/air_traffic/publications/*. For further information, you can contact the Rules and Regulations Group, Federal Aviation Administration, 800

Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

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

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

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

History

The FAA published a notice of proposed rulemaking (NPRM) for Docket No. FAA–2021–1083 in the **Federal Register** (86 FR 70783; December 13, 2021), amending RNAV route T–229 in the vicinity of Point Hope, AK, in support of a large and comprehensive T-route modernization project for the state of Alaska. Interested parties were invited to participate in this rulemaking effort by submitting comments on the proposal. No comments were received.

United States Area Navigation Routes are published in paragraph 6011 of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The RNAV route listed in this document will be published subsequently in FAA Order JO 7400.11.

Differences From the NPRM

In ''The Proposal'' section of the NPRM, the SURGE waypoint (WP) name identified in the T–229 proposed action was incorrect. The correct WP name is SUGRE WP. This action corrects the WP name to the SUGRE, AK, WP in The Rule section of the preamble. The WP name correction is editorial only and the latitude/longitude coordinates remain the same so there is no change to the alignment of T–229.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This action amends 14 CFR part 71 by amending RNAV route T–229 in the vicinity of Point Hope, AK, in support of a large and comprehensive T-route modernization project for the state of Alaska. The route amendment is described below.

T–229: T–229 extends between the Fairbanks, AK, VOR/Tactical Air Navigation (VORTAC) and the Point Hope, AK, Non-Directional Beacon (NDB). The Point Hope NDB is replaced by the new VANTY, AK, waypoint (WP) to provide a lowered Global Navigation Satellite System (GNSS) Minimum Enroute Altitude (MEA), from 4,000 feet Mean Sea Level (MSL) to 3,000 feet MSL, between the SUGRE, AK, WP and the new VANTY WP. The unaffected segments of the route remain unchanged.

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

Regulatory Notices and Analyses

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

Environmental Review

The FAA has determined that this airspace action of amending RNAV route T–229 in the vicinity of Point Hope, AK, qualifies for categorical exclusion under the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) and its implementing regulations at 40 CFR part 1500, and in accordance with FAA Order 1050.1F, Environmental Impacts: Policies and Procedures, paragraph 5–6.5a, which categorically excludes from further environmental impact review rulemaking actions that designate or modify classes of airspace areas, airways, routes, and reporting points (see 14 CFR part 71, Designation of Class A, B, C, D, and E Airspace Areas; Air Traffic Service Routes; and Reporting Points), and paragraph 5–6.5i, which categorically excludes from further environmental review the establishment of new or revised air traffic control procedures conducted at 3,000 feet or more above ground level (AGL); procedures conducted below 3,000 feet AGL that do not cause traffic to be routinely routed over noise sensitive areas; modifications to currently approved procedures conducted below 3,000 feet AGL that do not significantly increase noise over noise sensitive areas; and increases in minimum altitudes and landing minima. As such, this action is not expected to result in any potentially significant environmental impacts. In accordance with FAA Order 1050.1F, paragraph 5–2 regarding Extraordinary Circumstances, the FAA has reviewed this action for factors and circumstances in which a normally categorically excluded action may have a significant environmental impact requiring further analysis. Accordingly, the FAA has determined that no extraordinary circumstances exist that warrant preparation of an environmental assessment or environmental impact study.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Amendment

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

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

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 6011 United States Area Navigation Routes.

* * * * *

T–229 Fairbanks, AK (FAI) to VANTY, AK [Amended]

Fairbanks, AK (FAI)	VORTAC	(Lat. 64°48′00.25″ N, long. 148°00′43.11″ W)
Tanana, AK (TAL)	VOR/DME	(Lat. 65°10′37.65″ N, long. 152°10′39.18″ W)
Huslia, AK (HSL)	VOR/DME	(Lat. 65°42′28.35″ N, long. 156°21′47.11″ W)
Selawik, AK (WLK)	VOR/DME	(Lat. 66°35′58.11″ N, long. 159°59′26.98″ W)
Kotzebue, AK (OTZ)	VOR/DME	(Lat. 66°53′08.46″ N, long. 162°32′23.77″ W)
VANTY, AK	WP	(Lat. 68°20′40.68″ N, long. 166°47′53.61″ W)

* * * * *

Issued in Washington, DC, on August 10, 2022.

Scott M. Rosenbloom,

Manager, Airspace Rules and Regulations.

[FR Doc. 2022–17513 Filed 8–16–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 800, 801, 808, and 874

[Docket No. FDA–2020–D–1380]

Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled ''Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products.'' This guidance document is intended to describe hearing aids, personal sound amplification products (PSAPs), their respective intended uses, and the regulatory requirements that apply to these products. The FDA Reauthorization Act of 2017 (FDARA) directed FDA to update and finalize the draft guidance entitled ''Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products,'' issued on November 7, 2013. This final guidance fulfills this FDARA requirement and supersedes ''Guidance for Industry and FDA Staff: Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products,'' dated February 25, 2009.

DATES: The announcement of the guidance is published in the **Federal Register** on August 17, 2022.

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 Docket No. FDA–2020–D–1380 for ''Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 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 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products'' to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Shu-Chen Peng, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1224, Silver Spring, MD 20993–0002, 301–796–6481.

SUPPLEMENTARY INFORMATION:

I. Background

The FDA Reauthorization Act of 2017 (FDARA) (Pub. L. 115–52) directs FDA to establish a category of over-the-counter (OTC) hearing aids through rulemaking, and mandates that FDA establish various requirements for this category of devices. Published elsewhere in this edition of the **Federal Register**, FDA is issuing a final rule (''rule'') to establish the OTC category of hearing aids and to implement the requirements of FDARA. In the rule, FDA has also outlined multiple related changes to the overall regulatory framework for hearing aids to harmonize existing regulations with the new OTC category while continuing to provide a reasonable assurance of safety and effectiveness.

FDARA also directed FDA to update and finalize the draft guidance entitled ''Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products,'' issued on November 7, 2013. To fulfill this requirement of FDARA, FDA is issuing this final guidance, which supersedes the February 25, 2009, final guidance. This final guidance reflects the new regulatory framework for hearing aids in the rule.

This guidance document identifies current applicable legal requirements under the Federal Food, Drug, and Cosmetic Act for hearing aids and for PSAPs. This guidance is intended to describe hearing aids, PSAPs, their respective intended uses, and the regulatory requirements that apply to both types of products. For information on certain situations in which FDA does not intend to enforce certain regulatory requirements, you may refer to the preamble to the rule that is published elsewhere in this edition of the **Federal Register**.

A notice of availability of the draft guidance appeared in the **Federal Register** of October 20, 2021 (86 FR 58192). FDA considered comments received and revised the guidance as appropriate in response to the comments, including aligning the guidance with the rule.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov* and *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Persons unable to download an electronic copy of ''Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1832 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. 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 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:

21 CFR part	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
814	Premarket approval	0910–0231
800, 801, and 809	Medical Device Labeling Regulations	0910–0485
803	Medical Devices; Medical Device Reporting; Manufacturer reporting, importer reporting, user facility reporting, distributor reporting.	0910–0437
1000 through 1050	Electronic Products	0910–0025

Dated: August 5, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–17231 Filed 8–16–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 587

Publication of Russian Harmful Foreign Activities Sanctions Regulations Web General Licenses 6, 6A, 6B, 25C, 30A, and 44

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Publication of web general licenses.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing six general licenses (GLs) issued pursuant to the Russian Harmful Foreign Activities Sanctions Regulations: GLs 6, 6A, 6B, 25C, 30A, and 44, each of which was previously made available on OFAC's website.

DATES: GL 6 was issued on February 24, 2022. GL 6A was issued on March 24, 2022. GLs 6B, 25C, 30A, and 44 were issued on July 14, 2022. See **SUPPLEMENTARY INFORMATION** for additional relevant dates.

FOR FURTHER INFORMATION CONTACT: OFAC: Assistant Director for Licensing, 202–622–2480; Assistant Director for Regulatory Affairs, 202–622–4855; or Assistant Director for Sanctions Compliance & Evaluation, 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

This document and additional information concerning OFAC are available on OFAC's website: *www.treas.gov/ofac.*

Background

OFAC issued GL 6 on February 24, 2022. GL 6 contained no expiration date, but was replaced and superseded by GL 6A on March 24, 2022. GL 6A contained no expiration date, but was replaced and superseded by GL 6B on July 14, 2022. On July 14, 2022, OFAC also issued GLs 25C, 30A, and 44. GL 30A expires on December 16, 2022 at 12:01 a.m. eastern standard time; the remaining GLs contain no expiration date. GLs 6, 6A, 6B, 25C, 30A, and 44 each authorize certain transactions otherwise prohibited by the Russian Harmful Foreign Activities Sanctions Regulations, 31 CFR part 587, and at the time of issuance, each was made available on OFAC's website (*www.treas.gov/ofac*). The text of these GLs is provided below.

OFFICE OF FOREIGN ASSETS CONTROL

Executive Order 14024 of April 15, 2021

Blocking Property With Respect To Specified Harmful Foreign Activities of the Government of the Russian Federation

GENERAL LICENSE NO. 6

Transactions Related to the Exportation or Reexportation of Agricultural Commodities, Medicine, Medical Devices, Replacement Parts and Components, or Software Updates, or the Coronavirus Disease 2019 (COVID–19) Pandemic

(a) Except as provided in paragraph (c) of this general license, all transactions prohibited by Executive Order (E.O.) 14024 that are ordinarily incident and necessary to: (1) the exportation or reexportation of agricultural commodities, medicine, medical devices, replacement parts and components for medical devices, or software updates for medical devices to, from, or transiting the Russian Federation; or (2) the prevention, diagnosis, or treatment of COVID–19 (including research or clinical studies relating to COVID–19), are authorized.

(b) For the purposes of this general license, agricultural commodities, medicine, and medical devices are defined as follows:

(1) *Agricultural commodities.* For the purposes of this general license, agricultural commodities are products that fall within the term ''agricultural commodity'' as defined in section 102 of the Agricultural Trade Act of 1978 (7 U.S.C. 5602) and are intended for use as:

(i) Food for humans (including raw, processed, and packaged foods; live animals; vitamins and minerals; food additives or supplements; and bottled drinking water) or animals (including animal feeds);

(ii) Seeds for food crops;

(iii) Fertilizers or organic fertilizers; or

(iv) Reproductive materials (such as live animals, fertilized eggs, embryos, and semen) for the production of food animals.

(2) *Medicine.* For the purposes of this general license, medicine is an item that falls within the definition of the term ''drug'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(3) *Medical devices.* For the purposes of this general license, a medical device is an item that falls within the definition of ''device'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(c) This general license does not authorize the opening or maintaining of a correspondent account or payable-through account for or on behalf of any entity subject to Directive 2 under E.O. 14024, Prohibitions Related to Correspondent or Payable-Through Accounts and Processing of Transactions Involving Certain Foreign Financial Institutions.

Note to General License No. 6. Nothing in this general license relieves any person from compliance with any other Federal laws or requirements of other Federal agencies.

Andrea M. Gacki,

Director, Office of Foreign Assets Control

Dated: February 24, 2022

OFFICE OF FOREIGN ASSETS CONTROL

Russian Harmful Foreign Activities Sanctions Regulations 31 CFR Part 587

GENERAL LICENSE NO. 6A

Transactions Related to the Exportation or Reexportation of Agricultural Commodities, Medicine, Medical Devices, Replacement Parts and Components, or Software Updates, the Coronavirus Disease 2019 (COVID–19) Pandemic, or Clinical Trials

(a) Except as provided in paragraph (c) of this general license, all transactions prohibited by the Russian Harmful Foreign Activities Sanctions Regulations, 31 CFR part 587 (RuHSR), that are ordinarily incident and necessary to: (1) the exportation or reexportation of agricultural commodities, medicine, medical devices, replacement parts and components for medical devices, or software updates for medical devices to, from, or transiting the Russian Federation; (2) the prevention, diagnosis, or treatment of COVID–19 (including research or clinical studies relating to COVID–19); or (3) ongoing clinical trials and other medical research activities that were in effect prior to March 24, 2022, are authorized.

(b) For the purposes of this general license, agricultural commodities, medicine, and medical devices are defined as follows:

(1) *Agricultural commodities.* For the purposes of this general license, agricultural commodities are products that fall within the term ''agricultural commodity'' as defined in section 102 of the Agricultural Trade Act of 1978 (7 U.S.C. 5602) and are intended for use as:

(i) Food for humans (including raw, processed, and packaged foods; live animals; vitamins and minerals; food additives or supplements; and bottled drinking water) or animals (including animal feeds);

(ii) Seeds for food crops;

(iii) Fertilizers or organic fertilizers; or

(iv) Reproductive materials (such as live animals, fertilized eggs, embryos, and semen) for the production of food animals.

(2) *Medicine.* For the purposes of this general license, medicine is an item that falls within the definition of the term ''drug'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(3) *Medical devices.* For the purposes of this general license, a medical device is an item that falls within the definition of ''device'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(c) This general license does not authorize:

(1) The opening or maintaining of a correspondent account or payable-through account for or on behalf of any entity subject to Directive 2 under E.O. 14024, *Prohibitions Related to Correspondent or Payable-Through Accounts and Processing of Transactions Involving Certain Foreign Financial Institutions;*

(2) Any debit to an account on the books of a U.S. financial institution of the Central Bank of the Russian Federation, the National Wealth Fund of the Russian Federation, or the Ministry of Finance of the Russian Federation; or

(3) Any transaction prohibited by Executive Order (E.O.) 14066 or E.O. 14068.

(d) Effective March 24, 2022, General License No. 6, dated February 24, 2022, is replaced and superseded in its entirety by this General License No. 6A.

Note 1 to General License No. 6A. Transactions prohibited by E.O. 14066 or E.O. 14068 include new investment in certain sectors in the Russian Federation and the importation into the United States of certain products of Russian Federation origin, such as alcoholic beverages and fish, seafood, or preparations thereof.

Note 2 to General License No. 6A. Nothing in this general license relieves any person from compliance with any other Federal laws or requirements of other Federal agencies.

Andrea M. Gacki,

Director, Office of Foreign Assets Control

Dated: March 24, 2022

OFFICE OF FOREIGN ASSETS CONTROL

Russian Harmful Foreign Activities Sanctions Regulations 31 CFR Part 587

GENERAL LICENSE NO. 6B

Transactions Related to Agricultural Commodities, Medicine, Medical Devices, Replacement Parts and Components, or Software Updates, the Coronavirus Disease 2019 (COVID–19) Pandemic, or Clinical Trials

(a) Except as provided in paragraph (c) of this general license, all transactions prohibited by the Russian Harmful Foreign Activities Sanctions Regulations, 31 CFR part 587, related to: (1) the production, manufacturing, sale, or transport of agricultural commodities, agricultural equipment, medicine, medical devices, replacement parts and components for medical devices, or software updates for medical devices; (2) the prevention, diagnosis, or treatment of COVID–19 (including research or clinical studies relating to COVID–19); or (3) ongoing clinical trials and other medical research activities are authorized.

(b) For the purposes of this general license, agricultural commodities, medicine, and medical devices are defined as follows:

(1) *Agricultural commodities.* For the purposes of this general license, agricultural commodities are products that fall within the term ''agricultural commodity'' as defined in section 102 of the Agricultural Trade Act of 1978 (7 U.S.C. 5602) and are intended for use as:

(i) Food for humans (including raw, processed, and packaged foods; live animals; vitamins and minerals; food additives or supplements; and bottled drinking water) or animals (including animal feeds);

(ii) Seeds for food crops;

(iii) Fertilizers or organic fertilizers; or

(iv) Reproductive materials (such as live animals, fertilized eggs, embryos, and semen) for the production of food animals.

(2) *Medicine.* For the purposes of this general license, medicine is an item that falls within the definition of the term ''drug'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(3) *Medical devices.* For the purposes of this general license, a medical device is an item that falls within the definition of ''device'' in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(c) This general license does not authorize:

(1) The opening or maintaining of a correspondent account or payable-through account for or on behalf of any entity subject to Directive 2 under Executive Order (E.O.) 14024, *Prohibitions Related to Correspondent or Payable-Through Accounts and Processing of Transactions Involving Certain Foreign Financial Institutions;*

(2) Any debit to an account on the books of a U.S. financial institution of the Central Bank of the Russian Federation, the National Wealth Fund of the Russian Federation, or the Ministry of Finance of the Russian Federation; or

(3) Any transaction prohibited by E.O. 14066, E.O. 14068, or E.O. 14071.

(d) Effective July 14, 2022, General License No. 6A, dated March 24, 2022, is replaced and superseded in its entirety by this General License No. 6B.

Note 1 to General License No. 6B. Transactions prohibited by E.O. 14066, E.O. 14068, and E.O. 14071 include new investment in the Russian Federation and the importation into the United States of certain products of Russian Federation origin, such as alcoholic beverages and fish, seafood, or preparations thereof.

Note 2 to General License No. 6B. Nothing in this general license relieves any person from compliance with any other Federal laws or requirements of other Federal agencies.

Andrea M. Gacki,

Director, Office of Foreign Assets Control

Dated: July 14, 2022

OFFICE OF FOREIGN ASSETS CONTROL

Russian Harmful Foreign Activities Sanctions Regulations 31 CFR Part 587

GENERAL LICENSE NO. 25C

Authorizing Transactions Related to Telecommunications and Certain Internet-Based Communications

(a) Except as provided in paragraph (c) of this general license, all transactions ordinarily incident and necessary to the receipt or transmission of telecommunications involving the Russian Federation that are prohibited by the Russian Harmful Foreign Activities Sanctions Regulations, 31 CFR part 587 (RuHSR), are authorized.

(b) Except as provided in paragraph (c) of this general license, the exportation or reexportation, sale, or supply, directly or indirectly, from the United States or by U.S. persons, wherever located, to the Russian Federation of services, software, hardware, or technology incident to the exchange of communications over the internet, such as instant messaging, videoconferencing, chat and email, social networking, sharing of photos, movies, and documents, web browsing, blogging, web hosting, and domain name registration services, that is prohibited by the RuHSR, is authorized.

(c) This general license does not authorize:

(1) The opening or maintaining of a correspondent account or payable-through account for or on behalf of any entity subject to Directive 2 under Executive Order (E.O.) 14024, *Prohibitions Related to Correspondent or Payable-Through Accounts and Processing of Transactions Involving Certain Foreign Financial Institutions;*

(2) Any debit to an account on the books of a U.S. financial institution of the Central Bank of the Russian Federation, the National Wealth Fund of the Russian Federation, or the Ministry of Finance of the Russian Federation;

(3) Any transactions prohibited by E.O. 14066 or E.O. 14068; or

(4) Any transactions involving Joint Stock Company Channel One Russia, Joint Stock Company NTV Broadcasting Company, Television Station Russia-1, Limited Liability Company Algoritm, New Eastern Outlook, or Oriental Review, unless separately authorized.

(d) Effective July 14, 2022, General License No. 25B, dated June 2, 2022, is replaced and superseded in its entirety by this General License No. 25C.

Note to General License No. 25C. Nothing in this general license relieves any person from compliance with any other Federal laws or requirements of other Federal agencies, including export, reexport, and transfer (in-country) licensing requirements maintained by the Department of Commerce's Bureau of Industry and Security under the Export Administration Regulations, 15 CFR parts 730–774.

Andrea M. Gacki,

Director, Office of Foreign Assets Control

Dated: July 14, 2022

OFFICE OF FOREIGN ASSETS CONTROL

Russian Harmful Foreign Activities Sanctions Regulations 31 CFR Part 587

GENERAL LICENSE NO. 30A

Authorizing Transactions Involving SEFE Securing Energy for Europe GmbH Prohibited by Directive 3 Under Executive Order 14024

(a) Except as provided in paragraph (b) of this general license, all transactions involving SEFE Securing Energy for Europe GmbH (formerly known as Gazprom Germania GmbH), or any entity in which SEFE Securing Energy for Europe GmbH owns, directly or indirectly, a 50 percent or greater interest, that are prohibited by Directive 3 under Executive Order 14024, *Prohibitions Related to New Debt and Equity of Certain Russia-related Entities,* are authorized through 12:01 a.m. eastern standard time, December 16, 2022.

(b) This general license does not authorize any transactions otherwise prohibited by the Russian Harmful Foreign Activities Sanctions Regulations, 31 CFR part 587 (RuHSR), including transactions involving any person blocked pursuant to the RuHSR, unless separately authorized.

(c) Effective July 14, 2022, General License No. 30, dated May 2, 2022, is replaced and superseded in its entirety by this General License No. 30A.

Andrea M. Gacki,

Director, Office of Foreign Assets Control

Dated: July 14, 2022

OFFICE OF FOREIGN ASSETS CONTROL

Russian Harmful Foreign Activities Sanctions Regulations 31 CFR Part 587

GENERAL LICENSE NO. 44

Authorizing the Export or Reexport of Certain Accounting Services to U.S. Individuals Located in the Russian Federation

(a) Except as provided in paragraph (b) of this general license, all transactions ordinarily incident and necessary to the exportation, reexportation, sale, or supply, directly or indirectly, from the United States, or by a United States person, wherever located, of tax preparation or filing services to any individual who is a United States person located in the Russian Federation, which are prohibited by section 1(a)(ii) of Executive Order 14071, are authorized.

(b) This general license does not authorize any transactions otherwise prohibited by the Russian Harmful Foreign Activities Sanctions Regulations, 31 CFR part 587 (RuHSR), including transactions involving any person blocked pursuant to the RuHSR, unless separately authorized.

Andrea M. Gacki,

Director, Office of Foreign Assets Control

Dated: July 14, 2022

Andrea M. Gacki,

Director, Office of Foreign Assets Control.

[FR Doc. 2022–17646 Filed 8–16–22; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 591

Publication of Venezuela Sanctions Regulations Web General Licenses 40 and 40A

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Publication of web general licenses.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing two general licenses (GLs) issued in the Venezuela Sanctions program: GL 40, which was previously made available on OFAC's website and is now expired, and GL 40A, which was also previously made available on OFAC's website and expires on July 12, 2023.

DATES: GL 40 was issued on July 12, 2021. GL 40A was issued on July 7, 2022. See **SUPPLEMENTARY INFORMATION** for additional relevant dates.

FOR FURTHER INFORMATION CONTACT: OFAC: Assistant Director for Licensing, 202–622–2480; Assistant Director for Regulatory Affairs, 202–622–4855; or Assistant Director for Sanctions Compliance & Evaluation, 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

This document and additional information concerning OFAC are available on OFAC's website: *www.treas.gov/ofac.*

Background

On July 12, 2021, OFAC issued GL 40 to authorize certain transactions otherwise prohibited by the Venezuela Sanctions Regulations, 31 CFR part 591. GL 40 had an expiration date of July 8, 2022. On July 7, 2022, OFAC issued GL 40A, which replaced and superseded GL 40 and has an expiration date of July 12, 2023. GLs 40 and 40A were each made available on OFAC's website (*www.treas.gov/ofac*) at the time of publication. The text of GLs 40 and 40A is provided below.

OFFICE OF FOREIGN ASSETS CONTROL

Venezuela Sanctions Regulations 31 CFR part 591

GENERAL LICENSE NO. 40

Authorizing Certain Transactions Involving the Exportation or Reexportation of Liquefied Petroleum Gas to Venezuela

(a) Except as provided in paragraph (b) of this general license, all transactions and activities related to the exportation or reexportation, directly or indirectly, of liquefied petroleum gas to Venezuela, involving the Government of Venezuela, Petróleos de Venezuela, S.A. (PdVSA), or any entity in which PdVSA owns, directly or indirectly, a 50 percent or greater interest, that are prohibited by E.O. 13850 of November 1, 2018, as amended by E.O. 13857 of January 25, 2019, or E.O. 13884 of August 5, 2019, each as incorporated into the Venezuela Sanctions Regulations, 31 CFR part 591 (the VSR), are authorized through 12:01 a.m. eastern daylight time, July 8, 2022.

(b) This general license does not authorize:

(1) Any payment-in-kind of petroleum or petroleum products; or

(2) Any transactions or activities otherwise prohibited by the VSR, prohibited by any other part of 31 CFR chapter V, or involving any blocked persons other than PdVSA, any entity in which PdVSA owns, directly or indirectly, a 50 percent or greater interest, or any Government of Venezuela person that is blocked solely pursuant to E.O. 13884.

Note to General License No. 40: Nothing in this general license relieves any persons from compliance with the requirements of other Federal agencies, including the Department of Commerce's Bureau of Industry and Security.

Andrea Gacki,

Director, Office of Foreign Assets Control

Dated: July 12, 2021

OFFICE OF FOREIGN ASSETS CONTROL

Venezuela Sanctions Regulations 31 CFR Part 591

GENERAL LICENSE NO. 40A

Authorizing Certain Transactions Involving the Exportation or Reexportation of Liquefied Petroleum Gas to Venezuela

(a) Except as provided in paragraph (b) of this general license, all transactions and activities related to the exportation or reexportation, directly or indirectly, of liquefied petroleum gas to Venezuela, involving the Government of Venezuela, Petróleos de Venezuela, S.A. (PdVSA), or any entity in which PdVSA owns, directly or indirectly, a 50 percent or greater interest, that are prohibited by E.O. 13850 of November 1, 2018, as amended by E.O. 13857 of January 25, 2019, or E.O. 13884 of August 5, 2019, each as incorporated into the Venezuela Sanctions Regulations, 31 CFR part 591 (the VSR), are authorized through 12:01 a.m. eastern daylight time, July 12, 2023.

(b) This general license does not authorize:

(1) Any payment-in-kind of petroleum or petroleum products; or

(2) Any transactions or activities otherwise prohibited by the VSR, prohibited by any other part of 31 CFR chapter V, or involving any blocked persons other than PdVSA, any entity in which PdVSA owns, directly or indirectly, a 50 percent or greater interest, or any Government of Venezuela person that is blocked solely pursuant to E.O. 13884.

(c) Effective July 7, 2022, General License No. 40, dated July 12, 2021, is replaced and superseded in its entirety by this General License No. 40A.

Note to General License No. 40A: Nothing in this general license relieves any persons from compliance with the requirements of other Federal agencies, including the Department of Commerce's Bureau of Industry and Security.

Andrea Gacki,

Director, Office of Foreign Assets Control

Dated: July 7, 2022

Andrea M. Gacki,

Director, Office of Foreign Assets Control.

[FR Doc. 2022–17645 Filed 8–16–22; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 591

Publication of Venezuela Sanctions Regulations Web General Licenses 8I and 8J

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Publication of web general licenses.

SUMMARY: The Department of the Treasury's Office of Foreign Assets

Control (OFAC) is publishing two general licenses (GLs) issued in the Venezuela Sanctions program: GL 8I, which was previously made available on OFAC's website and is now expired, and GL 8J, which was also previously made available on OFAC's website and expires on December 1, 2022.

DATES: GL 8I was issued on November 24, 2021. GL 8J was issued on May 27, 2022. See **SUPPLEMENTARY INFORMATION** for additional relevant dates.

FOR FURTHER INFORMATION CONTACT: OFAC: Assistant Director for Licensing, 202–622–2480; Assistant Director for Regulatory Affairs, 202–622–4855; or Assistant Director for Sanctions Compliance & Evaluation, 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

This document and additional information concerning OFAC are available on OFAC's website: *www.treas.gov/ofac.*

Background

On November 24, 2021, OFAC issued GL 8I to authorize certain transactions otherwise prohibited by the Venezuela Sanctions Regulations, 31 CFR part 591. GL 8I had an expiration date of June 1, 2022. On May 27, 2022, OFAC issued GL 8J, replacing and superseding GL 8I, to authorize certain transactions otherwise prohibited by the Venezuela Sanctions Regulations, 31 CFR part 591. GL 8J expires on December 1, 2022. At the time of issuance, GLs 8I and 8J each were made available on OFAC's website (*www.treas.gov/ofac*). The text of GLs 8I and 8J is provided below.

OFFICE OF FOREIGN ASSETS CONTROL

Venezuela Sanctions Regulations 31 CFR Part 591

GENERAL LICENSE NO. 8I

Authorizing Transactions Involving Petróleos de Venezuela, S.A. (PdVSA) Necessary for the Limited Maintenance of Essential Operations in Venezuela or the Wind Down of Operations in Venezuela for Certain Entities

(a) Except as provided in paragraphs (c) and (d) of this general license, all transactions and activities prohibited by Executive Order (E.O.) 13850 of November 1, 2018, as amended by E.O. 13857 of January 25, 2019, or E.O. 13884 of August 5, 2019, each as incorporated into the Venezuela Sanctions Regulations, 31 CFR part 591 (the VSR), that are ordinarily incident and necessary to the limited maintenance of essential operations, contracts, or other agreements, that: (i) are for safety or the preservation of assets in Venezuela; (ii) involve PdVSA or any entity in which PdVSA owns, directly or indirectly, a 50 percent or greater interest; and (iii) were in effect prior to July 26, 2019, are authorized through 12:01 a.m. eastern daylight time, June 1, 2022, for the following entities and their subsidiaries (collectively, the ''Covered Entities''):

- Chevron Corporation
- Halliburton
- Schlumberger Limited
- Baker Hughes Holdings LLC
- Weatherford International, Public Limited Company

Note to paragraph (a): Transactions and activities necessary for safety or the preservation of assets in Venezuela that are authorized by paragraph (a) of this general license include: transactions and activities necessary to ensure the safety of personnel, or the integrity of operations and assets in Venezuela; participation in shareholder and board of directors meetings; making payments on third-party invoices for transactions and activities authorized by paragraph (a) of this general license, or incurred prior to April 21, 2020, provided such activity was authorized at the time it occurred; payment of local taxes and purchase of utility services in Venezuela; and payment of salaries for employees and contractors in Venezuela.

(b) Except as provided in paragraph (d) of this general license, all transactions and activities prohibited by E.O. 13850, as amended, or E.O. 13884, each as incorporated into the VSR, that are ordinarily incident and necessary to the wind down of operations, contracts, or other agreements in Venezuela involving PdVSA or any entity in which PdVSA owns, directly or indirectly, a 50 percent or greater interest, and that were in effect prior to July 26, 2019, are authorized through 12:01 a.m. eastern daylight time, June 1, 2022, for the Covered Entities.

(c) Paragraph (a) of this general license does not authorize:

(1) The drilling, lifting, or processing of, purchase or sale of, or transport or shipping of any Venezuelan-origin petroleum or petroleum products;

(2) The provision or receipt of insurance or reinsurance with respect to the transactions and activities described in paragraph (c)(1) of this general license;

(3) The design, construction, installation, repair, or improvement of any wells or other facilities or infrastructure in Venezuela or the purchasing or provision of any goods or services, except as required for safety;

(4) Contracting for additional personnel or services, except as required for safety; or

(5) The payment of any dividend, including in kind, to PdVSA, or any entity in which PdVSA owns, directly or indirectly, a 50 percent or greater interest.

(d) This general license does not authorize:

(1) Any transactions or dealings related to the exportation or reexportation of diluents, directly or indirectly, to Venezuela;

(2) Any loans to, accrual of additional debt by, or subsidization of PdVSA, or any entity in which PdVSA owns, directly or indirectly, a 50 percent or greater interest, including in kind, prohibited by E.O. 13808 of August 24, 2017, as amended by E.O. 13857, and incorporated into the VSR; or

(3) Any transactions or activities otherwise prohibited by the VSR, or any other part of 31 CFR chapter V, or any transactions or activities with any blocked person other than the blocked persons identified in paragraphs (a) and (b) of this general license.

(e) Effective November 24, 2021, General License No. 8H, dated June 1, 2021, is replaced and superseded in its entirety by this General License No. 8I.

Bradley T. Smith,

Acting Director, Office of Foreign Assets Control

Dated: November 24, 2021

OFFICE OF FOREIGN ASSETS CONTROL

Venezuela Sanctions Regulations 31 CFR Part 591

GENERAL LICENSE NO. 8J

Authorizing Transactions Involving Petróleos de Venezuela, S.A. (PdVSA) Necessary for the Limited Maintenance of Essential Operations in Venezuela or the Wind Down of Operations in Venezuela for Certain Entities

(a) Except as provided in paragraphs (c) and (d) of this general license, all transactions and activities prohibited by Executive Order (E.O.) 13850 of November 1, 2018, as amended by E.O. 13857 of January 25, 2019, or E.O. 13884 of August 5, 2019, each as incorporated into the Venezuela Sanctions Regulations, 31 CFR part 591 (the VSR), that are ordinarily incident and necessary to the limited maintenance of essential operations, contracts, or other agreements, that: (i) are for safety or the preservation of assets in Venezuela; (ii) involve PdVSA or any entity in which PdVSA owns, directly or indirectly, a 50 percent or greater interest; and (iii) were in effect prior to July 26, 2019, are authorized through 12:01 a.m. eastern standard time, December 1, 2022, for the following entities and their subsidiaries (collectively, the ''Covered Entities''):

- Chevron Corporation
- Halliburton
- Schlumberger Limited
- Baker Hughes Holdings LLC
- Weatherford International, Public Limited Company

Note to paragraph (a): Transactions and activities necessary for safety or the preservation of assets in Venezuela that are authorized by paragraph (a) of this general license include: transactions and activities necessary to ensure the safety of personnel, or the integrity of operations and assets in Venezuela; participation in shareholder and board of directors meetings; making payments on third-party invoices for transactions and activities authorized by paragraph (a) of this general license, or incurred prior to April 21, 2020, provided such activity was authorized at the time it occurred; payment of local taxes and purchase of utility services in Venezuela; and payment of salaries for employees and contractors in Venezuela.

(b) Except as provided in paragraph (d) of this general license, all transactions and activities prohibited by E.O. 13850, as amended, or E.O. 13884, each as incorporated into the VSR, that are ordinarily incident and necessary to the wind down of

operations, contracts, or other agreements in Venezuela involving PdVSA or any entity in which PdVSA owns, directly or indirectly, a 50 percent or greater interest, and that were in effect prior to July 26, 2019, are authorized through 12:01 a.m. eastern standard time, December 1, 2022, for the Covered Entities.

(c) Paragraph (a) of this general license does not authorize:

(1) The drilling, lifting, or processing of, purchase or sale of, or transport or shipping of any Venezuelan-origin petroleum or petroleum products;

(2) The provision or receipt of insurance or reinsurance with respect to the transactions and activities described in paragraph (c)(1) of this general license;

(3) The design, construction, installation, repair, or improvement of any wells or other facilities or infrastructure in Venezuela or the purchasing or provision of any goods or services, except as required for safety;

(4) Contracting for additional personnel or services, except as required for safety; or

(5) The payment of any dividend, including in kind, to PdVSA, or any entity in which PdVSA owns, directly or indirectly, a 50 percent or greater interest.

(d) This general license does not authorize:

(1) Any transactions or dealings related to the exportation or reexportation of diluents, directly or indirectly, to Venezuela;

(2) Any loans to, accrual of additional debt by, or subsidization of PdVSA, or any entity in which PdVSA owns, directly or indirectly, a 50 percent or greater interest, including in kind, prohibited by E.O. 13808 of August 24, 2017, as amended by E.O. 13857, and incorporated into the VSR; or

(3) Any transactions or activities otherwise prohibited by the VSR, or any other part of 31 CFR chapter V, or any transactions or activities with any blocked person other than the blocked persons identified in paragraphs (a) and (b) of this general license.

(e) Effective May 27, 2022, General License No. 8I, dated November 24, 2021, is replaced and superseded in its entirety by this General License No. 8J.

Andrea M. Gacki,

Director, Office of Foreign Assets Control

Dated: May 27, 2022

Andrea M. Gacki,

Director, Office of Foreign Assets Control.

[FR Doc. 2022–17644 Filed 8–16–22; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 38

RIN 2900–AR43

Requesting Disinterment of an Eligible Decedent From a National Cemetery

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: The Department of Veterans Affairs (VA) is amending its regulations governing disinterment of eligible decedents interred in VA national cemeteries to clarify that, if the individual who initiated the interment does not consent to a disinterment or is not alive to provide consent, or all living immediate family members are not in agreement, anyone seeking disinterment of an eligible decedent must obtain an order from a court or State instrumentality of competent jurisdiction to direct the disinterment.

DATES: This rule is effective September 16, 2022.

FOR FURTHER INFORMATION CONTACT: Alan Amelinckx, Management and Program Analyst, National Cemetery Administration, Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420. Telephone: 202–461–5658 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: On February 9, 2022, VA published in the **Federal Register** (87 FR 7402) a proposed rule revising its regulation to clarify that disinterment from a national cemetery will be approved only when a court order or State instrumentality of competent jurisdiction directs the disinterment, or when all living immediate family members of the decedent, and the individual who initiated the interment (whether or not the individual is a member of the immediate family), give their written consent. The public comment period ended on April 11, 2022. VA received one comment that generally supported the rule but expressed concern about costs associated for claimants requesting disinterment. The commenter restated VA's Paperwork Reduction Act burden analysis and advised VA to include those costs on VA Form 40–4970, Request for Disinterment, to avoid negative outcomes for families who would incur those costs. We clarify that the burden analysis is required to justify the collection of information and inform the public of the time and cost of the public's time in providing the information. Those ''costs'' are not transferred to individuals seeking to request disinterment through the submission of VA Form 40–4970. The revision to the form, which is currently approved by the Office of Management and Budget (OMB) under OMB control number 2900–0365, will not result in any increase or decrease in respondents, respondent burden hours, or respondent burden costs. Therefore, VA makes no changes based on the comment.

Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. The Office of Information and Regulatory Affairs has determined that this rule is not a significant regulatory action under Executive Order 12866. The Regulatory Impact Analysis associated with this rulemaking can be found as a supporting document at *www.regulations.gov.*

Regulatory Flexibility Act

The Secretary hereby certifies that this final rule will have no significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act (5 U.S.C. 601–612). This certification is justified because most disinterment requests are submitted by families. Although a local court or State instrumentality may be involved if all living family members do not consent to a contemplated disinterment request, or the individual who initiated the interment does not consent to the disinterment or is not alive to provide consent, processing and adjudicating a request for disinterment as directed by a court order or State instrumentality would likely be rare and would be conducted as part of that entity's routine operations. VA cannot estimate the number of entities that may be affected by this final rule given that each disinterment case is based on the unique needs of families. Therefore, pursuant to 5 U.S.C. 605(b), the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604 do not apply.

Unfunded Mandates

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

Paperwork Reduction Act

This final rule includes provisions constituting a revised collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521) that require approval by the Office of Management and Budget (OMB). Accordingly, under 44 U.S.C. 3507(d), VA has submitted a copy of this rulemaking action to OMB for review and approval. OMB has reviewed and approved this revised collection of information and assigned OMB control number 2900–0365.

Congressional Review Act

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

List of Subjects in 38 CFR Part 38

Administrative practice and procedure, Cemeteries, Claims, Crime, Veterans.

Signing Authority

Denis McDonough, Secretary of Veterans Affairs, approved this document on August 10, 2022, and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs.

Luvenia Potts,

Regulation Development Coordinator, Office of Regulation Policy & Management, Office of General Counsel, Department of Veterans Affairs.

For the reasons set forth in the preamble, VA amends 38 CFR part 38 as set forth below:

PART 38—NATIONAL CEMETERIES OF THE DEPARTMENT OF VETERANS AFFAIRS

■ 1. The authority citation for part 38 continues to read as follows:

Authority: 38 U.S.C. 107, 501, 512, 2306, 2402, 2403, 2404, 2407, 2408, 2411, 7105.

■ 2. Revise § 38.621 to read as follows:

§ 38.621 Disinterments.

(a) Interments of eligible decedents in national cemeteries are considered permanent and final. Disinterment will be permitted only for cogent reasons and with the prior written authorization of the National Cemetery District Executive Director or Cemetery Director responsible for the cemetery involved. Disinterment from a national cemetery will be approved only when:

(1) A court order or State instrumentality of competent jurisdiction directs the disinterment; or

(2) All living immediate family members of the decedent, and the individual who initiated the interment (whether or not the individual is a member of the immediate family), give their written consent.

(i) If the individual who initiated the interment does not consent, or is not alive to provide consent, or all living immediate family members are not in agreement, anyone seeking disinterment of an eligible decedent must provide VA with an order from a court or State instrumentality of competent jurisdiction to direct the disinterment as provided in paragraph (a)(1) of this section.

(ii) For purposes of this section, ''immediate family members'' are defined as surviving spouse, whether or not he or she is or was remarried; all adult children of the decedent; the appointed guardian(s) of minor children; and the appointed guardian(s) of the surviving spouse or of the adult child(ren) of the decedent. If the surviving spouse and all of the children of the decedent are deceased, the decedent's parents will be considered ''immediate family members.''

(b)(1) All requests to disinter remains as described in paragraph (a)(2) of this section must be submitted on VA Form 40–4970, Request for Disinterment, and must include the following information:

(i) A full statement of reasons for the proposed disinterment.

(ii) Notarized statement(s) by all living immediate family members of the decedent, and by the person who initiated the interment (whether or not the individual is a member of the immediate family), that all parties consent to the proposed disinterment.

(iii) A notarized statement by the person requesting the disinterment that those who supplied affidavits comprise all the living immediate family members of the deceased and the individual who initiated the interment.

(2) If the person provides a false certification on VA Form 40–4970, he or she may be subject to penalties, to include fine or imprisonment or both.

(c) Any VA-approved disinterment in this section must be accomplished without expense to the Government.

(The reporting and recordkeeping requirements contained in paragraph (b) of this section have been approved by the Office of Management and Budget under OMB control number 2900–0365)

(Authority: 38 U.S.C. 2404)

[FR Doc. 2022–17637 Filed 8–16–22; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 141

[EPA–HQ–OW–2022–0407; FRL–9834–01–OW]

Expedited Approval of Alternative Test Procedures for the Analysis of Contaminants Under the Safe Drinking Water Act; Analysis and Sampling Procedures

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This action announces the Environmental Protection Agency's (EPA's) approval of alternative testing methods for use in measuring the levels of contaminants in drinking water to determine compliance with national primary drinking water regulations. The Safe Drinking Water Act authorizes EPA to approve the use of alternative testing methods through publication in the **Federal Register**. EPA is using this streamlined authority to make seven additional methods available for analyzing drinking water samples. This expedited approach provides public water systems, laboratories, and primacy agencies with more timely access to new measurement techniques and greater flexibility in the selection of analytical methods, thereby reducing monitoring costs while maintaining public health protection.

DATES: This action is effective August 17, 2022.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–HQ–OW–2022–0407. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Glynda Smith, Technical Support Center, Standards and Risk Management Division, Office of Ground Water and Drinking Water (MS 140), Environmental Protection Agency, 26 West Martin Luther King Drive, Cincinnati, OH 45268; telephone number: (513) 569–7652; email address: *smith.glynda@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

Public water systems are the regulated entities required to measure contaminants in drinking water samples. In addition, EPA Regions as well as States and Tribal governments with authority to administer the regulatory program for public water systems under the Safe Drinking Water Act (SDWA) may measure contaminants in water samples. When EPA sets a monitoring requirement in its national primary drinking water regulations for a given contaminant, the agency also establishes (in the regulations) standardized test procedures for analysis of the contaminant. This action makes alternative testing methods available for particular drinking water contaminants beyond the testing methods currently established in the regulations. EPA is providing public water systems, required to test water samples, with a choice of using either a test procedure already established in the existing regulations or an alternative testing method that has been approved in this action or in prior expedited approval actions. Categories and entities that may ultimately be affected by this action include:

Category	Examples of potentially regulated entities	NAICS [1]
State, local, & Tribal governments	State, local, and Tribal governments that analyze water samples on behalf of public water systems required to conduct such analysis; State, local, and Tribal governments that directly operate community and non-transient non-community water systems required to monitor.	924110
Industry	Private operators of community and non-transient non-community water systems required to monitor.	221310
Municipalities	Municipal operators of community and non-transient non-community water systems required to monitor.	924110

[1] North American Industry Classification System.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be interested in this action. Other types of entities not listed in the table could also have some interest. To determine whether your facility is affected by this action, you should carefully examine the applicability language in the *Code of Federal Regulations* (CFR) at 40 CFR 141.2 (definition of a public water system). If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

Abbreviations and Acronyms Used in This Action

CFR: *Code of Federal Regulations*
EPA: United States Environmental Protection Agency
LED: Light emitting diode
NAICS: North American Industry Classification System
QC: Quality Control
SDWA: The Safe Drinking Water Act
VCSB: Voluntary Consensus Standard Bodies

II. Background

A. What is the purpose of this action?

In this action, EPA is approving seven analytical methods for determining contaminant concentrations in drinking water samples collected under SDWA. Regulated entities required to sample and monitor may use either the testing methods already established in existing regulations or the alternative testing methods being approved in this action or in prior expedited approval actions. The new methods are listed along with other methods similarly approved through previous expedited actions in 40 CFR part 141, appendix A to subpart C and on EPA's drinking water methods website at *https://www.epa.gov/dwanalyticalmethods.*

B. What is the basis for this action?

When EPA determines that an alternative analytical method is ''equally effective'' (*i.e.,* as effective as a method that has already been promulgated in the regulations), SDWA allows EPA to approve the use of the alternative testing method through publication in the **Federal Register** (see section 1401(1) of SDWA). EPA is using this streamlined approval authority to make seven additional methods available for determining contaminant concentrations in drinking water samples collected under SDWA. EPA has determined that, for each contaminant or group of contaminants listed in section III of this preamble, the additional testing methods being approved in this action are as effective as one or more of the testing methods already approved in the regulations for those contaminants. Section 1401(1) of SDWA states that the newly approved methods ''shall be treated as an alternative for public water systems to the quality control and testing procedures listed in the regulation.'' Accordingly, this action makes these additional seven analytical methods legally available as options for meeting EPA's monitoring requirements.

This action does not add regulatory language, but does, for informational purposes, update an appendix to the regulations at 40 CFR part 141 that lists all methods approved under section 1401(1) of SDWA. Accordingly, while this action is not a rule, it is updating CFR text and therefore is being published in the ''Final Rules'' section of the **Federal Register**.

III. Summary of Approvals

EPA is approving seven methods that are equally effective relative to methods previously promulgated in the regulations. By means of this action, these seven methods are added to appendix A to subpart C of 40 CFR part 141.

A. Methods Developed by EPA

1. EPA Method 904.0, Revision 1.0. Radium-228 in Drinking Water (USEPA 2022). EPA Method 904.0 (USEPA 1980) was published in the drinking water regulations at 40 CFR 141.25(a) as an approved method for radium-228. The approved method describes a single-point calibration, contains no quality control specifications, and provides no calculation for the drinking water detection limit. EPA Method 904.0, Revision 1.0 was developed in response to comments from stakeholders requesting a method revision that provides clearly defined calibration and quality control criteria to assure a more robust procedure capable of yielding consistent and reliable analytical results. The primary analytical steps in Revision 1.0 are unchanged relative to the approved method.

The revised method contains detailed instructions on preparing an appropriate calibration curve based on the allowable yield ranges instead of relying on a single-point calibration. Assessing the efficiency based on a yield range will improve the accuracy in the final

calculated activity whereas a single-point calibration assumes that every sample will yield the same mass of solid precipitate.

The revised method contains the quality control specifications that laboratories must follow in order to obtain and maintain Method 904.0, Revision 1.0 certification to analyze drinking water compliance samples. In addition to incorporation of specific quality control requirements and acceptance criteria, the revised method contains options for yield determinations. In EPA Method 904.0, two different yields are monitored based on the precipitated products; namely, radium-228 is separated from the sample by co-precipitation with barium sulfate, then ingrown actinium-228 is separated by co-precipitation with yttrium oxalate. The currently approved method relies on gravimetric determination of the final barium sulfate precipitate to estimate the fractional yield of radium carried on the precipitate. The revised method allows the option to incorporate barium-133 as a radiochemical yield monitor. Barium-133 is a non-interfering gamma emitter that is carried through the precipitation and complexation steps along with radium-228. Incorporation of a radiochemical yield monitor provides a sensitive option to assess yield based on activity instead of mass. The currently approved method also describes preparation of a final yttrium oxalate nonahydrate precipitate to determine the fractional yield of actinium-228 carried on the precipitate. Yttrium oxalate can be precipitated in the form of several different hydrates with the predominate form dependent on the pH. This issue is not discussed in the original method and can increase variability in the yield results. The revised method discusses the importance of pH control and includes the option to convert the yttrium oxalate nonahydrate to yttrium oxide to eliminate the issue posed by the presence of multiple hydrates.

The revised method contains an expanded ''calculations'' section that includes the appropriate equation for determining the radionuclide drinking water detection limit as defined in the regulations at 40 CFR 141.25(c).

EPA has determined that EPA Method 904.0, Revision 1.0 is equally effective for determining radium-228 in drinking water samples, relative to the approved method. The basis for this determination is discussed in greater detail in Smith 2022a. Therefore, EPA is approving EPA Method 904.0, Revision 1.0 for determining radium-228 in drinking water. EPA Method 904.0, Revision 1.0 is available at the National Service Center for Environmental Publications at *https://www.epa.gov/nscep.*

B. Methods Developed by Voluntary Consensus Standard Bodies (VCSB)

1. ASTM International. EPA compared the most recent versions of three ASTM International methods to the earlier versions of those methods that are currently approved in 40 CFR part 141. Changes between the earlier approved version and the most recent version of each method are described more fully in Smith 2022b. The revisions involve primarily editorial changes (*e.g.,* updated references, definitions, terminology, procedural clarifications, and reorganization of text). The revised methods are the same as the approved versions with respect to sample collection and handling protocols, sample preparation, analytical methodology, and method performance data; thus, EPA finds they are equally effective relative to the approved methods.

EPA is thus approving the use of the following ASTM methods for the contaminants and their respective regulations listed in the following table:

ASTM revised version	Approved method	Contaminant(s)	Regulation citations
D 4785–20 (ASTM 2020a)	D 4785–00 (ASTM 2000)	Radioactive iodine, gamma emitters	40 CFR 141.25(a).
D 4107–20 (ASTM 2020b)	D 4107–98 (ASTM 1998a)	Tritium	40 CFR 141.25(a).
D 5317–20 (ASTM 2020c)	D 5317–98 (ASTM 1998b)	2,4-D, Pentachlorophenol, Picloram, 2,4,5-TP	40 CFR 141.24(e)(1).

The ASTM methods are available from ASTM International, 100 Barr Harbor Drive, West Conshohocken, PA 19428–2959 or *https://www.astm.org.*

C. Methods Developed by Vendors

1. Tintometer Lovibond TB 3500 Method—Measurement of Drinking Water Turbidity of a Captured Sample Using a Lovibond White Light LED Portable Turbidimeter (Tintometer 2021a). The Tintometer Lovibond TB 3500 Method uses white light emitting diode (LED) nephelometry in a portable turbidimeter to measure turbidity in drinking water. The LED emits white light in the visible spectrum between 380 nm and 780 nm, with spectral peak response between 400 nm and 600 nm. The method is based on a comparison of the intensity of light scattered by a drinking water sample under defined conditions with the intensity of light scattered by a standard reference suspension.

Approved methods for turbidity are listed at 40 CFR 141.74(a)(1). The performance characteristics of the Lovibond TB 3500 Method were compared to the performance characteristics of the approved Hach FilterTrak Method 10133 (Hach Company 2000) and continuous online process Tintometer Lovibond PTV 1000 method (Tintometer 2016a). The validation study report (Tintometer 2021b) summarizes the results obtained from the turbidimeters tested at three different utilities. Each utility used surface water sources, but different treatment technologies. Method precision, bias, linearity, limits of detection, and reporting limits were determined at the first site, with subsequent sites being used for direct ATP candidate-, reference-, and process-method comparability.

EPA has determined that the Lovibond TB 3500 Method is equally effective relative to Hach FilterTrak Method 10133. The basis for this determination is discussed in Adams 2022a. Therefore, EPA is approving the Lovibond TB 3500 Method for determining turbidity in drinking water. A copy of the method is available from Tintometer, Inc., 6456 Parkland Drive, Sarasota, FL 34243.

2. Tintometer Lovibond TB 5000 Method—Measurement of Drinking Water Turbidity of a Captured Sample Using a Lovibond 660-nm LED Portable Turbidimeter (Tintometer 2021c). The Tintometer Lovibond TB 5000 Method uses light emitting diode (LED) nephelometry in a portable turbidimeter to measure turbidity in drinking water. The LED emits 660-nm light to reduce interferences due to dissolved organics and sample color. The method is based on a comparison of the intensity of light scattered by a drinking water sample under defined conditions with the intensity of light scattered by a standard reference suspension.

Approved methods for turbidity are listed at 40 CFR 141.74(a)(1). The

performance characteristics of the Lovibond TB 5000 Method were compared to the performance characteristics of the approved Hach FilterTrak Method 10133 (Hach Company 2000) and continuous online process Tintometer Lovibond PTV 2000 method (Tintometer 2016b). The validation study report (Tintometer 2021b) summarizes the results obtained from the turbidimeters placed online at three different utilities. Each utility used surface water sources, but different treatment technologies. Method precision, bias, linearity, limits of detection, and reporting limits were determined at the first site, with subsequent sites being used for direct ATP candidate-, reference-, and process-method comparability.

EPA has determined that the Lovibond TB 5000 Method is equally effective relative to Hach FilterTrak Method 10133. The basis for this determination is discussed in Adams 2022b. Therefore, EPA is approving the Lovibond TB 5000 Method for determining turbidity in drinking water. A copy of the method is available from Tintometer, Inc., 6456 Parkland Drive, Sarasota, FL 34243.

3. Tintometer Lovibond TB 6000 Method—Measurement of Drinking Water Turbidity of a Captured Sample Using a Lovibond Portable Laser Turbidimeter (Tintometer 2021d). The Tintometer Lovibond TB 6000 Method uses laser nephelometry in a portable turbidimeter to measure turbidity in drinking water. The method uses a laser diode with a peak emitting center wavelength between 650 nm and 690 nm. The method is based on a comparison of the intensity of light scattered by a drinking water sample under defined conditions with the intensity of light scattered by a standard reference suspension.

Approved methods for turbidity are listed at 40 CFR 141.74(a)(1). The performance characteristics of the Lovibond TB 6000 Method were compared to the performance characteristics of the approved Hach FilterTrak Method 10133 (Hach Company 2000) and continuous online process Tintometer Lovibond PTV 6000 method (Tintometer 2016c). The validation study report (Tintometer 2021b) summarizes the results obtained from the turbidimeters placed online at three different utilities. Each utility used surface water sources, but different treatment technologies. Method precision, bias, linearity, limits of detection, and reporting limits were determined at the first site, with subsequent sites being used for direct ATP candidate-, reference-, and process-method comparability.

EPA has determined that the Lovibond TB 6000 Method is equally effective relative to Hach Filter TrakMethod 10133. The basis for this determination is discussed in Adams 2022c. Therefore, EPA is approving the Lovibond TB 6000 Method for determining turbidity in drinking water. A copy of the method is available from Tintometer, Inc., 6456 Parkland Drive, Sarasota, FL 34243.

IV. Statutory and Executive Order Reviews

As noted in section II of this preamble, under the terms of SDWA section 1401(1), this streamlined method approval action is not a rule. Accordingly, the Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, does not apply because this action is not a rule for purposes of 5 U.S.C. 804(3). Similarly, this action is not subject to the Regulatory Flexibility Act because it is not subject to notice and comment requirements under the Administrative Procedure Act or any other statute. In addition, because this approval action is not a rule, but simply makes alternative testing methods available as options for monitoring under SDWA, EPA has concluded that other statutes and executive orders generally applicable to rulemaking do not apply to this approval action.

V. References

Adams, W. 2022a. Memo to the record describing basis for expedited approval of Tintometer Lovibond TB 3500 turbidimeter. February 9, 2022. (Available at *https://www.regulations.gov;* docket ID No. EPA–HQ–OW–2022–0407.)

Adams, W. 2022b. Memo to the record describing basis for expedited approval of Tintometer Lovibond TB 5000 turbidimeter. February 9, 2022. (Available at *https://www.regulations.gov;* docket ID No. EPA–HQ–OW–2022–0407.)

Adams, W. 2022c. Memo to the record describing basis for expedited approval of Tintometer Lovibond TB 6000 turbidimeter. February 9, 2022. (Available at *https://www.regulations.gov;* docket ID No. EPA–HQ–OW–2022–0407.)

ASTM International. 1998a. ASTM D 4107–98. Standard Test Method for Tritium in Drinking Water. ASTM International, 100 Barr Harbor Drive, West Conshohocken, PA 19428–2959. (Available at *https://www.astm.org.*)

ASTM International. 1998b. ASTM D 5317–98. Standard Test Method for Determination of Chlorinated Organic Acid Compounds in Water by Gas Chromatography with an Electron Capture Detector. ASTM International, 100 Barr Harbor Drive, West Conshohocken, PA 19428–2959. (Available at *https://www.astm.org.*)

ASTM International. 2000. ASTM D 4785–00. Standard Test Method for Low-Level Analysis of Iodine Radioisotopes in Water. ASTM International, 100 Barr Harbor Drive, West Conshohocken, PA 19428–2959. (Available at *https://www.astm.org.*)

ASTM International. 2020a. ASTM D 4785–20. Standard Test Method for Low-Level Analysis of Iodine Radioisotopes in Water. ASTM International, 100 Barr Harbor Drive, West Conshohocken, PA 19428–2959. (Available at *https://www.astm.org.*)

ASTM International. 2020b. ASTM D 4107–20. Standard Test Method for Tritium in Drinking Water. ASTM International, 100 Barr Harbor Drive, West Conshohocken, PA 19428–2959. (Available at *https://www.astm.org.*)

ASTM International. 2020c. ASTM D 5317–20. Standard Test Method for Determination of Chlorinated Organic Acid Compounds in Water by Gas Chromatography with an Electron Capture Detector. ASTM International, 100 Barr Harbor Drive, West Conshohocken, PA 19428–2959. (Available at *https://www.astm.org.*)

Hach Company. 2000. Hach FilterTrak Method 10133. Determination of Turbidity by Laser Nephelometry. January 2000, Revision 2.0. Hach Company, 5600 Lindbergh Drive, Loveland, Colorado 80539. (Available at *http://www.regulations.gov;* docket ID No. EPA–HQ–OW–2022–0407.)

Smith, G. 2022a. Memo to the record describing basis for expedited approval of EPA Method 904.0, Revision 1.0. January 10, 2022. (Available at *http://www.regulations.gov;* docket ID No. EPA–HQ–OW–2022–0407.)

Smith, G. 2022b. Memo to the record describing basis for expedited approval of updated methods from ASTM International. January 5, 2022. (Available at *https://www.regulations.gov;* docket ID No. EPA–HQ–OW–2022–0407.)

Tintometer 2016a. Continuous Measurement of Drinking Water Turbidity using a Lovibond PTV 1000 White Light LED Turbidimeter—The Lovibond White Light Method. December 2016. Revision 1.0. Tintometer, Inc. 6456 Parkland Drive, Sarasota, FL 34243. (Available at *https://www.regulations.gov;* docket ID No. EPA–HQ–OW–2022–0407.)

Tintometer 2016b. Continuous Measurement of Drinking Water Turbidity using a Lovibond PTV 2000 660-nm LED Turbidimeter—The Lovibond 660-nm LED Method. December 2016. Revision 1.0. Tintometer, Inc. 6456 Parkland Drive, Sarasota, FL 34243. (Available at *https://www.regulations.gov;* docket ID No. EPA–HQ–OW–2022–0407.)

Tintometer 2016c. Continuous Measurement of Drinking Water Turbidity using a Lovibond PTV 6000 Laser Turbidimeter—The Lovibond 6000 Laser

Method. December 2016. Revision 1.0. Tintometer, Inc. 6456 Parkland Drive, Sarasota, FL 34243. (Available at *https://www.regulations.gov;* docket ID No. EPA–HQ–OW–2022–0407.)
Tintometer 2021a. Lovibond TB 3500: Measurement of a Captured Sample using a Lovibond White Light LED Portable Turbidimeter. May 2021. Revision 1.0. Tintometer, Inc. 6456 Parkland Drive, Sarasota, FL 34243. (Available at *https://www.regulations.gov;* docket ID No. EPA–HQ–OW–2022–0407.)
Tintometer 2021b. Alternate Test Procedure (ATP) Validation Study Report for the Measurement of Drinking Water Turbidity up to 10 NTU using the Lovibond Portable Turbidimeter Methods. April 26, 2021. Tintometer, Inc. 6456 Parkland Drive, Sarasota, FL 34243. (Available at *https://www.regulations.gov;* docket ID No. EPA–HQ–OW–2022–0407.)
Tintometer 2021c. Lovibond TB 5000: Measurement of Drinking Water Turbidity of a Captured Sample using a Lovibond 660-nm LED Portable Turbidimeter. May 2021. Revision 1.0. Tintometer, Inc. 6456 Parkland Drive, Sarasota, FL 34243. (Available at *https://www.regulations.gov;* docket ID No. EPA–HQ–OW–2022–0407.)
Tintometer 2021d. Lovibond TB 6000: Measurement of Drinking Water Turbidity of a Captured Sample using a Lovibond Portable Laser Turbidimeter. May 2021. Revision 1.0. Tintometer, Inc. 6456 Parkland Drive, Sarasota, FL 34243. (Available at *https://www.regulations.gov;* docket ID No. EPA–HQ–OW–2022–0407.)
USEPA. 1980. EPA Method 904.0. Radium-228 in Drinking Water in ''Prescribed Procedures for Measurement of Radioactivity in Drinking Water,'' EPA–600/4–80–032, August 1980. (Available at *https://www.regulations.gov;* docket ID No. EPA–HQ–OW–2022–0407.)
USEPA. 2022. EPA Method 904.0, Revision 1.0. Radium-228 in Drinking Water. EPA 815–B–22–003. March 2022. (Available at *https://www.regulations.gov;* docket ID No. EPA–HQ–OW–2022–0407.)

List of Subjects in 40 CFR Part 141

Environmental protection, Chemicals, Indians—lands, Intergovernmental relations, Reporting and recordkeeping requirements, Water supply.

Jennifer L. McLain,

Director, Office of Ground Water and Drinking Water.

For the reasons stated in the preamble, the Environmental Protection Agency amends 40 CFR part 141 as follows:

PART 141—NATIONAL PRIMARY DRINKING WATER REGULATIONS

■ 1. The authority citation for part 141 continues to read as follows:

Authority: 42 U.S.C. 300f, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–4, 300j–9, and 300j–11.

■ 2. Amend appendix A to subpart C of Part 141 by:

■ a. Revise the table entitled ''ALTERNATIVE TESTING METHODS FOR CONTAMINANTS LISTED AT 40 CFR 141.24(e)(1)'';

■ b. In the table entitled ''ALTERNATIVE TESTING METHODS FOR CONTAMINANTS LISTED AT 40 CFR 141.25(a)'' revise the entries for ''Radium 228,'' ''Radioactive Iodine,'' ''Tritium,'' and ''Gamma Emitters'';

■ c. In the table entitled ''ALTERNATIVE TESTING METHODS FOR CONTAMINANTS LISTED AT 40 CFR 141.74(a)(1)'' revise the entry for ''Turbidity'';

■ d. Revise footnotes ''7'', ''10'', ''11'', ''12'', ''15'', ''18'', ''19'', ''27'', ''30'', ''47'', and ''50''; and,

■ e. Add footnotes 62 through 65.

The revisions and additions read as follows:

APPENDIX A TO SUBPART C OF PART 141—ALTERNATIVE TESTING METHODS APPROVED FOR ANALYSES UNDER THE SAFE DRINKING WATER ACT

* * * * *

ALTERNATIVE TESTING METHODS FOR CONTAMINANTS LISTED AT 40 CFR 141.24 (e)(1)

Contaminant	Methodology	EPA method	SM 21st edition [1]	SM 22nd edition,[28] SM 23rd edition [49]	SM Online [3]	ASTM [4]	Other
Benzene	Purge &Trap/Gas Chromatography/Mass Spectrometry.	[9] 524.3, [29] 524.4.					
Carbon tetrachloride.	Purge &Trap/Gas Chromatography/Mass Spectrometry.	[9] 524.3, [29] 524.4.					
Chlorobenzene	Purge &Trap/Gas Chromatography/Mass Spectrometry.	[9] 524.3, [29] 524.4.					
1,2-Dichlorobenzene.	Purge &Trap/Gas Chromatography/Mass Spectrometry.	[9] 524.3, [29] 524.4.					
1,4-Dichlorobenzene.	Purge &Trap/Gas Chromatography/Mass Spectrometry.	[9] 524.3, [29] 524.4.					
1,2-Dichloroethane	Purge &Trap/Gas Chromatography/Mass Spectrometry.	[9] 524.3, [29] 524.4.					
cis-Dichloroethylene.	Purge &Trap/Gas Chromatography/Mass Spectrometry.	[9] 524.3, [29] 524.4.					
trans-Dichloroethylene.	Purge &Trap/Gas Chromatography/Mass Spectrometry.	[9] 524.3, [29] 524.4.					
Dichloromethane	Purge &Trap/Gas Chromatography/Mass Spectrometry.	[9] 524.3, [29] 524.4.					

ALTERNATIVE TESTING METHODS FOR CONTAMINANTS LISTED AT 40 CFR 141.24 (e)(1)—Continued

Contaminant	Methodology	EPA method	SM 21st edition [1]	SM 22nd edition,[28] SM 23rd edition [49]	SM Online [3]	ASTM [4]	Other
1,2-Dichloropropane.	Purge &Trap/Gas Chromatography/Mass Spectrometry.	[9] 524.3, [29] 524.4.					
Ethylbenzene	Purge &Trap/Gas Chromatography/Mass Spectrometry.	[9] 524.3, [29] 524.4.					
Styrene	Purge &Trap/Gas Chromatography/Mass Spectrometry.	[9] 524.3, [29] 524.4.					
Tetrachloroethylene.	Purge &Trap/Gas Chromatography/Mass Spectrometry.	[9] 524.3, [29] 524.4.					
1,1,1-Trichloroethane.	Purge &Trap/Gas Chromatography/Mass Spectrometry.	[9] 524.3, [29] 524.4.					
Trichloroethylene	Purge &Trap/Gas Chromatography/Mass Spectrometry.	[9] 524.3, [29] 524.4.					
Toluene	Purge &Trap/Gas Chromatography/Mass Spectrometry.	[9] 524.3, [29] 524.4.					
1,2,4-Trichlorobenzene.	Purge &Trap/Gas Chromatography/Mass Spectrometry.	[9] 524.3, [29] 524.4.					
1,1-Dichloroethylene.	Purge &Trap/Gas Chromatography/Mass Spectrometry.	[9] 524.3, [29] 524.4.					
1,1,2-Trichlorethane.	Purge &Trap/Gas Chromatography/Mass Spectrometry.	[9] 524.3, [29] 524.4.					
Vinyl chloride	Purge &Trap/Gas Chromatography/Mass Spectrometry.	[9] 524.3, [29] 524.4.					
Xylenes (total)	Purge &Trap/Gas Chromatography/Mass Spectrometry.	[9] 524.3, [29] 524.4.					
2,4-D	Gas Chromatography/Electron Capture Detection (GC/ECD).		6640 B	6640 B	6640 B–01, B–06	D 5317–20.	
2,4,5-TP (Silvex)	Gas Chromatography/Electron Capture Detection (GC/ECD).		6640 B	6640 B	6640 B–01, B–06	D 5317–20.	
Alachlor	Solid Phase Extraction/Gas Chromatography/Mass Spectrometry (GC/MS).	[24] 525.3.					
Atrazine	Liquid Chromatography Electrospray Ionization Tandem Mass Spectrometry (LC/ESI–MS/MS).	[25] 536.					
	Solid Phase Extraction/Gas Chromatography/Mass Spectrometry (GC/MS)	[24] 525.3, [26] 523.					

ALTERNATIVE TESTING METHODS FOR CONTAMINANTS LISTED AT 40 CFR 141.24 (e)(1)—Continued

Contaminant	Methodology	EPA method	SM 21st edition [1]	SM 22nd edition,[28] SM 23rd edition [49]	SM Online [3]	ASTM [4]	Other
Benzo(a)pyrene	Solid Phase Extraction/Gas Chromatography/Mass Spectrometry (GC/MS).	[24] 525.3.					
Carbofuran	High-performance liquid chromatography (HPLC) with post-column derivatization and fluorescence detection.		6610 B	6610 B	6610 B–04.		
	Liquid Chromatography/Mass Spectrometry.						[58] ME 531
Chlordane	Solid Phase Extraction/Gas Chromatography/Mass Spectrometry (GC/MS).	[24] 525.3					
Dalapon	Ion Chromatography Electrospray Ionization Tandem Mass Spectrometry (IC–ESI–MS/MS).	[14] 557.					
	Gas Chromatography/Electron Capture Detection (GC/ECD).		6640 B	6640 B	6640 B–01, B–06.		
Di(2-ethylhexyl)adipate.	Solid Phase Extraction/Gas Chromatography/Mass Spectrometry (GC/MS).	[24] 525.3.					
Di(2-ethylhexyl)phthalate.	Solid Phase Extraction/Gas Chromatography/Mass Spectrometry (GC/MS).	[24] 525.3.					
Dibromochloropropane (DBCP).	Purge &Trap/Gas Chromatography/Mass Spectrometry.	[9] 524.3.					
Dinoseb	Gas Chromatography/Electron Capture Detection (GC/ECD).		6640 B	6640 B	6640 B–01, B–06.		
Endrin	Solid Phase Extraction/Gas Chromatography/Mass Spectrometry (GC/MS).	[24] 525.3.					
Ethyl dibromide (EDB).	Purge &Trap/Gas Chromatography/Mass Spectrometry.	[9] 524.3.					
Glyphosate	High-Performance Liquid Chromatography (HPLC) with Post-Column Derivatization and Fluorescence Detection.		6651 B	6651 B	6651 B–00, B–05.		

ALTERNATIVE TESTING METHODS FOR CONTAMINANTS LISTED AT 40 CFR 141.24 (e)(1)—Continued

Contaminant	Methodology	EPA method	SM 21st edition [1]	SM 22nd edition,[28] SM 23rd edition [49]	SM Online [3]	ASTM [4]	Other
Heptachlor	Solid Phase Extraction/Gas Chromatography/Mass Spectrometry (GC/MS).	[24] 525.3.					
Heptachlor Epoxide.	Solid Phase Extraction/Gas Chromatography/Mass Spectrometry (GC/MS).	[24] 525.3.					
Hexachlorobenzene.	Solid Phase Extraction/Gas Chromatography/Mass Spectrometry (GC/MS).	[24] 525.3.					
Hexachlorocyclopentadiene.	Solid Phase Extraction/Gas Chromatography/Mass Spectrometry (GC/MS).	[24] 525.3.					
Lindane	Solid Phase Extraction/Gas Chromatography/Mass Spectrometry (GC/MS).	[24] 525.3.					
Methoxychlor	Solid Phase Extraction/Gas Chromatography/Mass Spectrometry (GC/MS).	[24] 525.3.					
Oxamyl	High-performance liquid chromatography (HPLC) with post-column derivatization and fluorescence detection.		6610 B	6610 B	6610 B–04.		
	Liquid Chromatography/Mass Spectrometry.						[58] ME 531.
PCBs (as Aroclors)	Solid Phase Extraction/Gas Chromatography/Mass Spectrometry (GC/MS).	[24] 525.3.					
Pentachlorophenol	Gas Chromatography/Electron Capture Detection (GC/ECD).		6640 B	6640 B	6640 B–01, B–06	D 5317–20.	
	Solid Phase Extraction/Gas Chromatography/Mass Spectrometry (GC/MS).	[24] 525.3.					
Picloram	Gas Chromatography/Electron Capture Detection (GC/ECD).		6640 B	6640 B	6640 B–01, B–06	D 5317–20.	
Simazine	Liquid Chromatography Electrospray Ionization Tandem Mass Spectrometry (LC/ESI–MS/MS).	[25] 536.					

ALTERNATIVE TESTING METHODS FOR CONTAMINANTS LISTED AT 40 CFR 141.24 (e)(1)—Continued

Contaminant	Methodology	EPA method	SM 21st edition [1]	SM 22nd edition,[28] SM 23rd edition [49]	SM Online [3]	ASTM [4]	Other
	Solid Phase Extraction/Gas Chromatography/Mass Spectrometry (GC/MS).	[24] 525.3, [26] 523.					
Toxaphene	Solid Phase Extraction/Gas Chromatography/Mass Spectrometry (GC/MS).	[24] 525.3.					
Total Trihalomethanes.	Purge &Trap/Gas Chromatography/Mass Spectrometry.	[9] 524.3, [29] 524.4.					

ALTERNATIVE TESTING METHODS FOR CONTAMINANTS LISTED AT 40 CFR 141.25(a)

Contaminant	Methodology	EPA method	SM 21st edition [1]	SM 22nd edition,[28] SM 23rd edition [49]	ASTM [4]	SM Online [3]
*	*	*	*	*	*	*
Radium 228	Radiochemical	904.0, Rev. 1.0 [62]	7500–Ra D	7500–Ra D.		
	Gamma Spectrometry.			7500–Ra E		7500–Ra E–07.
*	*	*	*	*	*	*
Radioactive Iodine	Radiochemical		7500–I B, 7500–I C, 7500–I D.	7500–I B, 7500–I C, 7500–I D.	D 3649–06.	
	Gamma Ray Spectrometry.		7120	7120	D 4785–08, –20.	
*	*	*	*	*	*	*
Tritium	Liquid Scintillation		7500–^{3} H B	7500–^{3} H B	D 4107–08, –20	
Gamma Emitters	Gamma Ray Spectrometry.		7120, 7500–Cs B, 7500–I B.	7120, 7500–Cs B, 7500–I B.	D 3649–06, D 4785–08, –20.	

ALTERNATIVE TESTING METHODS FOR CONTAMINANTS LISTED AT 40 CFR 141.74(a)(1)

Organism	Methodology	SM 21st edition [1]	SM 22nd edition [28]	SM 23rd edition [49]	SM online [3]	Other
*	*	*	*	*	*	*
Turbidity	Nephelometric Method.	2130 B	2130 B	2130 B		Hach Method 8195, Rev. 3.0.[52]
	Laser Nephelometry (on-line).					Mitchell M5271,[10] Mitchell M5331, Rev. 1.2,[42] Lovibond PTV 6000.[46]
	LED Nephelometry (on-line).					Mitchell M5331,[11] Mitchell M5331, Rev. 1.2 [42], Lovibond PTV 2000.[45]
	LED Nephelometry (on-line).					AMI Turbiwell,[15] Lovibond PTV 1000.[44]
	LED Nephelometry (portable).					Orion AQ4500,[12] Lovibond TB 3500,[64] Lovibond TB 5000.[65]
	Laser Nephelometry (portable).					Lovibond TB 6000 [63].
	360° Nephelometry					Hach Method 10258, Rev. 1.0,[39] Hach Method 10258, Rev. 2.0.[51]

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[1] *Standard Methods for the Examination of Water and Wastewater,* 21st edition (2005). Available from American Public Health Association, 800 I Street NW, Washington, DC 20001–3710.

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[3] Standard Methods Online are available at *http://www.standardmethods.org.* The year in which each method was approved by the Standard Methods Committee is designated by the last two digits in the method number. The methods listed are the only online versions that may be used.

[4] Available from ASTM International, 100 Barr Harbor Drive, West Conshohocken, PA 19428–2959 or *http://astm.org.* The methods listed are the only alternative versions that may be used.

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[7] Method ME355.01, Revision 1.0. ''Determination of Cyanide in Drinking Water by GC/MS Headspace,'' May 26, 2009. Available at *https://www.nemi.gov* or from James Eaton, H & E Testing Laboratory, 221 State Street, Augusta, ME 04333. (207) 287–2727.

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[9] EPA Method 524.3, Version 1.0. ''Measurement of Purgeable Organic Compounds in Water by Capillary Column Gas Chromatography/Mass Spectrometry.'' June 2009. EPA 815–B–09–009. Available at *https://www.nemi.gov.*

[10] Mitchell Method M5271, Revision 1.1. ''Determination of Turbidity by Laser Nephelometry,'' March 5, 2009. Available at *https://www.nemi.gov* or from Leck Mitchell, Ph.D., PE, 656 Independence Valley Dr., Grand Junction, CO 81507.

[11] Mitchell Method M5331, Revision 1.1. ''Determination of Turbidity by LED Nephelometry,'' March 5, 2009. Available at *https://www.nemi.gov* or from Leck Mitchell, Ph.D., PE, 656 Independence Valley Dr., Grand Junction, CO 81507.

[12] Orion Method AQ4500, Revision 1.0. ''Determination of Turbidity by LED Nephelometry,'' May 8, 2009. Available at *https://www.nemi.gov* or from Thermo Scientific, 166 Cummings Center, Beverly, MA 01915, *http://www.thermo.com.*

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[14] EPA Method 557. ''Determination of Haloacetic Acids, Bromate, and Dalapon in Drinking Water by Ion Chromatography Electrospray Ionization Tandem Mass Spectrometry (IC–ESI–MS/MS),'' September 2009. EPA 815–B–09–012. Available at *https://www.nemi.gov.*

[15] AMI Turbiwell, ''Continuous Measurement of Turbidity Using a SWAN AMI Turbiwell Turbidimeter,'' August 2009. Available at *https://www.nemi.gov* or from Markus Bernasconi, SWAN Analytische Instrumente AG, Studbachstrasse 13, CH–8340 Hinwil, Switzerland.

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[18] EPA Method 302.0. ''Determination of Bromate in Drinking Water using Two-Dimensional Ion Chromatography with Suppressed Conductivity Detection,'' September 2009. EPA 815–B–09–014. Available at *https://www.nemi.gov.*

[19] EPA 415.3, Revision 1.2. ''Determination of Total Organic Carbon and Specific UV Absorbance at 254 nm in Source Water and Drinking Water,'' September 2009. EPA/600/R–09/122. Available at *http://www.epa.gov/water-research/epa-drinking-water-research-methods.*

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[24] EPA Method 525.3. ''Determination of Semivolatile Organic Chemicals in Drinking Water by Solid Phase Extraction and Capillary Column Gas Chromatography/Mass Spectrometry (GC/MS).'' February 2012. EPA/600/R–12/010. Available at *http://www.epa.gov/water-research/epa-drinking-water-research-methods.*

[25] EPA Method 536. ''Determination of Triazine Pesticides and their Degradates in Drinking Water by Liquid Chromatography Electrospray Ionization Tandem Mass Spectrometry (LC/ESI–MS/MS).'' October 2007. EPA 815–B–07–002. Available at the National Service Center for Environmental Publications at *https://www.epa.gov/nscep.*

[26] EPA Method 523. ''Determination of Triazine Pesticides and their Degradates in Drinking Water by Gas Chromatography/Mass Spectrometry (GC/MS).'' February 2011. EPA 815–R–11–002. Available at the National Service Center for Environmental Publications at *https://www.epa.gov/nscep.*

[27] EPA Method 1623.1. ''*Cryptosporidium* and *Giardia* in Water by Filtration/IMS/FA,'' 2012. EPA–816–R–12–001. Available at the National Service Center for Environmental Publications at *https://www.epa.gov/nscep.*

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[29] EPA Method 524.4, Version 1.0. ''Measurement of Purgeable Organic Compounds in Water by Gas Chromatography/Mass Spectrometry using Nitrogen Purge Gas.'' May 2013. EPA 815–R–13–002. Available at the National Service Center for Environmental Publications at *https://www.epa.gov/nscep.*

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[39] Hach Company. ''Hach Method 10258—Determination of Turbidity by 360° Nephelometry,'' January 2016. Revision 1.0. 5600 Lindbergh Drive, P.O. Box 389, Loveland, CO 80539.

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[42] Mitchell Method M5331, Revision 1.2. ''Determination of Turbidity by LED or Laser Nephelometry,'' February 2016. Available from Leck Mitchell, Ph.D., PE, 656 Independence Valley Dr., Grand Junction, CO 81507.

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[44] Lovibond PTV 1000. ''Continuous Measurement of Drinking Water Turbidity using a Lovibond PTV 1000 White Light LED Turbidimeter,'' December 2016. Revision 1.0. Available from Tintometer, Inc., 6456 Parkland Drive, Sarasota, FL 34243.

[45] Lovibond PTV 2000. ''Continuous Measurement of Drinking Water Turbidity Using a Lovibond PTV 2000 660-nm LED Turbidimeter,'' December 2016. Revision 1.0. Available from Tintometer, Inc., 6456 Parkland Drive, Sarasota, FL 34243.

[46] Lovibond PTV 6000. ''Continuous Measurement of Drinking Water Turbidity Using a Lovibond PTV 6000 Laser Turbidimeter,'' December 2016. Revision 1.0. Available from Tintometer, Inc., 6456 Parkland Drive, Sarasota, FL 34243.

[47] Thermo Fisher. ''Thermo Fisher method 557.1: Determination of Haloacetic Acids in Drinking Water using Two-Dimensional Ion Chromatography with Suppressed Conductivity Detection,'' January 2017. Version 1.0. Available from Thermo Fisher Scientific, 490 Lakeside Dr., Sunnyvale, CA 94085 (*Richard.jack@thermofisher.com*).

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[49] *Standard Methods for the Examination of Water and Wastewater,* 23rd edition (2017). Available from American Public Health Association, 800 I Street NW, Washington, DC 20001–3710.

[50] EPA Method 900.0, Rev. 1.0. ''Determination of Gross Alpha and Gross Beta in Drinking Water,'' February 2018. EPA 815–B–18–002. Available at the National Service Center for Environmental Publications at *https://www.epa.gov/nscep.*

[51] Hach Company. ''Hach Method 10258—Determination of Turbidity by 360° Nephelometry.'' March 2018. Revision 2.0. 5600 Lindbergh Drive, P.O. Box 389, Loveland, CO 80539.

[52] Hach Company. ''Hach Method 8195—Determination of Turbidity by Nephelometry.'' March 2018. Revision 3.0. 5600 Lindbergh Drive, P.O. Box 389, Loveland, CO 80539.

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[58] ME 531, Version 1.0. ''Measurement of N-Methylcarbamoyloximes and N-Methylcarbamates in Drinking Water by LC–MS/MS. September 2019. Maine Health Environmental Testing Laboratory, 221 State Street, Augusta, ME 04330.

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[62] EPA Method 904.0, Rev. 1.0. ''Radium-228 in Drinking Water.'' March 2022. EPA 815–B–22–003. Available at the National Service Center for Environmental Publications at *https://www.epa.gov/nscep.*

[63] Lovibond TB 6000. ''Measurement of Drinking Water Turbidity of a Captured Sample using a Lovibond Portable Laser Turbidimeter.'' May 2021. Revision 1.0. Available from Tintometer, Inc., 6456 Parkland Drive, Sarasota, FL 34243.

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[FR Doc. 2022–17651 Filed 8–16–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[EPA–HQ–SFUND–1990–0010, EPA–HQ–SFUND–1994–0001, EPA–HQ–SFUND–2002–0008, EPA–HQ–SFUND–2003–0010, EPA–HQ–OLEM–2021–0797, EPA–HQ–OLEM–2021–0798, EPA–HQ–OLEM–2021–0815, EPA–HQ–OLEM–2021–0922, EPA–HQ–OLEM–2021–0934, EPA–HQ–OLEM–2022–0111; FRL–10018–01–OLEM]

Deletion From the National Priorities List

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) announces the deletion of four sites and the partial deletion of six sites from the Superfund National Priorities List (NPL). The NPL, created under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, is an appendix of the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). The EPA and the states, through their designated state agencies, have determined that all appropriate response actions under CERCLA, other than operation and maintenance, monitoring, and five-year reviews, where applicable, have been completed. However, this deletion does

not preclude future actions under Superfund.

DATES: The document is effective on August 17, 2022.

ADDRESSES: *Docket:* EPA has established a docket for this action under the Docket Identification included in Table 1 in the **SUPPLEMENTARY INFORMATION** section of this document. All documents in the docket are listed on the *https://www.regulations.gov* website. The Final Close-Out Report (FCOR, for a full site deletion) or the Partial Deletion Justification (PDJ, for a partial site deletion) is the primary document which summarizes site information to support the deletion. It is typically written for a broad, non-technical audience and this document is included in the deletion docket for each of the 10 sites in this rulemaking. Although listed in the index, some information is not publicly available, *i.e.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Docket materials are available through *https://www.regulations.gov* or at the corresponding Regional Records Centers. Locations, addresses, and phone numbers-of the Regional Records Center follows.

- Region 1 (CT, ME, MA, NH, RI, VT), U.S. EPA New England, EMS Records and Information Center, 5 Post Office Square, Suite 100, Boston, MA 02109–3912; 617/918–1440.
- Region 3 (DE, DC, MD, PA, VA, WV), U.S. EPA, Library, 1650 Arch Street, Mail code 3MD13, Philadelphia, PA 19103; 215/814–3024.
- Region 4 (AL, FL, GA, KY, MS, NC, SC, TN), U.S. EPA, 61 Forsyth Street SW, Mail code 9T25, Atlanta, GA 30303; 404/562–8637.
- Region 5 (IL, IN, MI, MN, OH, WI), U.S. EPA Superfund Division Records Manager, Mail code SRC–7J, Metcalfe Federal Building, 7th Floor South, 77 West Jackson Boulevard, Chicago, IL 60604; 312/886–4465.
- Region 7 (IA, KS, MO, NE), U.S. EPA, 11201 Renner Blvd., Mail code SUPRSTAR, Lenexa, KS 66219; 913/551–7956.
- Region 8 (CO, MT, ND, SD, UT, WY), U.S. EPA, 1595 Wynkoop Street, Mail code Records Center, Denver, CO 80202–1129; 303/312–7273.
- EPA Headquarters Docket Center Reading Room (deletion dockets for all states), William Jefferson Clinton (WJC) West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20004, (202) 566–1744.

EPA staff listed below in the **FOR FURTHER INFORMATION CONTACT** section may assist the public in answering inquiries about deleted sites and accessing deletion support documentation, determining whether there are additional physical deletion dockets available, or if COVID restrictions affect deletion docket access.

The EPA continues to carefully and continuously monitor information from the Centers for Disease Control and Prevention (CDC), local area health departments, and our federal partners so that we can respond rapidly as conditions change regarding COVID.

FOR FURTHER INFORMATION CONTACT:

- Robert Lim, U.S. EPA Region 1 (CT, ME, MA, NH, RI, VT), U.S. EPA, *lim.robert@epa.gov,* 617/918–1392.
- Andrew Hass, U.S. EPA Region 3 (DE, DC, MD, PA, VA, WV), *hass.andrew@epa.gov,* 215/814–2049.
- Leigh Lattimore, U.S. EPA Region 4 (AL, FL, GA, KY, MS, NC, SC, TN), *lattimore.leigh@epa.gov,* 404/562–8768.
- Karen Cibulskis, U.S. EPA Region 5 (IL, IN, MI, MN, OH, WI), *cibulskis.karen@epa.gov,* 312/886–1843.
- David Wennerstrom, U.S. EPA Region 7 (IA, KS, MO, NE), *wennerstrom.david@epa.gov,* 913/551–7996.
- Linda Kiefer, U.S. EPA Region 8 (CO, MT, ND, SD, UT, WY), *kiefer.linda@epa.gov,* 303/312–6689.
- Charles Sands, U.S. EPA Headquarters, *sands.charles@epa.gov,* 202–566–1142.

SUPPLEMENTARY INFORMATION: The NPL, created under section 105 of CERCLA, as amended, is an appendix of the NCP. The NCP establishes the criteria that EPA uses to delete sites from the NPL. In accordance with 40 CFR 300.425(e), sites may be deleted from the NPL where no further response is appropriate. Partial deletion of sites is in accordance with 40 CFR 300.425(e) and are consistent with the Notice of Policy Change: Partial Deletion of Sites Listed on the National Priorities List, 60 FR 55466, (November 1, 1995). The sites to be deleted are listed in Table 1, including docket information containing reference documents with the rationale and data principally relied upon by the EPA to determine that the Superfund response is complete. The NCP permits activities to occur at a deleted site, or that media or parcel of a partially deleted site, including operation and maintenance of the remedy, monitoring, and five-year reviews. These activities for the site are entered in Table 1 in this **SUPPLEMENTARY INFORMATION** section, if applicable, under Footnote such that; 1 = site has continued operation and maintenance of the remedy, 2 = site receives continued monitoring, and 3 = site five-year reviews are conducted. As described in 40 CFR 300.425(e)(3) of the NCP, a site or portion of a site deleted from the NPL remains eligible for Fund-financed remedial action if future conditions warrant such actions.

TABLE 1

Site name	City/county, state	Type	Docket No.	Footnote
McKin Co	Gray, ME	Full	EPA–HQ–OLEM–2021–0922.	1, 2, 3
Tybouts Corner Landfill	New Castle County, DE	Partial	EPA–HQ–OLEM–2021–0797.	1, 3
C&R Battery Co., Inc	Chesterfield County, VA	Full	EPA–HQ–OLEM–2021–0798.	1, 3
Chem-Solv, Inc	Cheswold, DE	Full	EPA–HQ–OLEM–2021–0934.	1, 3
Koppers Co., Inc. (Charleston Plant)	Charleston, SC	Partial	EPA–HQ–SFUND–1994–0001.	1, 3
Brantley Landfill	Island, KY	Full	EPA–HQ–OLEM–2022–0111.	1, 2, 3
Summit National	Deerfield Township, OH	Partial	EPA–HQ–OLEM–2021–0815.	1, 3
Himco Dump	Elkhart, IN	Partial	EPA–HQ–SFUND–1990–0010.	1, 3

TABLE 1—Continued

Site name	City/county, state	Type	Docket No.	Footnote
Omaha Lead	Omaha, NE	Partial	EPA–HQ–SFUND–2003–0010.	1, 3
Libby Asbestos	Libby, MT	Partial	EPA–HQ–SFUND–2002–0008.	1, 3

Information concerning the sites to be deleted and partially deleted from the NPL, the proposed rule for the deletion and partial deletion of the sites, and information on receipt of public comment(s) and preparation of a Responsiveness Summary (if applicable) are included in Table 2 as follows:

TABLE 2

Site name	Date, proposed rule	FR citation	Public comment	Responsiveness summary	Full site deletion (full) or media/parcels/description for partial deletion
McKin Co	3/31/2022	87 FR 18761	Yes	Yes	Full.
Tybouts Corner Landfill	3/31/2022	87 FR 18761	Yes	Yes	2 parcels soil and groundwater approx. 78 acres.
C&R Battery Co., Inc	3/31/2022	87 FR 18761	Yes	Yes	Full.
Chem-Solv, Inc	3/31/2022	87 FR 18761	Yes	Yes	Full.
Koppers Co., Inc. (Charleston Plant).	3/31/2022	87 FR 18761	Yes	Yes	98 acres of soils, sediments and tidal marsh.
Brantley Landfill	3/31/2022	87 FR 18761	Yes	Yes	Full.
Summit National	3/31/2022	87 FR 18761	Yes	Yes	Land/soil portion of landfill, adjacent removal areas, and 45 down gradient parcels.
Himco Dump	3/31/2022	87 FR 18761	Yes	Yes	11.5-acre land/soil portion of the site plus adjacent soils.
Omaha Lead	3/31/2022	87 FR 18761	Yes	Yes	19 residential parcels.
Libby Asbestos	3/31/2022	87 FR 18761	Yes	Yes	OU 6 including 42 miles of railroad right of way between and in the towns of Libby and Troy, MT.

For the sites proposed for deletion, the closing date for comments in the proposed rule was May 2, 2022. The EPA received two public comments which addressed all ten sites included for deletion or partial deletion-and two additional public comments on the McKin Co. site in this final rule. EPA placed the comments in the dockets specified in Table 1, on *https://www.regulations.gov,* and in the appropriate Regional Records Center listed in the **ADDRESSES** section. One public comment-addressing all ten sites was supportive of the proposed deletion and of EPA actions. One public comment addressing all ten sites was an adverse comment. The commentor requested additional information present in the deletion docket be specified in the deletion rules; EPA provide a schedule to return contaminated groundwater to beneficial reuse; expressed concerns about institutional controls on land and groundwater use; and expressed concerns whether EPA met requirements of the Information Quality Act. EPA determined that it is appropriate to proceed with the deletion because all response actions at the sites are appropriate and complete, EPA complied with program and Agency requirements, guidance and the NCP. The criteria for deletion have been met. A Responsiveness Summary was prepared and placed in each site deletion docket on *https://www.regulations.gov,* and in the appropriate Regional Records Centers listed in the **ADDRESSES** section.

The McKin Co. site also received two adverse comments. One commentor did not agree with EPA's decision to delete the site from the NPL, concerned that possible remedial work still needs to be done. The second commentor raised concerns about future or planned development of the former McKin Co. property and if contaminants could be disturbed. EPA has completed all remedial work at the McKin Co. site and land use controls on the site will prevent development or disturbance of any contaminants. EPA has determined that it is appropriate to proceed with the deletion because all response actions at the site are complete and the criteria for deletion have been met. A Responsiveness Summary was prepared and placed in the docket, EPA–HQ–OLEM–2021–0922, on *https://www.regulations.gov,* and in the Regional Records Center listed in the **ADDRESSES** section.

For all other sites not specified above, no adverse comments were received.

EPA maintains the NPL as the list of sites that appear to present a significant risk to public health, welfare, or the environment. Deletion from the NPL does not preclude further remedial action. Whenever there is a significant release from a site deleted from the NPL, the deleted site may be restored to the NPL without application of the hazard ranking system. Deletion of a site from the NPL does not affect responsible party liability in the unlikely event that future conditions warrant further actions.

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous substances, Hazardous waste, Intergovernmental relations, Natural resources, Oil pollution, Penalties, Reporting and recordkeeping

requirements, Superfund, Water pollution control, Water supply.

Larry Douchand,

Office Director, Office of Superfund Remediation and Technology Innovation.

For reasons set out in the preamble, the EPA amends 40 CFR part 300 as follows:

PART 300—NATIONAL OIL AND HAZARDOUS SUBSTANCES POLLUTION CONTINGENCY PLAN

■ 1. The authority citation for part 300 continues to read as follows:

Authority: 33 U.S.C. 1251 *et seq.;* 42 U.S.C. 9601–9657; E.O. 13626, 77 FR 56749, 3 CFR, 2013 Comp., p. 306; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; E.O. 12580, 52 FR 2923, 3 CFR, 1987 Comp., p. 193.

■ 2. In appendix B to part 300 amend table 1 by:

■ a. Removing the entry for ''DE, Chem-Solv, Inc., Cheswold'';

■ b. Revising the entry for ''DE, Tybouts Corner Landfill, New Castle County'';

■ c. Revising the entry for ''IN, Himco Dump, Elkhart'';

■ d. Removing the entry for ''KY, Brantley Landfill, Island'';

■ e. Removing the entry for ''ME, McKin Co., and Gray'';

■ f. Revising the entries for ''OH, Summit National, Deerfield Township'' and ''SC, Koppers Co., Inc (Charleston Plant), Charleston''; and

■ g. Removing the entry for ''VA, C&R Battery Co., Inc, Chesterfield County''.

The revisions read as follows:

Appendix B to Part 300—National Priorities List

TABLE 1—GENERAL SUPERFUND SECTION

State	Site name	City/county	Notes (a)
DE	Tybouts Corner Landfill	New Castle County	P
*	* * * * *	*	*
IN	Himco Dump	Elkhart	P
*	* * * * *	*	*
OH	Summit National	Deerfield Township	P
*	* * * * *	*	*
SC	Koppers Co., Inc (Charleston Plant)	Charleston	P

* P = Sites with partial deletion(s).

[FR Doc. 2022–17480 Filed 8–16–22; 8:45 am]

BILLING CODE 6560–50–P

Proposed Rules

Federal Register
Vol. 87, No. 158
Wednesday, August 17, 2022

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

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–0994; Project Identifier MCAI–2022–00052–T]

RIN 2120–AA64

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

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain Gulfstream Aerospace LP Model Gulfstream G200 airplanes. This proposed AD was prompted by reports that wing flap fairing debonding and corrosion were discovered at certain areas of the lower skin on both wings. This proposed AD requires an inspection for corrosion in certain areas of the wing skin fairings, additional inspections if necessary, resealing the fairings with new fillet seal, and applicable corrective actions, as specified in the Civil Aviation Authority of Israel (CAAI) AD, which is proposed for incorporation by reference. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by October 3, 2022.

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

For CAAI service information identified in this NPRM, contact Civil Aviation Authority of Israel (CAAI), P.O. Box 1101, Golan Street, Airport City, 70100, Israel; telephone 972–3–9774665; fax 972–3–9774592; email *aip@mot.gov.il.* You may find this CAAI AD on the CAAI website at *www.caa.gov.il.* For Gulfstream service information identified in this NPRM, contact Gulfstream Aerospace Corporation, P.O. Box 2206, Mail Station D–25, Savannah, GA 31402–2206; telephone 800–810–4853; fax 912–965–3520; email *pubs@gulfstream.com;* internet *www.gulfstream.com/customer-support.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

Examining the AD Docket

You may examine the AD docket at *www.regulations.gov* by searching for and locating Docket No. FAA–2022–0994; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Dan Rodina, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th Street, Des Moines, WA 98198; telephone and fax 206–231–3225; email *dan.rodina@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2022–0994; Project Identifier MCAI–2022–00052–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, 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 the proposal 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 *www.regulations.gov,* including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this NPRM.

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 NPRM 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 NPRM, 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 NPRM. Submissions containing CBI should be sent to Dan Rodina, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th Street, Des Moines, WA 98198; telephone and fax 206–231–3225; email *dan.rodina@faa.gov.* Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The CAAI, which is the aviation authority for Israel, has issued AD ISR I–57–2021–12–4, dated January 1, 2022 (CAAI AD ISR I–57–2021–12–4) (also referred to after this as the Mandatory Continuing Airworthiness Information, or the MCAI), to correct an unsafe condition for certain Gulfstream Aerospace LP Model Gulfstream G200 airplanes.

This proposed AD was prompted by reports that wing flap fairing debonding and corrosion were discovered at the lower skin of rib 3 and rib 11 on both wings. The FAA is proposing this AD to

address flap fairing debonding and moisture intrusion that might lead to lower wing skin corrosion and cracking on both wings, and reduced structural integrity of the wings. See the MCAI for additional background information.

Related Service Information Under 1 CFR Part 51

CAAI AD ISR I–57–2021–12–4, dated January 1, 2022, describes procedures for an inspection for corrosion in the area of the wing skin (or doubler if installed) under the rib 3 and rib 11 fairings, a penetration or eddy current inspection for cracks if corrosion was found, a measurement of the thickness of remaining wing skin (or doubler) if no cracks were found, resealing of rib 3 and rib 11 fairings with new fillet seal, and applicable corrective actions. Corrective actions include cleaning and removing corrosion, crack repair, and repair of fairing installation locations with a certain thickness reduction. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the State of Design Authority, the FAA has been notified of the unsafe condition described in the MCAI and service information referenced above. The FAA is proposing this AD because the FAA evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop on other products of the same type design.

Proposed AD Requirements in This NPRM

This proposed AD requires accomplishing the actions specified in CAAI AD ISR I–57–2021–12–4 described previously, except for any differences identified as exceptions in the regulatory text of this proposed AD.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 168 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
29 work-hours × $85 per hour = $2,465	Minimal	$2,465	$414,120

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

ESTIMATED COSTS OF ON-CONDITION ACTIONS [*]

Labor cost	Parts cost	Cost per product
Up to 10 work-hours × $85 per hour = $850	$0	Up to $850.

* The FAA has received no definitive data on which to base the cost estimates for the on-condition repairs specified in this proposed AD.

The FAA has included all known costs in its cost estimate. According to the manufacturer, however, some or all of the costs of this proposed AD may be covered under warranty, thereby reducing the cost impact on affected operators.

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

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Gulfstream Aerospace LP (Type Certificate Previously Held by Israel Aircraft

Industries, Ltd.): Docket No. FAA–2022–0994; Project Identifier MCAI–2022–00052–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by October 3, 2022.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Gulfstream Aerospace LP Model Gulfstream G200 airplanes, certificated in any category, as identified in The Civil Aviation Authority of Israel (CAAI) AD ISR I–57–2021–12–4, dated January 1, 2022 (CAAI AD ISR I–57–2021–12–4).

(d) Subject

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

(e) Unsafe Condition

This AD was prompted by reports that wing flap fairing debonding and corrosion were discovered at lower skin of rib 3 and rib 11 on both wings. The FAA is issuing this AD to address flap fairing debonding and moisture intrusion that might lead to lower wing skin corrosion and cracking on both wings, and reduced structural integrity of the wings.

(f) Compliance

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

(g) Required Actions

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, CAAI AD ISR I–57–2021–12–4.

(h) Exceptions to Service Information Specifications

(1) Where CAAI AD ISR I–57–2021–12–4 refers to its effective date, this AD requires using the effective date of this AD.

(2) Where the Compliance paragraph of CAAI AD ISR I–57–2021–12–4 requires compliance at a certain time, replace the text ''at the next suitable planned maintenance inspection within the next 24 months from the effective date of this AD'' with ''within 24 months after the effective date of this AD.''

(3) Where the Action paragraph of CAAI AD ISR I–57–2021–12–4 refers to certain service information, replace the text ''Gulfstream Service Bulletin No. 200–57–426, dated January 01, 2022, or later approved revision,'' with ''Gulfstream Service Bulletin No. 200–57–426, Revision 1, dated June 16, 2022, or later approved revision.''

(4) Where the service information specified in CAAI AD ISR I–57–2021–12–4 specifies to report to Gulfstream if ''cracks were discovered'' and ''for any fairing installation location with one or more grid squares with thickness reduction of greater than 10%,'' for this AD, cracks and fairing installation locations with one or more grid squares with thickness reduction of greater than 10% must be repaired before further flight using a method approved by the Manager, Large Aircraft Section, International Validation Branch, FAA; or CAAI; or CAAI's authorized Designee. If approved by the authorized Designee, the approval must include the Designee's authorized signature.

(i) No Reporting Requirement

Although the service information referenced in CAAI AD ISR I–57–2021–12–4 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(j) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Large Aircraft Section, International Validation 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 Large Aircraft Section, International Validation Branch, send it to the attention of the person identified in paragraph (k)(2) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

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

(k) Related Information

(1) For CAAI AD ISR I–57–2021–12–4, dated January 1, 2022, contact Civil Aviation Authority of Israel (CAAI), P.O. Box 1101, Golan Street, Airport City, 70100, Israel; telephone 972–3–9774665; fax 972–3–9774592; email *aip@mot.gov.il.* You may find this CAAI AD on the CAAI website at *www.caa.gov.il.* You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. This material may be found in the AD docket at *www.regulations.gov* by searching for and locating Docket No. FAA–2022–0994.

(2) For more information about this AD, contact Dan Rodina, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA–2022–0994. 2200 South 216th Street, Des Moines, WA 98198; telephone and fax 206–231–3225; email *dan.rodina@faa.gov.*

Issued on August 4, 2022.

Christina Underwood,

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

[FR Doc. 2022–17119 Filed 8–16–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–0970; Airspace Docket No. 22–ASW–18]

RIN 2120–AA66

Proposed Revocation of Class E Airspace; Stratford, TX

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to remove the Class E airspace at Stratford, TX. The FAA is proposing this action due to the cancellation of the instrument procedures at the associated airport, and the airspace no longer being required.

DATES: Comments must be received on or before October 3, 2022.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590; telephone (202) 366–9826, or (800) 647–5527. You must identify FAA Docket No. FAA–2022–0970/Airspace Docket No. 22–ASW–18, at the beginning of your comments. You may also submit comments through the internet at *www.regulations.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays.

FAA Order JO 7400.11F, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would remove the Class E airspace extending upward from 700 feet above the surface at Stratford Field, Stratford, TX, due to the cancellation of the instrument procedures at this airport, and the airspace no longer being required.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2022–0970/Airspace Docket No. 22–ASW–18.'' The postcard will be date/time stamped and returned to the commenter.

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

Availability of NPRMs

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

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

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 by removing the Class E airspace extending upward from 700 feet above the surface at Stratford Field, Stratford, TX.

This action is the result of the instrument procedures at this airport being cancelled, and the airspace no longer being required.

Class E airspace designations are published in paragraph 6005 of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11.

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

Regulatory Notices and Analyses

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

Environmental Review

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

List of Subjects in 14 CFR 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

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

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

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

* * * * *

ASW TX E5 Stratford, TX [Remove]

Issued in Fort Worth, Texas, on August 11, 2022.

Martin A. Skinner,

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

[FR Doc. 2022–17563 Filed 8–16–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2022–0924; Airspace Docket No. 22–ASW–17]

RIN 2120–AA66

Proposed Amendment of Class E Airspace; Eagle Lake, TX

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend the Class E airspace at Eagle Lake, TX. The FAA is proposing this action due to an airspace review conducted as part of the decommissioning of the Eagle Lake very high frequency (VHF) omnidirectional range (VOR) as part of the VOR Minimal Operational Network (MON) Program. The geographic coordinates of the airport would also be updated to coincide with the FAA's aeronautical database.

DATES: Comments must be received on or before October 3, 2022.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590; telephone (202) 366–9826, or (800) 647–5527. You must identify FAA Docket No. FAA–2022–0924/Airspace Docket No. 22–ASW–17 at the beginning of your comments. You may also submit comments through the internet at *www.regulations.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays.

FAA Order JO 7400.11F, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

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

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2022–0924/Airspace Docket No. 22–ASW–17.'' The postcard will be date/time stamped and returned to the commenter.

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

Availability of NPRMs

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

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

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 by amending the Class E airspace extending upward from 700 feet above the surface at Eagle Lake Airport, Eagle Lake, TX, by removing the Eagle Lake VOR/DME and associated extension from the airspace legal description; and updating geographic coordinates of the airport to coincide with the FAA's aeronautical database.

This action is due to an airspace review conducted as part of the decommissioning of the Eagle Lake VOR, which provided navigation information for the instrument procedures at these airports, as part of the VOR MON Program.

Class E airspace designations are published in paragraph 6005 of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in FAA Order JO 7400.11.

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

Regulatory Notices and Analyses

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

Environmental Review

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

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

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

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

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

* * * * *

ASW TX E5 Eagle Lake, TX [Amended]

Eagle Lake Airport, TX

(Lat. 29°36′00″ N, long. 96°19′19″ W)

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of Eagle Lake Airport.

Issued in Fort Worth, Texas, on August 11, 2022.

Martin A. Skinner,

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

[FR Doc. 2022–17562 Filed 8–16–22; 8:45 am]

BILLING CODE 4910–13–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2022–0528; FRL–10113–01–R3]

Air Plan Approval; West Virginia; 2021 Amendments to West Virginia's Ambient Air Quality Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a state implementation plan (SIP) revision submitted by the State of West Virginia. This revision updates West Virginia's incorporation by reference of EPA's national ambient air quality standards (NAAQS) and the associated monitoring reference and equivalent methods. This action is being taken under the Clean Air Act (CAA).

DATES: Written comments must be received on or before September 16, 2022.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R03–OAR–2022–0528 at *www.regulations.gov,* or via email to *Gordon.Mike@epa.gov.* For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. For either manner of submission, EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be confidential business information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *www.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Serena Nichols, Planning & Implementation Branch (3AD30), Air & Radiation Division, U.S. Environmental Protection Agency, Region III, 1600 John F. Kennedy Boulevard, Philadelphia, Pennsylvania 19103–2852. The telephone number is (215) 814–2053. Ms. Nichols can also be reached via electronic mail at *Nichols.Serena@epa.gov.*

SUPPLEMENTARY INFORMATION: On May 11, 2021 the West Virginia Department of Environmental Protection (WVDEP) submitted a revision to its SIP pertaining to the amendments of Legislative Rule, 45CSR8—Ambient Air Quality Standards. The SIP submittal updates West Virginia's incorporation by reference of the NAAQS promulgated by EPA and found at 40 Code of Federal Regulations (CFR) part 50 and ambient air monitoring reference methods and equivalent methods promulgated by EPA and found at 40 CFR part 53 into West Virginia's legislative rules.

I. Summary of SIP Revision and EPA Analysis

WVDEP has historically chosen to incorporate by reference the Federal NAAQS, found at 40 CFR part 50, and the associated Federal ambient air monitoring reference methods and equivalent methods for these NAAQS found at 40 CFR part 53. When incorporating by reference these Federal regulations, WVDEP has specified that it is incorporating by reference these regulations as they existed on a certain date. The incorporation by reference of the NAAQS that is currently approved in the West Virginia SIP incorporates by reference 40 CFR parts 50 and 53 as they existed on June 1, 2019. West Virginia's May 11, 2021 SIP revision updates the State's incorporation by reference of the primary and secondary NAAQS and the ambient air monitoring reference and equivalent methods, found in 40 CFR parts 50 and 53, respectively, as of June 1, 2020. Since the last West Virginia incorporation by reference of June 1, 2019, EPA: (1) designated one new equivalent method for measuring concentrations of ozone in ambient air; (2) designated one new reference method for measuring concentrations of

nitrogen dioxide; (3) amended an existing reference method for measuring particulate matter (PM_{10}) in ambient air; (4) designated on new reference method for measuring concentrations of sulfur dioxide in ambient air; (5) designated one new equivalent method for measuring concentrations of nitrogen dioxide in ambient air. See 84 FR 44299 (August 23, 2019), 84 FR 50833 (September 26, 2019), 85 FR 5958 (February 2, 2020), 85 FR 27221 (May 7, 2020).

The amendments to the legislative rule include changes to section 45–8–1 (General), 45–8–2 (Definitions), and 45–8–3 (Adoption of Standards). The amendments update West Virginia's incorporation by reference of the primary and secondary NAAQS and the ambient air monitoring reference and equivalent methods from June 1, 2019 to June 1, 2020. West Virginia is incorporating the Federal rules in 40 CFR parts 50 and 53 as they existed on June 1, 2020 into 45–8–1 and 45–8–3. The amendment to section 45–8–2 changes the wording of the definition of both the CAA and ''Secretary.''

II. Proposed Action

EPA is proposing to approve the West Virginia SIP revision of May 11, 2021, updating the incorporation by reference of EPA's NAAQS and associated ambient air monitoring reference methods and equivalent methods. EPA is soliciting public comments on the update to West Virginia's incorporation by reference. Please note that EPA is not seeking public comment on the level of the NAAQS which West Virginia incorporated by reference into its regulations. An opportunity for public comment on the level of each individual NAAQS was given when EPA proposed each such NAAQS. Relevant comments will be considered before taking final action.

III. Incorporation by Reference

In this document, EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is proposing to incorporate by reference 45CSR8, as effective on June 1, 2021, discussed in section I. Summary of SIP Revision and EPA Analysis, of this preamble. EPA has made, and will continue to make, these materials generally available through *www.regulations.gov* and at the EPA Region III Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

IV. Statutory and Executive Order Reviews

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

Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this proposed rule, proposing to approve the West Virginia SIP revision updating its incorporation by reference of EPA's NAAQS and associated ambient air monitoring reference methods and equivalent methods, does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the State, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

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

Adam Ortiz,

Regional Administrator, Region III.

[FR Doc. 2022–17407 Filed 8–16–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2021–0936; FRL–9859–01–R5]

Air Plan Approval; Indiana; Opacity Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a revision to the Indiana State Implementation Plan (SIP), authorizing temporary alternative opacity limitations at the BP Products North America, Inc. (BP) facility in Whiting, Indiana during startup and shutdown. This proposed action is consistent with the Clean Air Act (CAA) and EPA regulations regarding emissions during these periods in the refinery sector.

DATES: Comments must be received on or before September 16, 2022.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2021–0936 at *https://www.regulations.gov,* or via email to *blakley.pamela@epa.gov*. For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. For either manner of submission, EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be

accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Matt Rau, Environmental Engineer, Control Strategies Section, Air Programs Branch (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–6524, *rau.matthew@epa.gov.* The EPA Region 5 office is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays and facility closures due to COVID–19.

SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, we mean EPA.

I. Background

On December 14, 2021, the Indiana Department of Environmental Management (IDEM) submitted a request to EPA to approve an addition to its SIP to allow BP a temporary alternative opacity limitation (TAOL) measurement for its Whiting, Indiana facility under 326 Indiana Administrative Code (IAC) 5–1–3, a revision that is codified at 326 IAC 5–1–8 and part of the State's SIP for opacity. At 326 IAC 5–1–3(d), the rule provides the IDEM Commissioner authority to approve a TAOL where they determine it is necessary that alternate TAOL is submitted to EPA as a SIP revision.

BP's Whiting facility currently employs electrostatic precipitators (ESPs) as part of its opacity control technology for two fluidized catalytic cracking units (FCUs), FCU 500 and FCU 600, used in production. BP has demonstrated to the IDEM Commissioner that use of these ESPs during periods of startup, shutdown, or hot standby present a safety hazard from coke residues on a solid catalyst within the FCUs. To address the safety hazard, BP proposed and demonstrated the efficacy of control technology borrowed from the National Emission Standards for Hazardous Air Pollutants (NESHAP) for Petroleum Refineries: Catalytic Cracking Units, Catalytic Reforming Units, and Sulfur Recovery Units, which is found at 40 CFR part 63, subpart UUU. BP will maintain the inlet velocity to the primary internal cyclones of the FCU catalyst regenerator at or above 20 feet per second. Indiana revised 326 IAC 5–1–8 to include the NESHAP control option as a TAOL for BP's FCU 500 and FCU 600 to ease the safety concerns when operating the ESP during these nonroutine operations.

Indiana provided a demonstration of compliance with CAA 110(l), which prohibit SIP revisions from interfering with attaining air quality standards and reasonable further progress requirements. The demonstration notes it is difficult for BP's FCU 500 and FCU 600 to meet the opacity limits in 326 IAC 5–1–8 during startup, shutdown, and hot standby [1] events with safety concerns when FCU emissions are routed through an active ESP. The demonstration notes that EPA refinery rules approved on December 1, 2015 (80 FR 75177), provide work practices for FCU startup, shutdown, and hot standby events. BP expects these events could occur a few times per year. BP provided data that shows it can meet the refinery rules work practice requirements. EPA regulations on the refinery sector will limit emissions from BP's FCU 500 and FCU 600 during periods of startup, shutdown, or hot standby.

II. Analysis of Indiana's Revision

EPA agrees that the TAOL for BP's Whiting facility follows the requirements in the 40 CFR part 63, subpart UUU, NESHAP, that this alternative technology conforms to 326 IAC 5–1–3, and that the revision to the Indiana SIP is appropriate. This opacity rule revision applies to BP's FCU 500 and FCU 600, and BP will be required to follow the same requirements contained in the NESHAP for the TAOL. Specifically, BP must maintain the inlet velocity to the primary internal cyclones of the FCUs at or above 20 feet per second during periods of startup, shutdown, or hot standby. This TAOL reflects an established option of a relevant NESHAP, which is at least as stringent as the general opacity rule. The records and calculations specified in the source specific TAOL will be sufficient to show BP Whiting's FCUs are complying with the TAOL.

III. What action is EPA taking?

EPA is proposing to approve Indiana's opacity rule section 326 IAC 5–1–8 as a revision to the Indiana SIP. The rule revision provides BP's FCU 500 and FCU 600 with a TAOL consistent with the requirements of 40 CFR part 63, subpart UUU.

IV. Incorporation by Reference

In this rule, EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is proposing to incorporate by reference Indiana Rule 326 IAC 5–1–8, effective December 8, 2021, as discussed in Section I of this preamble. EPA has made, and will continue to make, these documents generally available through *www.regulations.gov* and at the EPA Region 5 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

V. Statutory and Executive Order Reviews

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

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- 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);

[1] Hot standby as defined in the NESHAP at 40 CFR 63.1579.

• Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);

• Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and

• Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

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

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Particulate matter, Reporting and recordkeeping requirements.

Dated: August 9, 2022.

Debra Shore,

Regional Administrator, Region 5.

[FR Doc. 2022–17515 Filed 8–16–22; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[EPA–HQ–OLEM–2022–0319, EPA–HQ–OLEM–2022–0527, EPA–HQ–OLEM–2022–0579; FRL–10019–01–OLEM]

Proposed Deletion From the National Priorities List

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; notice of intent.

SUMMARY: The Environmental Protection Agency (EPA) is issuing a Notice of Intent to delete one site and partially delete two sites from the National Priorities List (NPL) and requests public comments on this proposed action. The NPL, promulgated pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, is an appendix of the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). The EPA and the state, through its designated state agency, have determined that all appropriate response actions under CERCLA, other than operations and maintenance of the remedy, monitoring and five-year reviews, where applicable, have been completed. However, this deletion does not preclude future actions under Superfund.

DATES: Comments regarding this proposed action must be submitted on or before September 16, 2022.

ADDRESSES: EPA has established a docket for this action under the Docket Identification numbers included in Table 1 in the **SUPPLEMENTARY INFORMATION** section of this document. Submit your comments, identified by the appropriate Docket ID number, by one of the following methods:

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

• *Email:* Table 2 in the **SUPPLEMENTARY INFORMATION** section of this document provides an email address to submit public comments for the proposed deletion action.

Instructions: Direct your comments to the Docket Identification number included in Table 1 in the **SUPPLEMENTARY INFORMATION** section of this document. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *https://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *https://www.regulations.gov* or email. The *https://www.regulations.gov* website is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through *https://www.regulations.gov,* 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. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: EPA has established a docket for this action under the Docket Identification included in Table 1 in the **SUPPLEMENTARY INFORMATION** section of this document. All documents in the docket are listed on the *https://www.regulations.gov* website. The Final Close-Out Report (FCOR, for a full site deletion) or the Partial Deletion Justification (PDJ, for a partial site deletion) is the primary document which summarizes site information to support the deletion. It is typically written for a broad, non-technical audience and this document is included in the deletion docket for each of the 3 sites in this rulemaking. Although listed in the index, some information is not publicly available, *i.e.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Docket materials are available through *https://www.regulations.gov* or at the corresponding Regional Records Center. Location, address, and phone number of the Regional Records Centers follows.

Regional Records Center:

• Region 4 (AL, FL, GA, KY, MS, NC, SC, TN), U.S. EPA, 61 Forsyth Street, SW, Mail code 9T25, Atlanta, GA 30303; 404/562–8637.

• Region 5 (IL, IN, MI, MN, OH, WI), U.S. EPA Superfund Division Records Manager, Mail code SRC–7J, Metcalfe Federal Building, 7th Floor South, 77

West Jackson Boulevard, Chicago, IL 60604; 312/886–4465.

- Region 6 (AR, LA, NM, OK, TX), US EPA Region 6 Records Center 1201 Elm St, Suite 500, Dallas, TX 75270; 214/665–7544
- EPA Headquarters Docket Center Reading Room (deletion dockets for all states), William Jefferson Clinton (WJC) West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20004, 202/566–1744.

EPA staff listed below in the **FOR FURTHER INFORMATION CONTACT** section may assist the public in answering inquiries about deleted sites and accessing deletion support documentation, determining whether there are additional physical deletion dockets available, or if COVID restrictions affect deletion docket access.

The EPA continues to carefully and continuously monitor information from the Centers for Disease Control and Prevention (CDC), local area health departments, and our federal partners so that we can respond rapidly as conditions change regarding COVID.

FOR FURTHER INFORMATION CONTACT:

- Leigh Lattimore, U.S. EPA Region 4 (AL, FL, GA, KY, MS, NC, SC, TN), *lattimore.leigh@epa.gov,* 404/562–8768.
- Karen Cibulskis, U.S. EPA Region 5 (IL, IN, MI, MN, OH, WI), *cibulskis.karen@epa.gov,* 312/886–1843.
- Brian Mueller, U.S. EPA Region 6 (AR, LA, NM, OK, TX), *mueller.brian@epa.gov,* 214/665–7167.
- Charles Sands, U.S. EPA Headquarters, *sands.charles@epa.gov,* 202–566–1142.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

EPA is issuing a proposed rule to delete one site and partially delete two sites from the National Priorities List (NPL) and requests public comments on this proposed action. The NPL constitutes Appendix B of 40 CFR part 300 which is the NCP, which EPA created under section 105 of the CERCLA statute of 1980, as amended. EPA maintains the NPL as those sites that appear to present a significant risk to public health, welfare, or the environment. Sites on the NPL may be the subject of remedial actions financed by the Hazardous Substance Superfund (Fund). These partial deletions are proposed in accordance with 40 CFR 300.425(e) and is consistent with the Notice of Policy Change: Partial Deletion of Sites Listed on the National Priorities List. 60 FR 55466, (November 1, 1995). As described in 40 CFR 300.425(e)(3) of the NCP, a site or portion of a site deleted from the NPL remains eligible for Fund-financed remedial action if future conditions warrant such actions.

EPA will accept comments on the proposal to delete or partially delete these sites for thirty (30) days after publication of this document in the **Federal Register**.

Section II of this document explains the criteria for deleting sites from the NPL. Section III of this document discusses procedures that EPA is using for this action. Section IV of this document discusses the site or portion of the site proposed for deletion and demonstrates how it meets the deletion criteria, including reference documents with the rationale and data principally relied upon by the EPA to determine that the Superfund response is complete.

II. NPL Deletion Criteria

The NCP establishes the criteria that EPA uses to delete sites from the NPL. In accordance with 40 CFR 300.425(e), sites may be deleted from the NPL where no further response is appropriate. In making such a determination pursuant to 40 CFR 300.425(e), EPA will consider, in consultation with the State, whether any of the following criteria have been met:

i. Responsible parties or other persons have implemented all appropriate response actions required;

ii. All appropriate Fund-financed response under CERCLA has been implemented, and no further response action by responsible parties is appropriate; or

iii. The remedial investigation has shown that the release poses no significant threat to public health or the environment and, therefore, the taking of remedial measures is not appropriate.

Pursuant to CERCLA section 121(c) and the NCP, EPA conducts five-year reviews to ensure the continued protectiveness of remedial actions where hazardous substances, pollutants, or contaminants remain at a site above levels that allow for unlimited use and unrestricted exposure. EPA conducts such five-year reviews even if a site is deleted from the NPL. EPA may initiate further action to ensure continued protectiveness at a deleted site if new information becomes available that indicates it is appropriate. Whenever there is a significant release from a site deleted from the NPL, the deleted site may be restored to the NPL without application of the hazard ranking system.

III. Deletion Procedures

The following procedures apply to the deletion or partial deletion of the sites in this proposed rule:

(1) EPA consulted with the respective state before developing this Notice of Intent for deletion.

(2) EPA has provided the state 30 working days for review of this proposed action prior to publication of it today.

(3) In accordance with the criteria discussed above, EPA has determined that no further response is appropriate.

(4) The state, through their designated state agency, has concurred with the proposed deletion action.

(5) Concurrently, with the publication of this Notice of Intent for deletion in the **Federal Register**, a notice is being published in a major local newspaper of general circulation near the site. The newspaper announces the 30-day public comment period concerning the proposed action for deletion.

(6) The EPA placed copies of documents supporting the proposed deletion in the deletion docket, made these items available for public inspection, and copying at the Regional Records Center identified above.

If comments are received within the 30-day comment period on this document, EPA will evaluate and respond accordingly to the comments before making a final decision to delete or partially delete the site. If necessary, EPA will prepare a Responsiveness Summary to address any significant public comments received. After the public comment period, if EPA determines it is still appropriate to delete or partially delete the site, the EPA will publish a final Notice of Deletion or Partial Deletion in the **Federal Register**. Public notices, public submissions and copies of the Responsiveness Summary, if prepared, will be made available to interested parties and included in the site information repositories listed above.

Deletion of a site or a portion of a site from the NPL does not itself create, alter, or revoke any individual's rights or obligations. Deletion of a site or a portion of a site from the NPL does not in any way alter EPA's right to take enforcement actions, as appropriate. The NPL is designed primarily for informational purposes and to assist EPA management. Section 300.425(e)(3) of the NCP states that the deletion of a site from the NPL does not preclude eligibility for future response actions,

should future conditions warrant such actions.

IV. Basis for Full Site or Partial Site Deletion

The site to be deleted or partially deleted from the NPL, the location of the site, and docket number with information including reference documents with the rationale and data principally relied upon by the EPA to determine that the Superfund response is complete are specified in Table 1. The NCP permits activities to occur at a deleted site or that media or parcel of a partially deleted site, including operation and maintenance of the remedy, monitoring, and five-year reviews. These activities for the site are entered in Table 1, if applicable, under Footnote such that; 1= site has continued operation and maintenance of the remedy, 2= site receives continued monitoring, and 3= site five-year reviews are conducted.

TABLE 1

Site name	City/county, state	Type	Docket No.	Footnote
U.S. Finishing/Cone Mills	Greenville, SC	Partial	EPA–HQ–OLEM–2022–0579	
Wauconda Sand & Gravel	Wauconda, IL	Partial	EPA–HQ–OLEM–2022–0319	1,2,3
River City Metal Finishing	San Antonio, TX	Full	EPA–HQ–OLEM–2022–0527	

Table 2 includes information concerning whether the full site is proposed for deletion from the NPL or a description of the area, media or Operable Units (OUs) of the NPL site proposed for partial deletion from the NPL, and an email address to which public comments may be submitted if the commenter does not comment using *https://www.regulations.gov.*

TABLE 2

Site name	Full site deletion (full) or media/parcels/ description for partial deletion	Email address for public comments
U.S. Finishing/Cone Mills	70-acres of Operable Unit 1 Main Facility which includes soil, surface water, and sediment.	*martin.scott@epa.gov.*
Wauconda Sand & Gravel	Approximately 76-acres of soil	*cibulskis.karen@epa.gov.*
River City Metal Finishing	Full	*tzhone.stephen@epa.gov.*

EPA maintains the NPL as the list of sites that appear to present a significant risk to public health, welfare, or the environment. Deletion from the NPL does not preclude further remedial action. Whenever there is a significant release from a site deleted from the NPL, the deleted site may be restored to the NPL without application of the hazard ranking system. Deletion of a site from the NPL does not affect responsible party liability in the unlikely event that future conditions warrant further actions.

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous substances, Hazardous waste, Intergovernmental relations, Natural resources, Oil pollution, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Authority: 33 U.S.C. 1251 *et seq.;* 42 U.S.C. 9601–9657; E.O. 13626, 77 FR 56749, 3 CFR, 2013 Comp., p. 306; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; E.O. 12580, 52 FR 2923, 3 CFR, 1987 Comp., p. 193.

Larry Douchand,

Office Director, Office of Superfund Remediation and Technology Innovation.

[FR Doc. 2022–17479 Filed 8–16–22; 8:45 am]

BILLING CODE 6560–50–P

Notices

Federal Register
Vol. 87, No. 158
Wednesday, August 17, 2022

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.

AGENCY FOR INTERNATIONAL DEVELOPMENT

Paperwork Reduction Act 60-Day Notice; Request for Comments

AGENCY: U.S. Agency for International Development (USAID).

ACTION: Notice and request for comments; announcement of Customer Service Survey.

SUMMARY: USAID's Performance Improvement Officer (PIO) will administer an annual, internal Customer Service Survey (CSS) and use staff feedback to improve customer service operations. USAID leadership uses CSS results to demonstrate their commitment to listening to customers, making data-informed decisions, and addressing customers' issues. In accordance with the Paperwork Reduction Act of 1995, USAID requests public comment on this collection from all interested individuals and organizations.

DATES: USAID intends to issue the survey in late winter/early spring 2023. Comments are due October 17, 2022.

ADDRESSES: Send all electronic comments to *mastrong@usaid.gov.* Include ''Announcement of Customer Service Survey'' in the subject line.

FOR FURTHER INFORMATION CONTACT: Maggie Strong, *mastrong@usaid.gov,* 202–921–5104.

SUPPLEMENTARY INFORMATION: The Customer Service Survey will be administered to USAID staff, including contractors. USAID staff of all hiring mechanisms have the opportunity to take the survey; participation is not mandatory. USAID uses data for internal decision-making and data will not be made public.

Margaret Emery Strong,

Senior Analyst, USAID.

[FR Doc. 2022–17633 Filed 8–16–22; 8:45 am]

BILLING CODE 6116–01–P

DEPARTMENT OF COMMERCE

Census Bureau

[Docket Number 220526–0123]

Soliciting Input or Suggestions on 2030 Census Preliminary Research

AGENCY: Census Bureau, Department of Commerce.

ACTION: Notice and request for comment.

SUMMARY: Early planning for the 2030 Census program began in Fiscal Year 2019 with building the program foundation and preparing for the official program kick-off and start of the Design Selection Phase in October 2021. The primary goal of the Design Selection Phase is to conduct the research, testing, and operational planning and design work to inform the selection of the 2030 Census operational design. We are issuing this notice to engage with our stakeholders on the development and implementation strategies that improve the way people participate in the 2030 Census. This notice also includes specific topics of interest to help guide input from stakeholders and other members of the public.

DATES: Comments on this notice must be received by November 15, 2022.

ADDRESSES: Interested persons are invited to submit written comments by email to *DCMD.2030.Research@census.gov.* You may also submit comments, identified by Docket Number USBC–2022–0004, to the Federal e-Rulemaking Portal: *http://www.regulations.gov.* All comments received are part of the public record. No comments will be posted to *http://www.regulations.gov* for public viewing until after the comment period has closed. Comments will generally be posted without change. All Personally Identifiable Information (for example, name and address) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information. You may submit attachments to electronic comments in Microsoft Word, Excel, or Adobe PDF file formats.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Jennifer Reichert, Chief, Decennial Census Management Division, 301–763–6712, and *DCMD.2030.Research@census.gov.*

SUPPLEMENTARY INFORMATION: In 2020, the Census Bureau conducted the most automated, modern, and dynamic decennial census in our nation's history. This included design changes that made it as easy and efficient as possible for people to respond to the census by offering response options through the internet and by telephone, in addition to the traditional paper response, thereby allowing people to respond to the census from any location at any time. This helped to get more people to respond on their own, which, in turn, reduced the need to conduct expensive in-person follow-up for the enumeration.

The 2020 Census Program used advertisements to motivate people to respond, and used different approaches to reach demographic groups and geographic areas. The Census Bureau's partnership program worked closely with national and local community, recreation, and faith-based organizations to host both in-person and virtual events within their communities. In addition, census workers left materials at households to encourage self-response.

Our Post-Enumeration Survey and Demographic Analysis estimates indicate that we may have had undercounts of certain populations, in particular the Black or African American population, the American Indian and Alaska Native population living on the reservations, the Hispanic or Latino population, and young children aged 0–4. The Census Bureau seeks input on potential new methods and techniques to reach these populations.

Full details of the 2020 Census Program can be found in the 2020 Census Operational Plan. Two vintages of this operational plan are available online at: *https://www.census.gov/programs-surveys/decennial-census/decade/2020/planning-management/plan/op-plans.html.*

The version 4.0 of the 2020 Census Operational Plan, published in early 2019, describes the mature plan for the census prior to the production phase of the 2020 Census. Version 5.0 of the 2020 Census Operational Plan provides some operational updates that summarize the as-performed state of the census operations in Chapter 5, as well as some other noteworthy schedule and pre-2020

test result updates. Version 4.0 of the 2020 Census Operational Plan document is considered the more complete document of the plans for performing the 2020 Census.

The Census Bureau plans to build on the experiences of the 2020 Census and identify further, potential operational updates to develop the 2030 Census design. Early planning for the 2030 Census is now underway, and includes conducting research, testing, and operational planning and design work to inform the selection of the 2030 Census operational design. This work will factor in past census experiences, evolving technology, and stakeholder feedback.

The 2030 Census program could encounter multiple factors that the census design will have to address, including:

- *Constrained fiscal environment:* Budget uncertainties place significant pressure on funding available for the research, testing, design, and development work.
- *Rapidly changing use of technology:* The rapid pace of change in the use of technology makes it challenging to plan for and adequately test the use of technologies before they become obsolete.
- *Distrust in government:* Concerns about the security and privacy of information given to the government impact response rates and pose difficulties in data collection.
- *Declining response rates:* Response rates for surveys and censuses have declined as people are overloaded with requests for information and concerned about privacy.
- *Increasingly diverse population:* The demographic and cultural makeup of the U.S. is increasing in complexity, requiring tailored outreach efforts to encourage response.
- *Informal, complex living arrangements:* Households are becoming more diverse and dynamic, making it a challenge to associate an identified person with a single location.
- *A mobile population:* The U.S. continues to be a highly mobile nation, which makes it more challenging to locate individuals and solicit their participation.

The Census Bureau is seeking input from the public that could help mitigate these challenges and encourage people to respond to the census. The census count benefits from broad participation. We specifically are interested in strategies that may improve or enhance the way people respond to the 2030 Census on their own. We invite the public to comment on the following topics:

A. *Reaching and motivating everyone.* As we lay the foundation for the 2030 Census, we are interested in recommendations that help us reach everyone—especially the Black or African American population, the American Indian or Alaska Native population living on a reservation, the Hispanic or Latino population, people who reported being of Some Other Race, and young children. The 2020 Post-Enumeration Survey and Demographic Analysis estimates suggest undercounts within these groups, and the Census Bureau remains committed to addressing the factors that may contribute to such undercounts. We are interested in insights that would help us understand how to reach these populations and motivate people to respond in the 2030 Census.

B. *Technology.* As technological advancements continue to improve, we are interested in technological advancements and developments that could make responding to the census more user-friendly, could further enhance our efforts to increase self-response, and could facilitate our work to collect data in person when necessary.

C. *New data sources.* The 2020 Census used administrative records (such as data from federal and state governments), third-party sources (data from commercial sources), internal data, and publicly available information to enhance operational efficiency and data quality. We are interested in learning about additional data sources, or methods of using them, that could continue increasing operational efficiency and effectiveness, and improving data quality.

D. *How we contact respondents.* Contact strategies will focus on encouraging respondents to complete the census on their own. We are interested in recommendations for tailoring contact strategies to maximize the number of households responding on their own, including tools we use to invite people to respond to the census, how often we reach out to each household, and the messages we use.

E. *Respondent support services.* We are interested in recommendations for supporting people as they respond by offering various types of support and in non-English languages. This may include providing support to people as they respond online or through telephone assistance.

The Census Bureau encourages commenters to structure their input or recommendations using the text in headings A to E as identifiers for their remarks. This structure will assist in reviewing the input and recommendations received in response to these specific topics. For example, a commenter submitting input or recommendations responsive to item A above, would reference ''Reaching and motivating everyone'' in the heading of their remarks.

Please note the following general points regarding the Census Bureau's use of comments and input:

(1) The Census Bureau will review and screen the submissions and may not incorporate all input/recommendations.

(2) While there is no compensation for submission, the Census Bureau encourages participation to help ensure broad and diverse input to inform the 2030 Census operational design.

Robert L. Santos, Director, Census Bureau, approved the publication of this Notice in the **Federal Register**.

Dated: August 10, 2022.

Shannon Wink,

Program Analyst, Policy Coordination Office, U.S. Census Bureau.

[FR Doc. 2022–17647 Filed 8–16–22; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; BIS Program Evaluation

The Department of Commerce will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. We invite 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. Public comments were previously requested via the **Federal Register** on June 9, 2022, during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: Bureau of Industry and Security, Commerce.

Title: BIS Program Evaluation.

OMB Control Number: 0694–0125.

Form Number(s): BIS 0694–0125.

Type of Request: Regular submission, revision, and extension of a current information collection.

Number of Respondents: 3,000.

Average Hours per Response: 10 minutes.

Burden Hours: 500.

Needs and Uses: The Bureau of Industry and Security (BIS) conducts seminars on various aspects of the export controls under BIS' jurisdiction. Feedback from these seminars are vital to ensuring the quality and relevance of outreach programs. Participants' completion of a voluntary survey provides BIS with immediate feedback on various program elements allowing BIS to improve and adjust its course offerings to meet the needs of the exporting community. BIS typically conducts over 30 seminars each year, at locations across the United States and overseas.

Affected Public: Business or other for-profit organizations.

Frequency: On Occasion.

Respondent's Obligation: Voluntary.

Legal Authority: Government Performance and Results Act (GPRA).

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view the Department of Commerce collections currently under review by OMB.

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 and entering either the title of the collection or the OMB Control Number 0694–0125.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2022–17626 Filed 8–16–22; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–533–863; A–475–832; A–570–026; A–580–878; A–583–856; C–533–864; C–475–833; C–570–027; C–580–879]

Corrosion-Resistant Steel Products From India, Italy, the People's Republic of China, the Republic of Korea, and Taiwan: Continuation of the Antidumping and Countervailing Duty Orders

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

SUMMARY: The U.S. Department of Commerce (Commerce) and the U.S. International Trade Commission (ITC) determined in their five-year (sunset) reviews that revocation of the antidumping duty (AD) orders on corrosion-resistant steel products (CORE) from India, Italy, the People's Republic of China (China), the Republic of Korea (Korea), and Taiwan and countervailing duty (CVD) orders on CORE from India, Italy, China, and Korea would likely lead to a continuation or recurrence of dumping and net countervailable subsidies, and material injury to an industry in the United States. As a result, Commerce is publishing a notice of continuation of these AD and CVD orders.

DATES: Applicable August 17, 2022.

FOR FURTHER INFORMATION CONTACT: Jaron Moore or Joshua Simonidis, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3640 or (202) 482–0608, respectively.

SUPPLEMENTARY INFORMATION:

Background

On July 25, 2016, Commerce published the AD orders on CORE from India, Italy, China, Korea, and Taiwan and the CVD orders on CORE from India, Italy, China, and Korea in the **Federal Register**.[1] On June 1, 2021, the ITC instituted [2] and Commerce initiated [3] sunset reviews of the *Orders,* pursuant to sections 751(c) and 752 of the Tariff Act of 1930, as amended (the Act). As a result of its reviews, Commerce determined that revocation of the *Orders* on CORE would likely lead to a continuation or recurrence of dumping and countervailable subsidies. Therefore, Commerce notified the ITC of the magnitude of the margins and net subsidy rates likely to prevail should the *Orders* be revoked.[4]

On August 8, 2022, 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 a continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.[5]

Scope of the Orders

The products covered by these *Orders* are certain flat-rolled steel products, either clad, plated, or coated with corrosion-resistant metals such as zinc, aluminum, or zinc-, aluminum-, nickel—or iron-based alloys, whether or not corrugated or painted, varnished, laminated, or coated with plastics or other non-metallic substances in addition to the metallic coating. The products covered include coils that have a width of 12.7 mm or greater, regardless of form of coil (*e.g.,* in successively superimposed layers, spirally oscillating, etc.). The products covered also include products not in coils (*e.g.,* in straight lengths) of a thickness less than 4.75 mm and a width that is 12.7 mm or greater and that measures at least 10 times the thickness. The products covered also include products not in coils (*e.g.,* in straight lengths) of a thickness of 4.75 mm or more and a width exceeding 150 mm and measuring at least twice the thickness. The products described above may be rectangular, square, circular, or other shape and include products of either rectangular or non-rectangular cross-section where such cross-section is achieved subsequent to the rolling process, *i.e.,* products which have been ''worked after rolling'' (*e.g.,* products which have been beveled or rounded at the edges). For purposes of the width and thickness requirements referenced above:

(1) where the nominal and actual measurements vary, a product is within the scope if application of either the nominal or actual measurement would place it within the scope based on the definitions set forth above, and

[1] *See Certain Corrosion-Resistant Steel Products from India, Italy, the People's Republic of China, the Republic of Korea and Taiwan: Amended Final Affirmative Antidumping Determination for India and Taiwan, and Antidumping Duty Orders,* 81 FR 48390 (July 25, 2016); *Certain Corrosion-Resistant Steel Products from India, Italy, the People's Republic of China, the Republic of Korea and Taiwan: Notice of Correction to the Antidumping Duty Orders,* 81 FR 58475 (August 25, 2016); and *Certain Corrosion-Resistant Steel Products from India, Italy, Republic of Korea and the People's Republic of China: Countervailing Duty Order,* 81 FR 48387 (July 25, 2016) (collectively, *Orders*).

[2] *See Institution of Five-Year (Sunset) Reviews,* 86 FR 29239 (June 1, 2021).

[3] *Id.*

[4] *See Corrosion-Resistant Steel Products From India, Italy, the People's Republic of China, the Republic of Korea, and Taiwan: Final Results of Expedited Sunset Reviews of Antidumping Duty Orders,* 86 FR 55581 (October 6, 2021); *see also Corrosion-Resistant Steel Products from India: Final Results of the Expedited First Sunset Review of the Countervailing Duty Order,* 86 FR 54927 (October 5, 2021); *Corrosion-Resistant Steel Products from Italy: Final Results of the Expedited First Sunset Review of the Countervailing Duty Order,* 86 FR 53637 (September 28, 2021); *Corrosion-Resistant Steel Products from the People's Republic of China: Final Results of the Expedited Five-Year Sunset Review of the Countervailing Duty Order,* 86 FR 46675 (August 19, 2021); and *Corrosion-Resistant Steel Products from the Republic of Korea: Final Results of the Expedited First Sunset Review of the Countervailing Duty Order,* 86 FR 54425 (October 1, 2021).

[5] *See Certain Corrosion-Resistant Steel Products from China, India, Italy, South Korea, and Taiwan,* 87 FR 48197 (August 8, 2022).

(2) where the width and thickness vary for a specific product (*e.g.,* the thickness of certain products with non-rectangular cross-section, the width of certain products with non-rectangular shape, *etc.*), the measurement at its greatest width or thickness applies.

Steel products included in the scope of these *Orders* are products in which: (1) iron predominates, by weight, over each of the other contained elements; (2) the carbon content is 2 percent or less, by weight; and (3) none of the elements listed below exceeds the quantity, by weight, respectively indicated:

- 2.50 percent of manganese, or
- 3.30 percent of silicon, or
- 1.50 percent of copper, or
- 1.50 percent of aluminum, or
- 1.25 percent of chromium, or
- 0.30 percent of cobalt, or
- 0.40 percent of lead, or
- 2.00 percent of nickel, or
- 0.30 percent of tungsten (also called wolfram), or
- 0.80 percent of molybdenum, or
- 0.10 percent of niobium (also called columbium), or
- 0.30 percent of vanadium, or
- 0.30 percent of zirconium.

Unless specifically excluded, products are included in this scope regardless of levels of boron and titanium.

For example, specifically included in this scope are vacuum degassed, fully stabilized (commonly referred to as interstitial-free (IF)) steels and high strength low alloy (HSLA) steels. IF steels are recognized as low carbon steels with micro-alloying levels of elements such as titanium and/or niobium added to stabilize carbon and nitrogen elements. HSLA steels are recognized as steels with micro-alloying levels of elements such as chromium, copper, niobium, titanium, vanadium, and molybdenum.

Furthermore, this scope also includes Advanced High Strength Steels (AHSS) and Ultra High Strength Steels (UHSS), both of which are considered high tensile strength and high elongation steels.

Subject merchandise also includes corrosion-resistant steel that has been further processed in a third country, including but not limited to annealing, tempering, painting, varnishing, trimming, cutting, punching and/or slitting or any other processing that would not otherwise remove the merchandise from the scope of these *Orders* if performed in the country of manufacture of the in-scope corrosion resistant steel.

All products that meet the written physical description, and in which the chemistry quantities do not exceed any one of the noted element levels listed above, are within the scope of these *Orders* unless specifically excluded. The following products are outside of and/or specifically excluded from the scope of these *Orders:*

- Flat-rolled steel products either plated or coated with tin, lead, chromium, chromium oxides, both tin and lead (terne plate), or both chromium and chromium oxides (tin free steel), whether or not painted, varnished or coated with plastics or other non-metallic substances in addition to the metallic coating;
- Clad products in straight lengths of 4.7625 mm or more in composite thickness and of a width which exceeds 150 mm and measures at least twice the thickness; and
- Certain clad stainless flat-rolled products, which are three-layered corrosion resistant flat-rolled steel products less than 4.75 mm in composite thickness that consist of a flat-rolled steel product clad on both sides with stainless steel in a 20%–60%–20% ratio.

The products subject to these *Orders* are currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) under item numbers: 7210.30.0030, 7210.30.0060, 7210.41.0000, 7210.49.0030, 7210.49.0040, 7210.49.0045, 7210.49.0091, 7210.49.0095, 7210.61.0000, 7210.69.0000, 7210.70.6030, 7210.70.6060, 7210.70.6090, 7210.90.6000, 7210.90.9000, 7212.20.0000, 7212.30.1030, 7212.30.1090, 7212.30.3000, 7212.30.5000, 7212.40.1000, 7212.40.5000, 7212.50.0000, and 7212.60.0000.[6]

The products subject to these *Orders* may also enter under the following HTSUS item numbers: 7210.90.1000, 7215.90.1000, 7215.90.3000, 7215.90.5000, 7217.20.1500, 7217.30.1530, 7217.30.1560, 7217.90.1000, 7217.90.5030, 7217.90.5060, 7217.90.5090, 7225.91.0000, 7225.92.0000, 7225.99.0090, 7226.99.0110, 7226.99.0130, 7226.99.0180, 7228.60.6000, 7228.60.8000, and 7229.90.1000.

The HTSUS subheadings above are provided for convenience and customs purposes only. The written description of the scope of these *Orders* are dispositive.

[6] On July 26, 2021, Commerce added two additional HTSUS numbers at the request of U.S. Customs and Border Protection. *See Certain Corrosion-Resistant Steel Products from the Republic of Korea: Final Results of Antidumping Duty Administrative Review, 2019–2020,* 86 FR 70111 (December 9, 2021).

Continuation of the Orders

As a result of the determinations by Commerce and the ITC that revocation of the *Orders* would likely lead to a continuation or recurrence of dumping, net countervailable subsidies, and material injury to an industry in the United States, pursuant to sections 751(c) and 751(d)(2) of the Act, Commerce hereby orders the continuation of the *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 the *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 reviews of the *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 an 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) and 751(d)(2) of the Act and published in accordance with 777(i) of the Act, and 19 CFR 351.218(f)(4).

Dated: August 9, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2022–17711 Filed 8–16–22; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–533–908]

Barium Chloride From India: Preliminary Negative Determination of Sales at Less Than Fair Value, Postponement of Final Determination

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

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that barium chloride from India is not being, or is not likely to be, sold in the United States at less than fair value (LTFV). The period of investigation (POI) is January 1, 2021, through December 31, 2021. Interested parties are invited to comment on this preliminary determination.

DATES: Applicable August 17, 2022.

FOR FURTHER INFORMATION CONTACT: Fred Baker, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2924.

SUPPLEMENTARY INFORMATION:

Background

This preliminary determination is made in accordance with section 733(b) of the Tariff Act of 1930, as amended (the Act). Commerce published the notice of initiation of this investigation on February 8, 2022.[1] On May 20, 2022, Commerce postponed the preliminary determination of this investigation until August 10, 2022.[2]

For a complete description of the events that followed the initiation of this investigation, *see* the Preliminary Decision Memorandum.[3] A list of topics included in the Preliminary Decision Memorandum is included as Appendix II to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Scope of the Investigation

The product covered by this investigation is barium chloride from India. For a complete description of the scope of this investigation, *see* Appendix I.

Scope Comments

In accordance with the preamble to Commerce's regulations,[4] the *Initiation Notice* set aside a period of time for parties to raise issues regarding product coverage (*i.e.,* scope).[5] One interested party commented on the scope of the investigation as it appeared in the *Initiation Notice.* On July 6, 2022, Commerce issued its preliminary determination regarding the scope of the investigation.[6] For a summary of the product coverage comments submitted to the record for this investigation, and accompanying analysis of all comments timely received, *see* the Preliminary Scope Decision Memorandum. Based on an analysis of the comments received, Commerce preliminarily determined to make no changes to the scope language as it appeared in the *Initiation Notice. See* the scope in Appendix I to this notice. Commerce established a separate briefing schedule for interested parties to address the preliminary scope determination.[7] No parties filed scope case briefs addressing the Preliminary Scope Decision Memorandum.

Methodology

Commerce is conducting this investigation in accordance with section 731 of the Act. Commerce has calculated export prices in accordance with section 772(a) of the Act. Normal value is calculated in accordance with section 773 of the Act. For a full description of the methodology underlying the preliminary determination, *see* the Preliminary Decision Memorandum.

Preliminary Determination

Commerce preliminarily determines that the following estimated weighted-average dumping margin exists:

Exporter/producer	Estimated weighted-average dumping margin (percent)
Chaitanya Chemicals/ Chaitanya Barium India Pvt Ltd[8]	0.00

Commerce preliminarily determines that Chaitanya/CBI has not made sales of barium chloride at LTFV. Further, because Chaitanya/CBI, the only individually examined respondent in this investigation, is the only party for which an estimated weighted-average dumping margin has been calculated for this preliminary determination, Commerce preliminarily determines that barium chloride from India has not been sold in the United States at LTFV during the POI, and Commerce is publishing this notice of a negative preliminary determination.

Consistent with section 733(d) of the Act, Commerce has not calculated an estimated weighted-average dumping margin for all other producers and exporters because it has not made an affirmative preliminary determination of sales at LTFV.

Suspension of Liquidation

Because Commerce has made a negative preliminary determination of sales at LTFV with regard to subject merchandise, Commerce will not direct U.S. Customs and Border Protection to suspend liquidation or to require a cash deposit of estimated antidumping duties for entries of barium chloride from India.

Disclosure

Commerce intends to disclose its calculations and analysis performed to interested parties in this preliminary determination within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b).

Verification

As provided in section 782(i)(1) of the Act, Commerce intends to verify the information relied upon in making its final determination.

Public Comment

Case briefs or other written comments on non-scope issues may be submitted to the Assistant Secretary for Enforcement and Compliance.[9]

[1] *See Barium Chloride from India: Initiation of Less-Than-Fair-Value Investigation,* 87 FR 7100 (February 8, 2022) (*Initiation Notice*).

[2] *See Barium Chloride from India: Postponement of Preliminary Determination in the Less-Than-Fair-Value Investigation,* 87 FR 30871 (May 20, 2022).

[3] *See* Memorandum, ''Decision Memorandum for the Preliminary Determination in the Less-Than-Fair-Value Investigation of Barium Chloride from India'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[4] *See Antidumping Duties; Countervailing Duties, Final Rule,* 62 FR 27296, 27323 (May 19, 1997).

[5] *See Initiation Notice,* 87 FR at 7104.

[6] *See* Memorandum, ''Antidumping and Countervailing Duty Investigations of Barium Chloride from India: Preliminary Scope Decision Memorandum,'' dated July 6, 2022 (Preliminary Scope Decision Memorandum).

[7] *Id.* at 1.

[8] Commerce preliminarily determines that Chaitanya Chemicals (Chaitanya) and Chaitanya Barium India Pvt Ltd (CBI) should be treated as a single entity (collectively, Chaitanya/CBI), in accordance with section 771(33)(A) and (F) of the Act and 19 CFR 351.401(f). *See* Preliminary Decision Memorandum. For a complete discussion, *see* Memorandum, ''Preliminary Affiliation and Collapsing Memorandum: Less-Than-Fair-Value Investigation of Barium Chloride from India,'' dated concurrently with this memorandum.

[9] Case briefs, other written comments, and rebuttal briefs submitted by parties in response to this preliminary LTFV determination should not

Continued

Interested parties will be notified of the timeline for the submission of such case briefs and written comments at a later date. Rebuttal briefs, limited to issues raised in case briefs, may be submitted no later than seven days after the deadline date for case briefs.[10] Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information, until further notice.[11] Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in this investigation are encouraged to submit with each argument: (1) a statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the date of publication of this notice. Requests should contain the party's name, address, and telephone number, the number of participants, whether any participant is a foreign national, and a list of the issues to be discussed. If a request for a hearing is made, Commerce intends to hold the hearing at a time and date to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

Postponement of Final Determination

Section 735(a)(2) of the Act provides that a final determination may be postponed until not later than 135 days after the date of the publication of the preliminary determination if, in the event of a negative preliminary determination, a request for such postponement is made by the petitioner. Pursuant to 19 CFR 351.210(e), on July 28, 2022, Chemical Products Corporation (the petitioner) requested that Commerce postpone the final determination in the event of a negative preliminary determination.[12] In accordance with section 735(a)(2)(B) of the Act and 19 CFR 351.210(b)(2)(i), because: (1) the preliminary determination is negative; (2) the petitioner has requested postponement of the final determination; and (3) no compelling reasons for denial exist, Commerce is postponing the final determination. Accordingly, Commerce will make its final determination no later than 135 days after the date of publication of this preliminary determination, pursuant to section 735(a)(2) of the Act.

U.S. International Trade Commission Notification

In accordance with section 733(f) of the Act, Commerce will notify the U.S. International Trade Commission (ITC) of its preliminary determination. If Commerce's final determination is affirmative, then the ITC will determine before the later of 120 days after the date of this preliminary determination or 45 days after the final determination whether imports of barium chloride are materially injuring, or threaten material injury to, the U.S. industry.

Notification to Interested Parties

This determination is issued and published in accordance with sections 733(f) and 777(i)(1) of the Act, and 19 CFR 351.205(c).

Dated: August 10, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The merchandise covered by this investigation is barium chloride, a chemical compound having the formulas BaCl2 or BaCl2-2H2O, currently classifiable under subheading 2827.39.4500 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheading is provided for convenience and customs purposes, the written description of the scope of this investigation is dispositive.

Appendix II

List of Topics Discussed in the Preliminary Decision Memorandum

[FR Doc. 2022–17622 Filed 8–16–22; 8:45 am]

BILLING CODE 3510–DS–P

include scope-related issues. The scope case briefs deadline was July 20, 2022. *See* Preliminary Scope Decision Memorandum at 1.

[10] *See* 19 CFR 351.309; *see also* 19 CFR 351.303 (for general filing requirements).

[11] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

[12] *See* Petitioner's Letter, ''Antidumping Investigation of Barium Chloride from India: Petitioner's Request for Postponement of Final Determination,'' dated July 28, 2022.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–533–906]

Sodium Nitrite From India: Preliminary Affirmative Determination of Sales at Less Than Fair Value, Postponement of Final Determination, and Extension of Provisional Measures

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

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that sodium nitrite from India is being, or is likely to be, sold in the United States at less than fair value (LTFV). The period of investigation (POI) is January 1, 2021, through December 31, 2021. Interested parties are invited to comment on this preliminary determination.

DATES: Applicable August 17, 2022.

FOR FURTHER INFORMATION CONTACT: Patrick Barton, or Joy Zhang, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0012 or (202) 482–1168, respectively.

SUPPLEMENTARY INFORMATION:

Background

This preliminary determination is made in accordance with section 733(b) of the Tariff Act of 1930, as amended (the Act). Commerce published the notice of initiation of this investigation on February 8, 2022.[1] On June 8, 2022, Commerce postponed the preliminary determination of this investigation until August 11, 2022.[2] For a complete description of the events that followed the initiation of this investigation, *see* the Preliminary Decision Memorandum.[3] A list of topics included in the Preliminary Decision Memorandum is included as Appendix II to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's

[1] *See Sodium Nitrite from India and the Russian Federation: Initiation of Less-Than-Fair-Value Investigations,* 87 FR 7122 (February 8, 2022) (*Initiation Notice*).

[2] *See Sodium Nitrite from India: Postponement of Preliminary Determinations in the Less-Than-Fair-Value Investigation,* 87 FR 34851 (June 8, 2022).

[3] *See* Memorandum, ''Decision Memorandum for the Preliminary Determination in the Less-Than-Fair-Value Investigation of Sodium Nitrite from India'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Scope of the Investigation

The product covered by this investigation is sodium nitrite from India. For a complete description of the scope of this investigation, *see* Appendix I.

Scope Comments

In accordance with the preamble to Commerce's regulations,[4] the *Initiation Notice* set aside a period of time for parties to raise issues regarding product coverage (*i.e.,* scope).[5] No interested parties submitted comments on the scope of this investigation.

Methodology

Commerce is conducting this investigation in accordance with section 731 of the Act. Commerce has calculated export prices in accordance with section 772(a) of the Act. Normal value is calculated in accordance with section 773 of the Act. For a full description of the methodology underlying the preliminary determination, *see* the Preliminary Decision Memorandum.

All-Others Rate

Sections 733(d)(1)(ii) and 735(c)(5)(A) of the Act provide that in the preliminary determination, Commerce shall determine an estimated all-others rate for all exporters and producers not individually examined. This rate shall be an amount equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding any zero and *de minimis* margins, and any margins determined entirely under section 776 of the Act.

Commerce calculated an individual estimated weighted-average dumping margin for Deepak Nitrite Limited (Deepak), the only individually examined exporter/producer in this investigation. Because the only individually calculated dumping margin is not zero, *de minimis,* or based entirely on facts otherwise available, the estimated weighted-average dumping margin calculated for Deepak is the margin assigned to all other producers and exporters, pursuant to section 735(c)(5)(A) of the Act.

Preliminary Determination

Commerce preliminarily determines that the following estimated weighted-average dumping margins exist:

Exporter/producer	Estimated weighted-average dumping margin	Cash deposit rate (adjusted for subsidy offset(s)) (percent) [6]
Deepak Nitrite Limited	58.13	57.24
All Others	58.13	57.24

Suspension of Liquidation

In accordance with section 733(d)(2) of the Act, Commerce will direct U.S. Customs and Border Protection (CBP) to suspend liquidation of entries of subject merchandise, as described in Appendix I, entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**. Further, pursuant to section 733(d)(1)(B) of the Act and 19 CFR 351.205(d), Commerce will instruct CBP to require a cash deposit equal to the estimated weighted-average dumping margin or the estimated all-others rate, as follows: (1) the cash deposit rate for the respondents listed above will be equal to the company-specific estimated weighted-average dumping margins determined in this preliminary determination; (2) if the exporter is not a respondent identified above, but the producer is, then the cash deposit rate will be equal to the company-specific estimated weighted-average dumping margin established for that producer of the subject merchandise; and (3) the cash deposit rate for all other producers and exporters will be equal to the all-others estimated weighted-average dumping margin.

Commerce normally adjusts cash deposits for estimated antidumping duties by the amount of export subsidies countervailed in a companion countervailing duty (CVD) proceeding when CVD provisional measures are in effect. Accordingly, where Commerce preliminarily made an affirmative determination for countervailable export subsidies, Commerce has offset the estimated weighted-average dumping margin by the appropriate CVD rate. Any such adjusted cash deposit rate may be found in the ''Preliminary Determination'' section, above.

Should provisional measures in the companion CVD investigation expire prior to the expiration of provisional measures in this LTFV investigation, Commerce will direct CBP to begin collecting estimated antidumping duty cash deposits unadjusted for countervailed export subsidies at the time that the provisional CVD measures expire.

These suspension of liquidation instructions will remain in effect until further notice.

Disclosure

Commerce intends to disclose its calculations and analysis performed to interested parties in this preliminary determination within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b).

Verification

As provided in section 782(i)(1) of the Act, Commerce intends to verify the information relied upon in making its final determination.

Public Comment

Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance no later than seven days after the date on which the last verification report is issued in this investigation.[7] Rebuttal briefs may be submitted seven days after the date that case briefs are due. Note that Commerce

[4] *See Antidumping Duties; Countervailing Duties, Final Rule,* 62 FR 27296, 27323 (May 19, 1997).

[5] *See Initiation Notice.*

[6] *See* Memorandum, ''Less-Than-Fair-Value Investigation of Sodium Nitrite from India: Preliminary Determination Analysis Memorandum for Deepak Nitrite Limited,'' dated concurrently with this memorandum.

[7] *See* 19 CFR 351.309; *see also* 19 CFR 351.303 (for general filing requirements).

has temporarily modified certain of its requirements for serving documents containing business proprietary information, until further notice.[8] Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in this investigation are encouraged to submit with each argument: (1) a statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the date of publication of this notice. Requests should contain the party's name, address, and telephone number, the number of participants, whether any participant is a foreign national, and a list of the issues to be discussed. If a request for a hearing is made, Commerce intends to hold the hearing at a time and date to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

Postponement of Final Determination and Extension of Provisional Measures

Section 735(a)(2) of the Act provides that a final determination may be postponed until not later than 135 days after the date of the publication of the preliminary determination if, in the event of an affirmative preliminary determination, a request for such postponement is made by exporters who account for a significant proportion of exports of the subject merchandise, or in the event of a negative preliminary determination, a request for such postponement is made by the petitioner. Section 351.210(e)(2) of Commerce's regulations requires that a request by exporters for postponement of the final determination be accompanied by a request for extension of provisional measures from a four-month period to a period not more than six months in duration.

On August 10, 2022, pursuant to 19 CFR 351.210(e), Deepak requested that Commerce postpone the final determination and that provisional measures be extended to a period not to exceed six months.[9] In accordance with section 735(a)(2)(A) of the Act and 19 CFR 351.210(b)(2)(ii), because: (1) the preliminary determination is affirmative; (2) the requesting exporter accounts for a significant proportion of exports of the subject merchandise; and (3) no compelling reasons for denial exist, Commerce is postponing the final determination and extending the provisional measures from a four-month period to a period not greater than six months. Accordingly, Commerce will make its final determination no later than 135 days after the date of publication of this preliminary determination.

U.S. International Trade Commission Notification

In accordance with section 733(f) of the Act, Commerce will notify the U.S. International Trade Commission (ITC) of its preliminary determination. If the final determination is affirmative, the ITC will determine before the later of 120 days after the date of this preliminary determination or 45 days after the final determination whether imports of sodium nitrite from India are materially injuring, or threaten material injury to, the U.S. industry.

Notification to Interested Parties

This determination is issued and published in accordance with sections 733(f) and 777(i)(1) of the Act, and 19 CFR 351.205(c) and 19 CFR 351.210(g).

Dated: August 11, 2022.

Lisa W. Wang,

Assistant Secretary for Enforcement and Compliance.

Appendix I—Scope of the Investigation

The product covered by this investigation is sodium nitrite in any form, at any purity level. In addition, the sodium nitrite covered by this investigation may or may not contain an anticaking agent. Examples of names commonly used to reference sodium nitrite are nitrous acid, sodium salt, anti-rust, diazotizing salts, erinitrit, and filmerine. Sodium nitrite's chemical composition is NaNO2, and it is generally classified under subheading 2834.10.1000 of the Harmonized Tariff Schedule of the United States (HTSUS). The American Chemical Society Chemical Abstract Service (CAS) has assigned the name ''sodium nitrite'' to sodium nitrite. The CAS registry number is 7632–00–0. For purposes of the scope of this investigation, the narrative description is dispositive, not the tariff heading, CAS registry number or CAS name, which are provided for convenience and customs purposes.

Appendix II—List of Topics Discussed in the Preliminary Decision Memorandum

[FR Doc. 2022–17721 Filed 8–16–22; 8:45 am]

BILLING CODE 3510–DS–P

[8] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

[9] *See* Deepak's Letter, ''Sodium Nitrite from India; A–533–906; Request to Extend Date for Final Determination and Agreement to Extend Provisional Measures,'' dated August 10, 2022.

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC189]

South Atlantic Fishery Management Council; Public Hearings

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

ACTION: Notice of public hearings.

SUMMARY: The South Atlantic Fishery Management Council (Council) will hold two public hearings via webinar pertaining to Amendment 51 and Amendment 52 to the Fishery Management Plan (FMP) for the Snapper Grouper Fishery of the South Atlantic Region. These amendments address catch levels, sector allocations, and changes to management measures for the South Atlantic stocks of snowy grouper and golden tilefish, and modifications to recreational management measures for South Atlantic blueline tilefish.

DATES: The public hearings will take place September 6 and 7, 2022, beginning at 6 p.m., EDT. For specific dates and times, see **SUPPLEMENTARY INFORMATION**.

ADDRESSES: The public hearings will be held via webinar. Information, including a link to webinar registration will be posted on the Council's website at: *https://safmc.net/public-hearings-scoping-2/* as it becomes available.

Council address: South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, N Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Kim Iverson, Public Information Officer, SAFMC; phone: (843) 571–4366 or toll free: (866) SAFMC–10; fax: (843) 769–4520; email: *kim.iverson@safmc.net.*

SUPPLEMENTARY INFORMATION: Public hearing documents, an online public comment form, and other materials will be posted to the Council's website at *https://safmc.net/public-hearings-scoping-2/* by August 23, 2022. Comments will be accepted through 5

p.m. on September 9, 2022. During the hearings, Council staff will provide an overview of actions being considered in each amendment. Staff will answer clarifying questions on the presented information and the proposed actions. Following the presentation and questions, the public will have the opportunity to provide comments on the amendment.

Amendment 51 to the Snapper Grouper FMP

The Council must adjust catch levels for snowy grouper in response to the most recent stock assessment for the species in the region conducted through the Southeast Data, Assessment, and Review (SEDAR) stock assessment process, SEDAR 36 Update (2020). The assessment indicated the stock continues to be overfished and is undergoing overfishing. A rebuilding plan is already in place for snowy grouper; however, catch levels must be adjusted based on the new catch level recommendations from the Council's Scientific and Statistical Committee (SSC). The Council is considering modifications to the overfishing limit, acceptable biological catch, annual catch limit, sector allocations, and recreational management and accountability measures.

Amendment 52 to the Snapper Grouper FMP

The stock of golden tilefish in the South Atlantic was most recently assessed through SEDAR 66 (2020), which indicated the stock is not overfished nor undergoing overfishing but is near the overfishing threshold. The Council must adjust catch levels based on the new catch level recommendations from the Council's SSC. The Council is considering modifications to the overfishing limit, acceptable biological catch, annual catch limit, sector allocations, commercial management measures, and recreational accountability measures. The Council is also considering modifications to South Atlantic blueline tilefish recreational management and accountability measures.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for auxiliary aids should be directed to the Council office (see **ADDRESSES**) 3 days prior to the meeting.

Note: The times and sequence specified in this agenda are subject to change.

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

Dated: August 11, 2022.

Rey Israel Marquez,

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

[FR Doc. 2022–17634 Filed 8–16–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC231]

Fisheries of the South Atlantic; Southeast Data, Assessment, and Review (SEDAR); Public Meeting

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

ACTION: Notice of SEDAR 82 South Atlantic Gray Triggerfish Pre-Data Workshop Webinar.

SUMMARY: The SEDAR 82 assessment of the South Atlantic stock of Gray Triggerfish will consist of a data workshop, a series of assessment webinars, and a review workshop. See **SUPPLEMENTARY INFORMATION**.

DATES: The SEDAR 82 South Atlantic Gray Triggerfish Pre-Data Workshop webinar is scheduled for September 7, 2022, from 9 a.m. until 12 p.m., Eastern. The established times may be adjusted as necessary to accommodate the timely completion of discussion relevant to the assessment process. Such adjustments may result in the meeting being extended from or completed prior to the time established by this notice.

ADDRESSES: The meeting will be held via webinar. The webinar is open to members of the public. Registration for the webinar is available by contacting the SEDAR coordinator via email at *Kathleen.Howington@safmc.net.*

SEDAR address: South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, N Charleston, SC 29405; *www.sedarweb.org.*

FOR FURTHER INFORMATION CONTACT: Kathleen Howington, SEDAR Coordinator, 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405; phone: (843) 571–4371; email: *Kathleen.Howington@safmc.net.*

SUPPLEMENTARY INFORMATION: The Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils, in conjunction with NOAA Fisheries and the Atlantic and Gulf States Marine Fisheries Commissions, have implemented the Southeast Data, Assessment and Review (SEDAR) process, a multi-step method for determining the status of fish stocks in the Southeast Region. SEDAR is a three-step process including: (1) Data Workshop; (2) Assessment Process utilizing webinars; and (3) Review Workshop. The product of the Data Workshop is a data report which compiles and evaluates potential datasets and recommends which datasets are appropriate for assessment analyses. The product of the Assessment Process is a stock assessment report which describes the fisheries, evaluates the status of the stock, estimates biological benchmarks, projects future population conditions, and recommends research and monitoring needs. The assessment is independently peer reviewed at the Review Workshop. The product of the Review Workshop is a Summary documenting panel opinions regarding the strengths and weaknesses of the stock assessment and input data. Participants for SEDAR Workshops are appointed by the Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils and NOAA Fisheries Southeast Regional Office, Highly Migratory Species Management Division, and Southeast Fisheries Science Center. Participants include: data collectors and database managers; stock assessment scientists, biologists, and researchers; constituency representatives including fishermen, environmentalists, and non-governmental organizations (NGOs); international experts; and staff of Councils, Commissions, and state and federal agencies.

The items of discussion at the SEDAR 82 South Atlantic Gray Triggerfish Pre-Data Workshop webinar are as follows: discard mortality, workshop logistics, and any other known data issues.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

This meeting is accessible to people with disabilities. Requests for auxiliary aids should be directed to the South Atlantic Fishery Management Council office (see **ADDRESSES**) at least 5 business days prior to the meeting.

Note: The times and sequence specified in this agenda are subject to change.

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

Dated: August 11, 2022.

Rey Israel Marquez,

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

[FR Doc. 2022–17635 Filed 8–16–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC270]

South Atlantic Fishery Management Council; Public Meetings

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

ACTION: Notice of public meetings.

SUMMARY: The South Atlantic Fishery Management Council (Council) will hold meetings of the following: Snapper Grouper Committee; Mackerel Cobia Committee; and Southeast Data, Assessment and Review (SEDAR) Committee. The meeting week will also include a discussion with Samuel D. Rauch, III, Deputy Assistant Administrator for Regulatory Programs with NOAA Fisheries, a formal public comment session, public hearings, and a meeting of the Full Council.

DATES: The Council meeting will be held from 8:30 a.m. on Monday, September 12, 2022, until 12 p.m. on Friday, September 16, 2022.

ADDRESSES:

Meeting address: The meeting will be held at the Town and Country Inn, 2008 Savannah Highway, Charleston, SC 29407; phone: (843) 571–1000. The meeting will also be available via webinar. Registration is required. See **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Kim Iverson, Public Information Officer, SAFMC; phone: (843) 302–8440 or toll free: (866) SAFMC–10; fax: (843) 769–4520; email: *kim.iverson@safmc.net.*

SUPPLEMENTARY INFORMATION: Meeting information, including agendas, overviews, and briefing book materials will be posted on the Council's website at: *http://safmc.net/safmc-meetings/council-meetings/.* Webinar registration links for the meeting will also be available from the Council's website.

Public comment: Public comment on agenda items may be submitted through the Council's online comment form available from the Council's website at: *http://safmc.net/safmc-meetings/council-meetings/.* Comments will be accepted from August 26, 2022, until September 16, 2022. These comments are accessible to the public, part of the Administrative Record of the meeting, and immediately available for Council consideration.

The items of discussion in the individual meeting agendas are as follows: *Council Session I, Monday, September 12, 2022, 8:30 a.m. until 5 p.m.*

The Council will receive reports from state agencies, Council liaisons, NOAA Office of Law Enforcement, and the U.S. Coast Guard. The Council will receive an update on the Dolphin Wahoo Management Strategy Evaluation (MSE) stakeholder workshops, input from the Golden Crab and Spiny Lobster Advisory Panels, and updates on the Commercial Electronic Logbook Amendment and the National Saltwater Recreational Fisheries Policy. The Council will also review the Acceptable Biological Catch (ABC) Control Rule Amendment and consider input from its advisory panels. A public hearing on the amendment will be held during the meeting week. The Council will also receive an update on East Coast Climate Change Scenario Planning. *Snapper Grouper Committee, Tuesday, September 13, 2022, 8:30 a.m. until 4:30 p.m., Wednesday, September 14, 2022, from 8:30 a.m. until 3:45 p.m. and Thursday, September 15, 2022, from 8:30 a.m. until 10:30 a.m.*

The Committee will receive a brief on an Exempted Fishing Permit request to continue a research project allowing the collection of speckled hind to study genetic population structure, connectivity, and life history. The Committee will review Snapper Grouper Regulatory Amendment 35 (Release Mortality Reduction and Red Snapper Catch Levels) and provide further guidance on actions to explore in the amendment to reduce the number of dead releases in the fishery.

The Committee will review the Recreational Permitting and Reporting Amendment (Snapper Grouper Amendment 46) and consider input from the Snapper Grouper Recreational Permitting and Reporting Technical Advisory Panel. The Committee will receive a presentation on yellowtail snapper interim analyses, input from the Council's Scientific and Statistical Committee (SSC), and a yellowtail snapper fishery overview. Management measures for gag grouper will be discussed as included in Snapper Grouper Amendment 53 and the amendment will be considered for approval for public hearings.

The Committee will review input received from shareholders during discussion of Snapper Grouper Amendment 48 addressing the wreckfish fishery and consider approving the amendment for public hearings. The Committee will review Snapper Grouper Amendment 52, addressing management of golden tilefish and blueline tilefish, and Amendment 51, addressing management of snowy grouper. Input received during earlier public hearings for both amendments will be considered. In addition, public hearings for both amendments will be held during the Council meeting.

The Committee will review Snapper Grouper Amendment 49, addressing management of greater amberjack, and consider recommending the amendment for final approval by the Council. A public hearing for Snapper Grouper Amendment 49 will be held as part of the meeting week. Finally, the Committee will provide recommendations for topics to be considered during the fall 2022 meeting of the Snapper Grouper Advisory Panel and for a meeting of golden tilefish endorsement holders. *Discussion with Samuel D. Rauch, III, Deputy Assistant Administrator for Regulatory Programs, NOAA Fisheries Tuesday, September 13, 2022, 4:30 p.m. until 5 p.m.*

Formal Public Comment, Wednesday, September 14, 2022, 4 p.m.—Public comment will be accepted from individuals attending the meeting in person and via webinar on all items on the Council meeting agenda. The Council Chair will determine the amount of time provided to each commenter based on the number of individuals wishing to comment.

Mackerel Cobia Committee, Thursday, September 15, 2022, 10 a.m. Until 2:30 p.m.

The Committee will receive an overview of Amendment 33 to the Coastal Migratory Pelagic Fishery Management Plan (FMP) for the Gulf of Mexico and South Atlantic affecting Gulf of Mexico king mackerel and review the joint FMP objectives. The Committee will also receive a summary of recent developments in the Atlantic Spanish mackerel fishery, a presentation on the Spanish mackerel assessment, recommendations from the SSC, and a fishery overview. The Committee will provide input on topics for the fall 2022 meeting of the Mackerel Cobia Advisory Panel.

SEDAR Committee, Thursday, September 15, 2022, 2:30 p.m. Until 3:30 p.m.

The Committee will receive a report from the SEDAR Steering Committee, a projects update, and approve the Scopes of Work for the king mackerel, gag grouper, and red porgy assessments.

Council Session II, Thursday, September 15, 2022, 3:30 p.m. Until 5 p.m. and Friday, September 16, 2022, 8:30 a.m. Until 12 p.m.

The Council will elect a chair and vice chair, receive a briefing on any legal issues, if needed, and present the 2021 Law Enforcement Officer of the Year award. The Council will receive staff reports and provide topics for the Habitat Advisory Panel meeting.

The Council will receive reports from NOAA Fisheries Southeast Regional Office and the Southeast Fisheries Science Center. The Council will receive Committee reports, review its workplan for the next quarter, upcoming meetings, and take action as necessary. The Council will discuss any other business as needed.

Documents regarding these issues are available from the Council office (see **ADDRESSES**).

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during these meetings. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for auxiliary aids should be directed to the Council office (see **ADDRESSES**) 5 days prior to the meeting.

Note: The times and sequence specified in this agenda are subject to change.

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

Dated: August 11, 2022.

Rey Israel Marquez,

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

[FR Doc. 2022–17636 Filed 8–16–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC109]

Notice of Availability of the Deepwater Horizon Oil Spill Alabama Trustee Implementation Group Alabama Swift Tract Living Shoreline Project: Final Supplemental Environmental Assessment

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

ACTION: Notice of availability.

SUMMARY: This Alabama Trustee Implementation Group (TIG) Alabama Swift Tract Living Shoreline Project: Final Supplemental Environmental Assessment (Final Supplemental EA) describes, and in conjunction with the associated Finding of No Significant Impact (FONSI), selects the preferred restoration alternative, which consists of the removal of rocks from the Bon Secour Bay bottom near the original Swift Tract Living Shoreline Project's action area and the placement of the removed rocks on a nearby breakwater. The proposed action falls within the general scope of the purpose and need for the original Swift Tract Living Shoreline Project, which was identified and evaluated in the Deepwater Horizon Oil Spill Programmatic and Phase III Early Restoration Plan and Early Restoration Programmatic Environmental Impact Statement (Phase III ERP/PEIS). The proposed action is also consistent with the Deepwater Horizon Oil Spill Final Programmatic Damage Assessment and Restoration Plan and Final Programmatic Environmental Impact Statement (PDARP/PEIS), as it focuses on the restoration of injuries to Alabama's natural resources and services—in particular to Restoration Type: ''Wetlands, Coastal, and Nearshore Habitats,'' using funds made available in early restoration and through the DWH Consent Decree. The Federal Trustees of the Alabama TIG have determined that the implementation of the Final Supplemental EA is not a major Federal action significantly affecting the quality of the human environment within the context of the National Environmental Policy Act (NEPA). Therefore, they have concluded a FONSI is appropriate, and, therefore, an Environmental Impact Statement will not be prepared.

ADDRESSES:

Obtaining Documents: You may access the Final Supplemental EA from the ''News'' section of the Alabama TIG website at: *http://www.gulfspillrestoration.noaa.gov/restoration-areas/alabama.* Alternatively, you may request a CD of the Final Supplemental EA (see **FOR FURTHER INFORMATION CONTACT** below).

FOR FURTHER INFORMATION CONTACT: National Oceanic and Atmospheric Administration—Stella Wilson, NOAA Restoration Center, 850–332–4169, *Estelle.Wilson@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Introduction

On April 20, 2010, the mobile offshore drilling unit *Deepwater Horizon,* which was being used to drill a well for BP Exploration and Production, Inc. (BP), in the Macondo prospect (Mississippi Canyon 252–MC252), experienced a significant explosion, fire, and subsequent sinking in the Gulf of Mexico, resulting in an unprecedented volume of oil and other discharges from the rig and from the wellhead on the seabed. The *Deepwater Horizon* oil spill is the largest off shore oil spill in U.S. history, discharging millions of barrels of oil over a period of 87 days. In addition, well over one million gallons of dispersants were applied to the waters of the spill area in an attempt to disperse the spilled oil. An undetermined amount of natural gas was also released into the environment as a result of the spill.

The Deepwater Horizon Federal and State natural resource trustees (Trustees) conducted the natural resource damage assessment (NRDA) for the *Deepwater Horizon* oil spill under OPA (OPA; 33 U.S.C. 2701 *et seq.*). Pursuant to OPA, Federal and State agencies act as trustees on behalf of the public to assess natural resource injuries and losses and to determine the actions required to compensate the public for those injuries and losses. OPA further instructs the designated trustees to develop and implement a plan for the restoration, rehabilitation, replacement, or acquisition of the equivalent of the injured natural resources under their trusteeship, including the loss of use and services from those resources from the time of injury until the time of restoration to baseline (the resource quality and conditions that would exist if the spill had not occurred) is complete. The *Deepwater Horizon* Trustees are:

- U.S. Department of the Interior (DOI), as represented by the National Park Service, U.S. Fish and Wildlife Service, and Bureau of Land Management;

- National Oceanic and Atmospheric Administration (NOAA), on behalf of the U.S. Department of Commerce;
- U.S. Department of Agriculture (USDA);
- U.S. Environmental Protection Agency (EPA);
- State of Louisiana Coastal Protection and Restoration Authority (CPRA), Oil Spill Coordinator's Office (LOSCO), Department of Environmental Quality (LDEQ), Department of Wildlife and Fisheries (LDWF), and Department of Natural Resources (LDNR);
- State of Mississippi Department of Environmental Quality;
- State of Alabama Department of Conservation and Natural Resources and Geological Survey of Alabama;
- State of Florida Department of Environmental Protection and Fish and Wildlife Conservation Commission; and
- State of Texas: Texas Parks and Wildlife Department, Texas General Land Office, and Texas Commission on Environmental Quality.

The Trustees reached and finalized a settlement of their natural resource damage claims with BP in an April 4, 2016, Consent Decree approved by the United States District Court for the Eastern District of Louisiana. Pursuant to that Consent Decree, restoration projects in the Alabama Restoration Area are selected and implemented by the Alabama TIG.

Background

Notice of Availability of the *Deepwater Horizon* Oil Spill Alabama Trustee Implementation Group Draft Living Shoreline Supplemental Environmental Assessment (Draft Supplemental EA) was published in the **Federal Register** at 87 FR 10339 on February 24, 2022. The public comment period for the Draft Supplemental EA closed on March 28, 2022. One public comment was received during the comment period. It was reviewed and taken into consideration in the preparation of the Final Supplemental EA. All correspondence received is provided in the DWH Administrative Record.

Overview of the Alabama TIG Final Supplemental EA

As described in Section III of this Final Supplemental EA (the ''OPA Summary''), the Alabama TIG has determined that the proposed corrective action does not alter its original conclusions for the Swift Tract Living Shorelines Project under OPA and its implementing regulations. Thus, the Alabama TIG concludes that implementation of the corrective action proposed in this Supplemental EA does not require further OPA evaluation, and this Supplemental EA focuses its analysis on the potential environmental impacts of the proposed corrective action under NEPA.

This Supplemental EA provides NEPA analysis for the Swift Tract Living Shorelines Project proposed corrective action by supplementing the NEPA analysis for the Phase III ERP/PEIS. The supplemental NEPA analysis provided in this Swift Tract Supplemental EA augments and incorporates by reference the applicable sections (Chapter 11, Affected Environment, Environmental Consequences for the Swift Tract Restoration Project) of the Phase III ERP/PEIS. This supplemental analysis considers any additional environmental impacts that would result from implementation of the corrective action that are not described and analyzed in the Phase III ERP/PEIS.

The Final Supplemental EA evaluates the proposed removal of rocks from the bay bottom near the Swift Tract Living Shoreline Project action area and the placement of the removed rocks on a nearby The Nature Conservancy (TNC) breakwater. The proposed rock removal and breakwater placement locations are adjacent to, but outside of, the project action area identified in the Final Phase III ERP/PEIS. Due to the close proximity of the new removal and placement areas to the existing Swift Tract breakwater, the Affected Environment for the proposed removal and placement areas would be the same as that evaluated for the Swift Tract breakwater in the Phase III ERP/PEIS. The environmental consequences of the proposed corrective action are also anticipated to fall generally within the scope of the environmental consequences evaluated for the original project. Therefore, the Environmental Consequences reviewed in the Swift Tract project evaluation, in Chapter 11, Section 11.4 of the Final Phase III ERP/PEIS, are reviewed in the Supplemental EA to evaluate the likely environmental consequences of the proposed corrective action and the ''No Action'' alternatives to determine whether implementation of the proposed corrective action may alter the conclusions made in the Final Phase III ERP/PEIS. Under the ''No Action'' alternative, the rocks currently located on the water bottom would not be removed from the water bottom and would instead be left in place.

In the Supplemental EA, the Alabama TIG concludes that implementation of the proposed action would not significantly impact the quality of the human environment and, therefore, that an environmental impact statement for this action is not necessary. The Alabama TIG thus proposes implementation of the preferred corrective action, removal of the rock material from the bay bottom near the living shoreline constructed during the original Swift Tract Living Shoreline Project and placement of that rock material on the nearby TNC breakwater.

Administrative Record

The documents comprising the Administrative Record for the Supplemental EA can be viewed electronically at *http://www.doi.gov/deepwaterhorizon/adminrecord.*

Authority

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

Dated: August 12, 2022.

Carrie Dianne Robinson,

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

[FR Doc. 2022–17719 Filed 8–16–22; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Public Meetings for Recommending a National Estuarine Research Reserve Site[S] in the Green Bay Coastal Area of Lake Michigan

AGENCY: Office for Coastal Management, National Ocean Service, National Oceanic and Atmospheric Administration, Department of Commerce.

ACTION: Public meeting notice.

SUMMARY: Notice is hereby given that two public meetings will be held for the purpose of providing information and receiving comments on the preliminary recommendation by the State of Wisconsin that portions of the Green Bay coastal area of Lake Michigan be proposed to National Oceanic and Atmospheric Administration (NOAA) for designation as a National Estuarine Research Reserve.

DATES: The in-person public meeting will be held at 1 p.m. on September 7, 2022, in the S.T.E.M. Innovation Center at the University of Wisconsin Green Bay campus, located at 2019 Technology Way, Green Bay, WI 54311.

The virtual public meeting will be held at 3:30 p.m. on September 8, 2022,

at: *https://wisconsin-edu.zoom.us/j/99551264991?pwd=QUlPc0dhWSthRUFGaDYvakZvNG1XUT09.* If requested upon joining the virtual meeting, the meeting ID is 995 5126 4991, and the attendee access code is NERR. Participants may also join the meeting by phone by using this toll-free number +1 312 626 6799, and meeting ID 995 5126 4991, and attendee access code 688730.

Both public meetings will present the same information.

The State agency holding the meetings is the University of Wisconsin-Green Bay. NOAA's Office for Coastal Management will assist with the meetings.

ADDRESSES: This hearing will present the State's proposed nomination. Detailed information on the proposed site[s] can be found on the University of Wisconsin-Green Bay website: *https://www.uwgb.edu/national-estuarine-research-reserves/.*

The views of interested persons and organizations regarding the proposed nomination are solicited. This information may be expressed verbally and in written statements. A presentation about the proposal and the National Estuarine Research Reserve System will be provided at both meetings. Written comments may also be sent to: Emily Tyner, University of Wisconsin-Green Bay Director of Freshwater Strategy, at *tynere@uwgb.edu.* All written comments must be received no later than seven days following the public meetings [September 15, 2022]. All comments received will be considered by the State when formally nominating a site or sites to NOAA.

FOR FURTHER INFORMATION CONTACT: Ms. Erica Seiden, Office for Coastal Management, National Ocean Service, NOAA, 1305 East West Highway, N/OCM, Silver Spring, MD 20910 or by email at *erica.seiden@noaa.gov* or phone at 240–388–9209.

SUPPLEMENTARY INFORMATION: The research reserve system is a Federal and State partnership program administered by the Federal government, specifically NOAA. The research reserve system currently has 30 sites and protects more than 1.3 million acres (5,260 square kilometers) of estuarine and Great Lakes habitat for long-term research, monitoring, education, and stewardship. Established by the Coastal Zone Management Act of 1972, each reserve is managed by a lead State agency or university, with input from local partners. NOAA provides partial funding and national programmatic guidance.

This particular site selection effort is a culmination of several years of local, grassroots-support for a research reserve in Wisconsin. The proposed site[s] presented at this meeting follow a comprehensive evaluation process that sought the views of the public, affected landowners, and other interested parties. State and local agency representatives, Tribal nations, as well as estuarine experts, served as committee members and evaluated site proposals.

Federal Domestic Assistance Catalog Number 11.420 (Coastal Zone Management) Research Reserves.

Keelin S. Kuipers,

Deputy Director, Office for Coastal Management, National Ocean Service, National Oceanic and Atmospheric Administration.

[FR Doc. 2022–17675 Filed 8–16–22; 8:45 am]

BILLING CODE 3510–JE–P

CONSUMER PRODUCT SAFETY COMMISSION

Public Availability of Consumer Product Safety Commission FY 2020 Service Contract Inventory, FY 2019 Service Contract Inventory Analysis, and Plan for FY 2020 Inventory Analysis

AGENCY: Consumer Product Safety Commission.

ACTION: Notice.

SUMMARY: The Consumer Product Safety Commission (CPSC), in accordance with Division C of the Consolidated Appropriations Act, 2010, is announcing the availability of CPSC's service contract inventory for fiscal year (FY) 2020, CPSC's FY 2019 service contract inventory analysis, and the plan for analyzing CPSC's FY 2020 service contract inventory.

FOR FURTHER INFORMATION CONTACT: Eddie Ahmad, Procurement Analyst, Division of Procurement Services, Division of Procurement Services, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814. Telephone: 301–504–7884; email: *aahmad@cpsc.gov.*

SUPPLEMENTARY INFORMATION: On December 16, 2009, the Consolidated Appropriations Act, 2010 (Consolidated Appropriations Act), Public Law 111–117, became law. Section 743(a) of the Consolidated Appropriations Act, titled, ''Service Contract Inventory Requirement,'' requires agencies to submit to the Office of Management and Budget (OMB), an annual inventory of service contracts awarded or extended through the exercise of an option on or after April 1, 2010, and describes the contents of the inventory. The contents of the inventory must include:

(A) A description of the services purchased by the executive agency and the role the services played in achieving agency objectives, regardless of whether such a purchase was made through a contract or task order;

(B) The organizational component of the executive agency administering the contract, and the organizational component of the agency whose requirements are being met through contractor performance of the service;

(C) The total dollar amount obligated for services under the contract and the funding source for the contract;

(D) The total dollar amount invoiced for services under the contract;

(E) The contract type and date of award;

(F) The name of the contractor and place of performance;

(G) The number and work location of contractor and subcontractor employees, expressed as full-time equivalents for direct labor, compensated under the contract;

(H) Whether the contract is a personal services contract; and

(I) Whether the contract was awarded on a noncompetitive basis, regardless of date of award.

Section 743(a)(3)(A) through (I) of the Consolidated Appropriations Act. Section 743(c) of the Consolidated Appropriations Act requires agencies to ''publish in the Federal Register a notice that the inventory is available to the public.''

Consequently, through this notice, we are announcing that the CPSC's service contract inventory for FY 2020 is available to the public.[1] The inventory provides information on service contract actions that the CPSC made in FY 2020 per the Federal Acquisition Regulation (FAR) requirements in FAR part 4.1703. The information is organized by function to show how contracted resources are distributed throughout the CPSC. OMB posted a consolidated government-wide Service Contract Inventory for FY 2020 at *https://www.acquisition.gov/service-contract-inventory.* You can access the CPSC's inventories by limiting the ''Contracting Agency Name'' field on each spreadsheet to ''Consumer Product Safety Commission.''

Additionally, CPSC's Division of Procurement Services has posted CPSC's FY 2019 service contract inventory analysis and the plan for analyzing the FY 2020 inventory on CPSC's website at the following link: *https://www.cpsc.gov/Agency-Reports/Service-Contract-Inventory.* The FY

[1] The Commission voted 5–0 to publish this notice.

2019 inventory analysis was developed in accordance with guidance issued on October 17, 2016 by the Office of Management and Budget (OMB), Office of Procurement Policy (OFPP).

Abioye Mosheim,

Acting Secretary, Consumer Product Safety Commission.

[FR Doc. 2022–17714 Filed 8–16–22; 8:45 am]

BILLING CODE 6355–01–P

CONSUMER PRODUCT SAFETY COMMISSION

[Docket No. CPSC–2009–0073]

Agency Information Collection Activities; Proposed Collection; Comment Request; Virginia Graeme Baker Pool and Spa Safety Act; Compliance Form

AGENCY: Consumer Product Safety Commission.

ACTION: Notice.

SUMMARY: As required by the Paperwork Reduction Act of 1995, the Consumer Product Safety Commission (CPSC) requests comments on a proposed extension of approval of a collection of information regarding a form used to verify whether pools and spas are in compliance with the Virginia Graeme Baker Pool and Spa Safety Act. The Office of Management and Budget (OMB) previously approved the collection of information under OMB Control No. 3041–0142. CPSC will consider all comments received in response to this notice before requesting an extension of approval of this collection of information from OMB.

DATES: Submit written or electronic comments on the collection of information by October 17, 2022.

ADDRESSES: You may submit comments, identified by Docket No. CPSC–2009–0073, by any of the following methods:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: *https://www.regulations.gov.* Follow the instructions for submitting comments. Do not submit through this website: confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. CPSC typically does not accept comments submitted by electronic mail (email), except as described below.

Mail/Hand Delivery/Courier Written Submissions: CPSC encourages you to submit electronic comments by using the Federal eRulemaking Portal. You may, however, submit comments by mail, hand delivery, or courier to: Office of the Secretary, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504–7479.

Instructions: All submissions must include the agency name and docket number. CPSC may post all comments without change, including any personal identifiers, contact information, or other personal information provided, to: *https://www.regulations.gov.* If you wish to submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public, you must submit such comments by mail, hand delivery, or courier, or by email to: *cpsc-os@cpsc.gov.*

Docket: For access to the docket to view the verification of compliance form ''2022 VGBA Form'', or the comments received, go to: *https://www.regulations.gov,* and insert the docket number, CPSC–2009–0073, into the ''Search'' box, and follow the prompts.

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

FOR FURTHER INFORMATION CONTACT: Cynthia Gillham, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; (301) 504–7991, or by email to: *cgillham@cpsc.gov.*

SUPPLEMENTARY INFORMATION: CPSC seeks to renew the following currently approved collection of information:

Title: Virginia Graeme Baker Pool and Spa Safety Act Verification of Compliance Form

OMB Number: 3041–0142

Type of Review: Renewal of collection

Frequency of Response: On occasion

Affected Public: Public pools and spa facilities

Estimated Number of Respondents: 50 pools or facilities

Estimated Time per Response: 3 hours to inspect a pool or spa facility

Total Estimated Annual Burden: The total testing burden hours are 150 (50 inspections × 3 hours per inspection). We estimate there will be 50 inspections conducted throughout the fiscal year based on CPSC plans for inspections, past compliance rates and trends, as well as available staff resources. We estimate that hourly compensation for the time required for inspecting is $64.02 (U.S. Bureau of Labor Statistics, ''Employer Costs for Employee Compensation,'' March 2022, Table 4, total compensation for management, professional, and related workers in private service-producing industries: *https://www.bls.gov/news.release/ecec.t04.htm*). The total annual cost of time to inspect all facilities is estimated to be $9,603 ($64.02 × 150).

General Description of Collection

The Virginia Graeme Baker Pool and Spa Safety Act (Act), 15 U.S.C. Ch. 106, applies to public swimming pools and spas, and it requires that each swimming pool and spa drain cover manufactured, distributed, or entered into commerce in the United States shall conform to the entrapment protection standards of the ASME/ANSI A112.19.8 performance standard or any successor standard regulating such swimming pool or drain cover under section 1404(b) of the Act.

On August 5, 2011, the CPSC published a final rule incorporating by reference ANSI/APSP–16 2011 as the successor standard, effective September 6, 2011. 76 FR 47436. On May 24, 2019, the CPSC published a direct final rule incorporating by reference ANSI/APSP–16 2017 as the next successor standard. 84 FR 24021. The Act requires that, in addition to having the anti-entrapment devices or systems, each public pool and spa in the United States with a single main drain other than an unblockable drain shall be equipped with one or more of the following devices or systems designed to prevent entrapment by pool or spa drains: a safety vacuum release system, suction-limiting vent system, gravity drainage system, automatic pump shut-off system or drain disablement. The CPSC will collect information through the verification of compliance form to identify drain covers, pools, and spas that do not meet the performance requirements in ANSI/APSP–16 2017 and the Act. CPSC staff or the designated State or local government official will take approximately 3 hours to inspect the pool and fill out the checklist on the verification of compliance form. The 2022 VGBA Form they will use is available for viewing at *https://www.regulations.gov* under docket number, CPSC–2009–0073, ''Supporting and Related Material.''

Request for Comments

The CPSC solicits written comments from all interested persons about the proposed collection of information. The

CPSC specifically solicits information relevant to the following topics:

—Whether the collection of information described above is necessary for the proper performance of the Commission's functions, including whether the information would have practical utility;
—Whether the estimated burden of the proposed collection of information is accurate;
—Whether the quality, utility, and clarity of the information to be collected could be enhanced; and
—Whether the burden imposed by the collection of information could be minimized by use of automated, electronic or other technological collection techniques, or other forms of information technology.

Abioye Mosheim,

Acting Secretary, Consumer Product Safety Commission.

[FR Doc. 2022–17655 Filed 8–16–22; 8:45 am]

BILLING CODE 6355–01–P

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Agency Information Collection Activities; Comment Request; Application Package for AmeriCorps Program Life Cycle Evaluation—Climate Change Bundled Evaluation

AGENCY: Corporation for National and Community Service.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Corporation for National and Community Service, operating as AmeriCorps, is proposing a new information collection.

DATES: Written comments must be submitted to the individual and office listed in the **ADDRESSES** section by October 17, 2022.

ADDRESSES: You may submit comments, identified by the title of the information collection activity, by any of the following methods:

(1) By mail sent to: AmeriCorps, Attention Jehyra M. Asencio-Yace, 250 E Street SW, Washington, DC 20525.

(2) By hand delivery or by courier to the AmeriCorps mailroom at the mail address given in paragraph (1) above, between 9 a.m. and 4 p.m. Eastern Time, Monday through Friday, except Federal holidays.

(3) Electronically through *www.regulations.gov.*

Comments submitted in response to this notice may be made available to the public through *regulations.gov.* 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 comment that may be made available to the public, notwithstanding the inclusion of the routine notice.

FOR FURTHER INFORMATION CONTACT: Xiaodong Zhang, 703–251–0883, or by email at *xiaodong.zhang@icf.com.*

SUPPLEMENTARY INFORMATION:

Title of Collection: AmeriCorps Program Life Cycle Evaluation—Climate Change Bundled Evaluation.

OMB Control Number: TBD. *Type of Review:* New.

Respondents/Affected Public: Grantee and sponsor organizations, national service members, community members, and partner organization staff.

Total Estimated Number of Annual Responses: 610 responses.

Total Estimated Number of Annual Burden Hours: 232 hours.

Abstract: The purpose of this evaluation is to provide insight on the implementation of the climate change bundle programs and explore variation in activities for education and training, disaster response, conservation, wildfire mitigation, and energy efficiency. It will explore the ways in which the programs influence community resilience. It will also examine changes in attitudes and behaviors toward civic engagement among national service members and the development of job skills, including skills for green jobs. Finally, it will examine how the programs are serving vulnerable communities and at-risk populations. The research questions for this evaluation will be:

1. How do programs/members connect their work to climate change?
2. To what extent does the program include opportunities to increase equity?
3. To what extent is the program operating as intended?
4. What are some promising practices and some challenges in implementing the climate change grant programs?
5. What were the barriers and facilitators to meet the intended outcomes of the program?
6. What are the lessons learned that can inform the field or be useful for practitioners that work in this space?
7. What is the likelihood that the program will be sustained beyond the grant?
8. How were the communities and community members impacted by climate change prior to the program?
9. What types of communities are being helped by the climate change grant programs?
10. To what extent are programs focused on vulnerable populations and communities?
11. What are the demographic characteristics of national service members (*e.g.,* gender, age, race, ethnicity, education)?
12. How did the COVID–19 pandemic affect program operations?
13. How did the COVID–19 pandemic affect national service members?
14. What partner organizations are involved (*e.g.,* community organizations, local agencies)? What are their roles in the program?
15. What is the breadth (number and type of partnership), quality, and quantity of the partnership(s) (number and frequency of joint activities and their strength)?
16. How were partnerships built and maintained?
17. How do grantee and sponsor organizations work with partners to build community resilience?
18. To what extent do the climate change grant programs:

a. improve energy efficiency and increase the use of renewable energy sources?

b. help communities prepare, respond, and recover from natural disasters and other climate change effects?

c. preserve public lands and waterways and protect or restore biodiversity?

d. increase community members' knowledge, attitudes, and behaviors around climate change?

e. build capacity of the community to be resilient?

19. How do the climate change grant programs lead to increased civic engagement?
20. In what ways does participation in the climate change grant programs influence national service members' job skills development toward green jobs?
21. To what extent does participation in the climate change grant programs:

a. increase national service members' functional and technical job skills?

b. increase national service members' interest/willingness to pursue a career in a green job?

c. lead to a job after their service?

d. lead to a career in a green job after their service?

ICF will conduct a bundled evaluation of grantees and sponsors

with an explicit emphasis on activities related to addressing climate change. By bundling, this evaluation combines programs and projects with similar program approaches into a single evaluation. Spanning 32 months, the evaluation includes up to 30 grantees and sponsors to examine program design, implementation, and outcomes using surveys, interviews, and focus groups with a wide range of stakeholders including grantee and sponsor staff, partner organizations, national service members, and community members. This is a new information collection.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. 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 shall have 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 respondents, including through the use of automated collection techniques 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. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose, or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install, and use technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel to be able to respond to a collection of information, to search data sources, and to complete and review the collection of information; and to transmit or otherwise disclose the information. All written comments will be available for public inspection on regulations.gov.

Dated: August 11, 2022.

Mary Hyde,

Director, Office of Research and Evaluation.

[FR Doc. 2022–17650 Filed 8–16–22; 8:45 am]

BILLING CODE 6050–28–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2022–SCC–0105]

Agency Information Collection Activities; Comment Request; Study of the Impact of English Learner Reclassification Policies

AGENCY: Institute of Education Science (IES), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing a new information collection.

DATES: Interested persons are invited to submit comments on or before October 17, 2022.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2022–SCC–0105. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the *regulations.gov* site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov*. Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the PRA Coordinator of the Strategic Collections and Clearance Governance and Strategy Division, U.S. Department of Education, 400 Maryland Ave. SW, LBJ, Room 6W208C, Washington, DC 20202–8240.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Tracy Rimdzius, 202–245–7283.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Study of the Impact of English Learner Reclassification Policies.

OMB Control Number: 1850–NEW.

Type of Review: A new information collection.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 30.

Total Estimated Number of Annual Burden Hours: 817.

Abstract: The data collection described in this submission will assist policymakers in understanding the impact of reclassification policies that exit students from English learner (EL) status. Specifically, the study will examine (1) whether reclassification was implemented more consistently across districts within states after the start of the Every Student Succeeds Act (ESSA) and (2) whether reclassification at current thresholds helps, harms, or is neutral for former ELs' instructional opportunities, experiences, achievement, and attainment. Data for the study will come from extant state longitudinal data systems and publicly available data on state policies.

Dated: August 12, 2022.

Juliana Pearson,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2022–17681 Filed 8–16–22; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Annual Updates to the Income-Contingent Repayment (ICR) Plan Formula for 2022—William D. Ford Federal Direct Loan Program

AGENCY: Federal Student Aid, Department of Education.

ACTION: Notice.

SUMMARY: The Secretary announces the annual updates to the ICR plan formula for 2022 to give notice to borrowers and the public regarding how monthly ICR payment amounts will be calculated for the 2022–2023 year under the William D. Ford Federal Direct Loan (Direct Loan) Program, Assistance Listing Number 84.063.

DATES: The adjustments to the income percentage factors for the ICR plan formula contained in this notice are applicable from July 1, 2022, to June 30, 2023, for any borrower who enters the ICR plan or has a monthly payment amount under the ICR plan recalculated during that period.

FOR FURTHER INFORMATION CONTACT: Travis Sturlaugson, U.S. Department of Education, 830 First Street NE, Room 113H3, Washington, DC 20202. Telephone: (202) 377–4174. Email: *travis.sturlaugson@ed.gov*.

If you are deaf, hard of hearing, or have a speech disability and wish to access telecommunications relay services, please dial 7–1–1.

SUPPLEMENTARY INFORMATION: Under the Direct Loan Program, borrowers may choose to repay their non-defaulted Direct Subsidized Loans, Direct Unsubsidized Loans, Direct PLUS Loans made to graduate or professional students, and Direct Consolidation Loans under the ICR plan. The ICR plan bases the borrower's monthly payment amount on the borrower's Adjusted Gross Income (AGI), family size, loan amount, and the interest rate applicable to each of the borrower's loans.

ICR is one of several ''income-driven'' repayment plans that provide a monthly payment amount based on the borrower's income and family size. The other income-driven repayment plans are the Income-Based Repayment (IBR) plan, the Pay As You Earn Repayment (PAYE) plan, and the Revised Pay As You Earn Repayment (REPAYE) plan. The IBR, PAYE, and REPAYE plans generally result in lower payment amounts than the ICR plan.

A Direct Loan borrower who repays under the ICR plan pays the lesser of: (1) the monthly amount that would be required over a 12-year repayment period with fixed payments, multiplied by an income percentage factor; or (2) 20 percent of their discretionary income.

We adjust the income percentage factors annually to reflect changes in inflation and announce the adjusted factors in the **Federal Register**, as required by 34 CFR 685.209(b)(1)(ii)(A). We use the adjusted income percentage factors to calculate a borrower's monthly ICR payment amount when the borrower initially applies for the ICR plan or when the borrower submits annual income documentation, as required under the ICR plan. This notice contains the adjusted income percentage factors for 2022, examples of how the monthly ICR payment amount is calculated, and charts showing sample repayment amounts based on the adjusted ICR plan formula. This information is included in the following three attachments:

- *Attachment 1—Income Percentage Factors for 2022*
- *Attachment 2—Examples of the Calculations of Monthly Repayment Amounts*
- *Attachment 3—Charts Showing Sample Repayment Amounts for Single and Married Borrowers*

In Attachment 1, to reflect changes in inflation, we updated the income percentage factors that were published in the **Federal Register** on April 14, 2021 (86 FR 19607). Specifically, we have revised the table of income percentage factors by changing the dollar amounts of the incomes shown by a percentage equal to the estimated percentage change between the not-seasonally-adjusted Consumer Price Index for all urban consumers for December 2021 and December 2022.

The income percentage factors reflected in Attachment 1 may cause a borrower's payments to be lower than they were in prior years, even if the borrower's income is the same as in the prior year. The revised repayment amount more accurately reflects the impact of inflation on the borrower's current ability to repay.

Accessible Format: On request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document 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 this 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.

Program Authority: 20 U.S.C. 1087 *et seq*.

Richard Cordray,

Chief Operating Officer, Federal Student Aid.

Attachment 1—Income Percentage Factors for 2022

INCOME PERCENTAGE FACTORS FOR 2022

Single		Married/head of household	
AGI	% Factor	AGI	% Factor
$12,922	55.00	$12,922	50.52
$17,780	57.79	20,389	56.68
$22,879	60.57	24,296	59.56
$28,093	66.23	31,764	67.79
$33,071	71.89	39,351	75.22
$39,351	80.33	49,425	87.61
$49,425	88.77	61,987	100.00
$61,988	100.00	74,555	100.00
$74,555	100.00	93,405	109.40

INCOME PERCENTAGE FACTORS FOR 2022—Continued

Single		Married/head of household	
AGI	% Factor	AGI	% Factor
$89,605	111.80	124,811	125.00
$114,735	123.50	168,784	140.60
$162,505	141.20	236,052	150.00
$186,326	150.00	385,726	200.00
$331,879	200.00	.....	.....

Attachment 2—Examples of the Calculations of Monthly Repayment Amounts

General notes about the examples in this attachment:

- We have a calculator that borrowers can use to estimate what their payment amounts would be under the ICR plan. The calculator is called the ''Loan Simulator'' and is available at *studentaid.gov/loan-simulator*. Based on information entered into the calculator by the borrower (for example, income, family size, and tax filing status), this calculator provides a detailed, individualized assessment of a borrower's loans and repayment plan options, including the ICR plan.
- The interest rates used in the examples are for illustration only. The actual interest rates on an individual borrower's Direct Loans depend on the loan type and when the loan was first disbursed.
- The Poverty Guideline amounts used in the examples are from the 2022 U.S. Department of Health and Human Services (HHS) Poverty Guidelines for the 48 contiguous States and the District of Columbia. Different Poverty Guidelines apply to residents of Alaska and Hawaii. The Poverty Guidelines for 2022 were published in the **Federal Register** on January 21, 2022 (87 FR 3315).
- All of the examples use an income percentage factor corresponding to an adjusted gross income (AGI) in the table in Attachment 1. If an AGI is not listed in the income percentage factors table in Attachment 1, the applicable income percentage can be calculated by following the instructions under the ''Interpolation'' heading later in this attachment.
- Married borrowers may repay their Direct Loans jointly under the ICR plan. If a married couple elects this option, we determine a joint ICR payment amount based on the combined outstanding balances of each borrower's Direct Loans and the combined AGIs of both borrowers. We then prorate the joint payment amount for each borrower based on the proportion of that borrower's debt to the total outstanding balance. We bill each borrower separately.
- For example, if a married couple, John and Briana, has a total outstanding Direct Loan debt of $60,000, of which $40,000 belongs to John and $20,000 to Briana, we would apportion 67 percent of the monthly ICR payment to John and the remaining 33 percent to Briana. To take advantage of a joint ICR payment, married couples need not file taxes jointly; they may file separately and subsequently provide the other spouse's tax information to the borrower's Federal loan servicer.

Calculating the Monthly Payment Amount Using a Standard Amortization and a 12-Year Repayment Period

The formula to amortize a loan with a standard schedule (in which each payment is the same over the course of the repayment period) is as follows:

$$M = P \times < (I \div 12) \div [1 - \{1 + (I \div 12)\} \wedge -N] >$$

In the formula—

- M is the monthly payment amount;
- P is the outstanding principal balance of the loan at the time the loan entered repayment;
- I is the annual interest rate on the loan, expressed as a decimal (for example, for a loan with an interest rate of 6 percent, 0.06); and
- N is the total number of months in the repayment period (for example, for a loan with a 12-year repayment period, 144 months).

For example, assume that Billy has a $10,000 Direct Unsubsidized Loan with an interest rate of 6 percent.

Step 1: To solve for M, first simplify the numerator of the fraction by which we multiply P, the outstanding principal balance. To do this divide I (the interest rate expressed as a decimal) by 12. In this example, Billy's interest rate is 6 percent. As a decimal, 6 percent is 0.06.

- $0.06 \div 12 = 0.005$

Step 2: Next, simplify the denominator of the fraction by which we multiply P. To do this divide I (the interest rate expressed as a decimal) by 12. Then, add one. Next, raise the sum of the two figures to the negative power that corresponds to the length of the repayment period in months. In this example, because we are amortizing a loan to calculate the monthly payment amount under the ICR plan, the applicable figure is 12 years, which is 144 months. Finally, subtract the result from one.

- $0.06 \div 12 = 0.005$
- $1 + 0.005 = 1.005$
- $1.005 \wedge -144 = 0.48762628$
- $1 - 0.48762628 = 0.51237372$

Step 3: Next, resolve the fraction by dividing the result from Step 1 by the result from Step 2.

- $0.005 \div 0.51237372 = 0.0097585$

Step 4: Finally, solve for M, the monthly payment amount, by multiplying the outstanding principal balance of the loan by the result of Step 3.

- $\$10{,}000 \times 0.0097585 = \$97.59$

The remainder of the examples in this attachment will only show the results of the formula. In each of the examples, the Direct Loan amounts represent the outstanding principal balance at the time the loans entered repayment.

Example 1. Kesha is single with no dependents and has $15,000 in Direct Subsidized and Unsubsidized Loans. The interest rate on Kesha's loans is 6 percent, and she has an AGI of $33,072.

Step 1: Determine the total monthly payment amount based on what Kesha would pay over 12 years using standard amortization. To do this, use the formula that precedes Example 1. In this example, the monthly payment amount would be $146.38.

Step 2: Multiply the result of Step 1 by the income percentage factor shown in the income percentage factors table (see Attachment 1 to this notice) that corresponds to Kesha's AGI. In this example, an AGI of $33,072 corresponds to an income percentage factor of 71.89 percent.

- $0.7189 \times \$146.38 = \$105.23$

Step 3: Now, determine the monthly payment amount equal to 20 percent of Kesha's discretionary income (discretionary income is AGI minus the HHS Poverty Guideline amount for a borrower's family size and State of residence). To do this, subtract the HHS

Poverty Guideline amount for a family of one from Kesha's AGI, multiply the result by 20 percent, and then divide by 12:

- $33,071 − $13,590 = $19,481
- $19,481 × 0.20 = $3,896.20
- $3,896.20 ÷ 12 = $324.68

Step 4: Compare the amount from Step 2 with the amount from Step 3. In this example, Kesha would pay the amount calculated under Step 2 ($105.23), since this is the lesser of the two payment amounts.

Note: In this example, Kesha would have a lower payment under the ICR plan than under the other income-driven repayment plans. Specifically, Kesha's monthly payment would be $105.73 under the PAYE and REPAYE plans, and $158.59 under the IBR plan.

Example 2. Paul is married to Jesse and they have no dependents. They file their Federal income tax return jointly. Paul has a Direct Loan balance of $10,000, and Jesse has a Direct Loan balance of $15,000. Each of their Direct Loans has an interest rate of 6 percent.

Paul and Jesse have a combined AGI of $93,405 and are repaying their loans jointly under the ICR plan (for general information regarding joint ICR payments for married couples, see the fifth and sixth bullets under the heading ''General notes about the examples in this attachment'').

Step 1: Add Paul's and Jesse's Direct Loan balances to determine their combined aggregate loan balance:

- $10,000 + $15,000 = $25,000

Step 2: Determine the combined monthly payment amount for Paul and Jesse based on what both borrowers would pay over 12 years using standard amortization. To do this, use the formula that precedes Example 1. In this example, their combined monthly payment amount would be $243.96.

Step 3: Multiply the result of Step 2 by the income percentage factor shown in the income percentage factors table (see Attachment 1 to this notice) that corresponds to Paul and Jesse's combined AGI. In this example, the combined AGI of $93,405 corresponds to an income percentage factor of 109.40 percent.

- 1.094 × $243.96 = $266.90

Step 4: Now, determine the monthly payment amount equal to 20 percent of Paul and Jesse's combined discretionary income (discretionary income is AGI minus the HHS Poverty Guideline amount for a borrower's family size and State of residence). To do this, subtract the Poverty Guideline amount for a family of two from the combined AGI, multiply the result by 20 percent, and then divide by 12:

- $93,405—$18,310 = $75,095
- $75,095 × 0.20 = $15,019
- $15,019 ÷ 12 = $1,251.58

Step 5: Compare the amount from Step 3 with the amount from Step 4. Paul and Jesse would jointly pay the amount calculated under Step 3 ($266.90), since this is the lesser of the two amounts.

Note: For Paul and Jesse, the ICR plan provides the lowest monthly payment of any income-driven repayment plan available. Paul and Jesse would not be eligible for the IBR or PAYE plans, and they would have a combined monthly payment under the REPAYE plan of $549.50.

Step 6: Because Paul and Jesse are jointly repaying their Direct Loans under the ICR plan, the monthly payment amount calculated under Step 5 applies to Paul's and Jesse's combined loans. To determine the amount for which each borrower will be responsible, prorate the amount calculated under Step 4 by each spouse's share of the combined Direct Loan debt. Paul has a Direct Loan debt of $10,000 and Jesse has a Direct Loan debt of $15,000. For Paul, the monthly payment amount will be:

- $10,000 ÷ ($10,000 + $15,000) = 40 percent
- 0.40 × $266.90 = $106.76

For Jesse, the monthly payment amount will be:

- $15,000 ÷ ($10,000 + $15,000) = 60 percent
- 0.60 × $266.90 = $160.14

Example 3. Santiago is single with no dependents and has a combined balance of $60,000 in Direct Subsidized and Unsubsidized Loans. Each of Santiago's loans has an interest rate of 6 percent, and Santiago's AGI is $39,350.

Step 1: Determine the total monthly payment amount based on what Santiago would pay over 12 years using standard amortization. To do this, use the formula that precedes Example 1. In this example, the monthly payment amount would be $585.51.

Step 2: Multiply the result of Step 1 by the income percentage factor shown in the income percentage factors table (see Attachment 1 to this notice) that corresponds to Santiago's AGI. In this example, an AGI of $39,350 corresponds to an income percentage factor of 80.33 percent.

- 0.8033 × $585.51 = $470.34

Step 3: Now, determine the monthly payment amount equal to 20 percent of Santiago's discretionary income (discretionary income is AGI minus the HHS Poverty Guideline amount for a borrower's family size and State of residence). To do this, subtract the HHS Poverty Guideline amount for a family of one from Santiago's AGI, multiply the result by 20 percent, and then divide by 12:

- $39,351 − $13,590 = $25,761
- $25,761 × 0.20 = $5,152.20
- $5,152.20 ÷ 12 = $429.35

Step 4: Compare the amount from Step 2 with the amount from Step 3. In this example, Santiago would pay the amount calculated under Step 3 ($429.35), since this is the lesser of the two amounts.

Note: Santiago would have a lower payment under each of the other income-driven plans. Specifically, Santiago's payment would be $158.04 under the PAYE and REPAYE plans and $237.06 under the IBR plan.

Interpolation. If an AGI is not included on the income percentage factor table, calculate the income percentage factor through linear interpolation. For example, assume that Jocelyn is single with an AGI of $50,000.

Step 1: Find the closest AGI listed that is less than Jocelyn's AGI of $50,000 ($49,425) and the closest AGI listed that is greater than Jocelyn's AGI of $50,000 ($61,988).

Step 2: Subtract the lower amount from the higher amount (for this discussion we will call the result the ''income interval''):

- $61,988 − $49,425 = $12,563

Step 3: Determine the difference between the two income percentage factors that correspond to the AGIs used in Step 2 (for this discussion, we will call the result the ''income percentage factor interval''):

- 100.00 percent − 88.77 percent = 11.23 percent

Step 4: Subtract from Jocelyn's AGI the closest AGI shown on the chart that is less than Jocelyn's AGI of $50,000:

- $50,000 − $49,425 = $575

Step 5: Divide the result of Step 4 by the income interval determined in Step 2:

- $575 ÷ $12,563 = 4.57 percent

Step 6: Multiply the result of Step 5 by the income percentage factor interval that was calculated in Step 3:

- 11.23 percent × 4.57 percent = 0.51 percent

Step 7: Add the result of Step 6 to the lower of the two income percentage factors used in Step 3 to calculate the income percentage factor interval for an AGI of $50,000:

- 0.51 percent + 88.77 percent = 89.28 percent (rounded to the nearest hundredth)

The result is the income percentage factor that we will use to calculate

Jocelyn's monthly repayment amount under the ICR plan.

Attachment 3—Charts Showing Sample Income-Driven Repayment Amounts for Single and Married Borrowers

Below are two charts that provide first-year payment amount estimates for a variety of loan debt sizes and AGIs under each of the income-driven repayment plans and the 10-Year Standard Repayment Plan. The first chart is for single borrowers who have a family size of one. The second chart is for a borrower who is married or a head of household and who has a family size of three. The calculations in Attachment 3 assume that the loan debt has an interest rate of 6 percent. For married borrowers, the calculations assume that the borrower files a joint Federal income tax return and that the borrower's spouse does not have Federal student loans. A field with a ''-'' character indicates that the borrower in the example would not be eligible to enter the applicable income-driven repayment plan based on the borrower's AGI, loan debt, and family size.

SAMPLE FIRST-YEAR MONTHLY REPAYMENT AMOUNTS FOR A SINGLE BORROWER

Initial debt	Plan	Family size = 1				
		AGI				
		$20,000	$40,000	$60,000	$80,000	$100,000
$20,000	ICR	$107	$158	$195	$204	$228
	IBR	0	.....	.....	.....	.....
	PAYE	0	163	330	.....	.....
	REPAYE	0	163	330	497	663
	10-Year Standard	222	222	222	222	222
40,000	ICR	107	316	390	407	455
	IBR	0	245	.....	.....	.....
	PAYE	0	163	330	.....	.....
	REPAYE	0	163	330	497	663
	10-Year Standard	444	444	444	444	444
60,000	ICR	107	440	586	611	683
	IBR	0	245	495	.....	.....
	PAYE	0	163	330	497	663
	REPAYE	0	163	330	497	663
	10-Year Standard	666	666	666	666	666
80,000	ICR	107	440	774	814	911
	IBR	0	245	495	745	.....
	PAYE	0	163	330	497	663
	REPAYE	0	163	330	497	663
	10-Year Standard	888	888	888	888	888
100,000	ICR	107	440	774	1,018	1,138
	IBR	0	245	495	745	995
	PAYE	0	163	330	497	663
	REPAYE	0	163	330	497	663
	10-Year Standard	1,110	1,110	1,110	1,110	1,110

SAMPLE FIRST-YEAR MONTHLY REPAYMENT AMOUNTS FOR A MARRIED OR HEAD-OF-HOUSEHOLD BORROWER

Initial debt	Plan	Family size = 3				
		AGI				
		$20,000	$40,000	$60,000	$80,000	$100,000
$20,000	ICR	$0	$148	$195	$200	$220
	IBR	0	68	.....	.....	.....
	PAYE	0	45	.....	.....	.....
	REPAYE	0	45	212	379	545
	10-Year Standard	222	222	222	222	222
40,000	ICR	0	283	390	401	440
	IBR	0	68	318	.....	.....
	PAYE	0	45	212	379	.....
	REPAYE	0	45	212	379	545
	10-Year Standard	444	444	444	444	444
60,000	ICR	0	283	586	601	660
	IBR	0	68	318	568	.....
	PAYE	0	45	226	379	545
	REPAYE	0	45	226	392	559
	10-Year Standard	666	666	666	666	666
80,000	ICR	0	283	616	802	880
	IBR	0	68	318	568	818
	PAYE	0	45	212	379	545
	REPAYE	0	45	212	379	545
	10-Year Standard	888	888	888	888	888
100,000	ICR	0	283	616	950	1,100
	IBR	0	68	318	568	818

SAMPLE FIRST-YEAR MONTHLY REPAYMENT AMOUNTS FOR A MARRIED OR HEAD-OF-HOUSEHOLD BORROWER—Continued

Initial debt	Plan	Family size = 3				
		AGI				
		$20,000	$40,000	$60,000	$80,000	$100,000
	PAYE	0	45	212	379	545
	REPAYE	0	45	212	379	545
	10-Year Standard	1,110	1,110	1,110	1,110	1,110

[FR Doc. 2022–17696 Filed 8–16–22; 8:45 am]
BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Agency Information Collection Extension

AGENCY: Department of Energy.

ACTION: Submission for Office of Management and Budget (OMB) review; comment request.

SUMMARY: The Department of Energy (DOE) has submitted an information collection request to the OMB for reinstatement under the provisions of the Paperwork Reduction Act of 1995. The information collection requests a three-year approval of its collection, titled United States Energy and Employment Report, OMB Control Number 1910–5179. The proposed collection will collect data from businesses in in-scope industries, quantifying and qualifying employment among energy activities, workforce demographics and the industry's perception on the difficulty of recruiting qualified workers. The data will be used to generate an annual US Energy and Employment Report.

DATES: Comments regarding this collection must be received on or before September 16, 2022. If you anticipate that you will be submitting comments but find it difficult to do so within the period allowed by this notice, please advise the OMB Desk Officer of your intention to make a submission as soon as possible. The Desk Officer may be telephoned at (202) 881–8585.

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: David Keyser at *David.Keyser@hq.doe.gov* or (240) 751–8483.

SUPPLEMENTARY INFORMATION: This information collection request contains:

(1) *OMB No.:* 1910–5179;

(2) *Information Collection Request Title:* United States Energy and Employment Report;

(3) *Type of Request:* Reinstatement, with change, of a previously approved collection for which approval has expired;

(4) *Purpose:* The rapidly changing nature of energy production, distribution, and consumption throughout the U.S. economy is having a dramatic impact on job creation and economic competitiveness, but is inadequately understood and, in some sectors, incompletely measured by traditional labor market sources. The US Energy and Employment Report Survey will collect data from businesses in in-scope industries, quantifying and qualifying employment among energy activities, workforce demographics and the industry's perception on the difficulty of recruiting qualified workers. The data will be used to generate an annual US Energy and Employment Report;

(5) *Annual Estimated Number of Respondents:* 40,000;

(6) *Annual Estimated Number of Total Responses:* 40,000;

(7) *Annual Estimated Number of Burden Hours:* 9,094;

(8) *Annual Estimated Reporting and Recordkeeping Cost Burden:* $1 million.

Statutory Authority: Sec. 301 of the Department of Energy Organization Act (42 U.S.C. 7151); sec. 5 of the Federal Energy Administration Act of 1974 (15 U.S.C. 764); and sec. 103 of the Energy Reorganization Act of 1974 (42 U.S.C. 5813).

Signing Authority: This document of the Department of Energy was signed on August 12, 2022, by Betony Jones, Director of the Office of Energy Jobs, pursuant to delegated authority from the 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 August 12, 2022.

Treena V. Garrett,

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

[FR Doc. 2022–17718 Filed 8–16–22; 8:45 am]
BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP22–1115–000.

Applicants: Transcontinental Gas Pipe Line Company, LLC.

Description: § 4(d) Rate Filing: Non-Conforming—Atlantic Sunrise—Chesapeake to be effective 9/1/2022.

Filed Date: 8/9/22.

Accession Number: 20220809–5071.

Comment Date: 5 p.m. ET 8/22/22.

Docket Numbers: RP22–1116–000.

Applicants: Transcontinental Gas Pipe Line Company, LLC.

Description: § 4(d) Rate Filing: List of Non-Conforming Service Agreements and Negot Rate (ASR_Chief Rls to CEM) to be effective 9/1/2022.

Filed Date: 8/9/22.

Accession Number: 20220809–5094.

Comment Date: 5 p.m. ET 8/22/22.

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.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

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: August 10, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–17694 Filed 8–16–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER19–404–005.

Applicants: Public Service Company of Colorado.

Description: Compliance filing: 2022–08–11 Att O–SPS–Tbl 11, Tbl 21A–Priority Order to be effective 2/1/2019.

Filed Date: 8/11/22.

Accession Number: 20220811–5034.

Comment Date: 5 p.m. ET 9/1/22.

Docket Numbers: ER21–283–004.

Applicants: Hillcrest Solar I, LLC.

Description: Refund Report: refund report Aug 2022 to be effective N/A.

Filed Date: 8/11/22.

Accession Number: 20220811–5115.

Comment Date: 5 p.m. ET 9/1/22.

Docket Numbers: ER22–1804–000.

Applicants: Yaphank Fuel Cell Park, LLC.

Description: Refund Report: Refund report to be effective N/A.

Filed Date: 8/11/22.

Accession Number: 20220811–5085.

Comment Date: 5 p.m. ET 9/1/22.

Docket Numbers: ER22–1905–001.

Applicants: Southwest Power Pool, Inc.

Description: Tariff Amendment: Deficiency Response—Revisions to Define Electromagnetic Transient Study to be effective 8/1/2022.

Filed Date: 8/11/22.

Accession Number: 20220811–5011.

Comment Date: 5 p.m. ET 9/1/22.

Docket Numbers: ER22–2631–000.

Applicants: Public Service Company of Colorado.

Description: Tariff Amendment: 2020–08–10 PSCoES PLGIA–591–0.1.0–NOC to be effective 8/11/2022.

Filed Date: 8/10/22.

Accession Number: 20220810–5122.

Comment Date: 5 p.m. ET 8/31/22.

Docket Numbers: ER22–2632–000.

Applicants: Vistra Corp., Joppa BESS LLC, Edwards BESS LLC.

Description: Request for Waiver, et al. of Vistra Corp.

Filed Date: 8/5/22.

Accession Number: 20220805–5156.

Comment Date: 5 p.m. ET 8/26/22.

Docket Numbers: ER22–2633–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: 3923R1 Seven Cowboy Wind Project GIA to be effective 8/8/2022.

Filed Date: 8/11/22.

Accession Number: 20220811–5037.

Comment Date: 5 p.m. ET 9/1/22.

Docket Numbers: ER22–2634–000.

Applicants: Buffalo Ridge Wind, LLC.

Description: Baseline eTariff Filing: Buffalo Ridge Wind, LLC Application for Market-Based Rate Authority 8/11/2022 to be effective 10/11/2022.

Filed Date: 8/11/22.

Accession Number: 20220811–5041.

Comment Date: 5 p.m. ET 9/1/22.

Docket Numbers: ER22–2635–000.

Applicants: Virginia Electric and Power Company, PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Virginia Electric and Power Company submits tariff filing per 35.13(a)(2)(iii: Dominion revisions to PJM Tariff Att. H–16C (Other Post-Employment Benefits Exp) to be effective 10/11/2022.

Filed Date: 8/11/22.

Accession Number: 20220811–5044.

Comment Date: 5 p.m. ET 9/1/22.

Docket Numbers: ER22–2636–000.

Applicants: Florida Power & Light Company.

Description: § 205(d) Rate Filing: FPL–FPU Amendment to Service Agreement No. 5 and Transfer of Records to be effective 12/31/9998.

Filed Date: 8/11/22.

Accession Number: 20220811–5054.

Comment Date: 5 p.m. ET 9/1/22.

Docket Numbers: ER22–2637–000.

Applicants: Gulf Power Company.

Description: Tariff Amendment: Notice of Cancellation—Service Agreement No. 5 to be effective 12/31/9998.

Filed Date: 8/11/22.

Accession Number: 20220811–5056.

Comment Date: 5 p.m. ET 9/1/22.

Docket Numbers: ER22–2638–000.

Applicants: Bellevue Solar, LLC.

Description: Tariff Amendment: Notice of Cancellation of FERC Electric MBR Tariff, Original Volume No. 1 to be effective 10/10/2022.

Filed Date: 8/11/22.

Accession Number: 20220811–5071.

Comment Date: 5 p.m. ET 9/1/22.

Docket Numbers: ER22–2639–000.

Applicants: Yamhill Solar, LLC.

Description: Tariff Amendment: Notice of Cancellation of FERC Electric MBR Tariff, Original Volume No. 1 to be effective 10/10/2022.

Filed Date: 8/11/22.

Accession Number: 20220811–5072.

Comment Date: 5 p.m. ET 9/1/22.

Docket Numbers: ER22–2640–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: First Revised ISA No. 2794; Queue No. AF1–262 to be effective 7/14/2022.

Filed Date: 8/11/22.

Accession Number: 20220811–5087.

Comment Date: 5 p.m. ET 9/1/22.

Docket Numbers: ER22–2641–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Original NSA, Service Agreement No. 6587; Queue No. AB1–132 to be effective 7/12/2022.

Filed Date: 8/11/22.

Accession Number: 20220811–5122.

Comment Date: 5 p.m. ET 9/1/22.

Docket Numbers: ER22–2642–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Amendment to WMPA, Service Agreement No. 5376; Queue No. AE1–098 to be effective 3/29/2019.

Filed Date: 8/11/22.

Accession Number: 20220811–5124.

Comment Date: 5 p.m. ET 9/1/22.

Docket Numbers: ER22–2643–000.

Applicants: Three Corners Solar, LLC.

Description: Baseline eTariff Filing: Market-Based Rate Application to be effective 10/11/2022.

Filed Date: 8/11/22.

Accession Number: 20220811–5125.

Comment Date: 5 p.m. ET 9/1/22.

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: August 11, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–17686 Filed 8–16–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER22–2536–000]

Kossuth County Wind, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Kossuth County Wind, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is August 31, 2022.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov*. To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

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://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. 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.

Dated: August 11, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–17684 Filed 8–16–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER22–2552–000]

Java Solar, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Java Solar, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is August 31, 2022.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov*. To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

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://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. 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.

Dated: August 11, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–17683 Filed 8–16–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER22–2601–000]

Walleye Wind, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Walleye Wind, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is August 31, 2022.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov*. To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

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://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. 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.

Dated: August 11, 2022..

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–17687 Filed 8–16–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER22–2472–000]

Lockhart Transmission Holdings, LLC; Supplemental Notice That Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Lockhart Transmission Holdings, LLC's filing includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is August 30, 2022.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov*. To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

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://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. 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.

Dated: August 10, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–17692 Filed 8–16–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC22–100–000.

Applicants: Golden Fields Solar I, LLC, Imperial Valley Solar 2, LLC, Innovative Solar 31, LLC, Innovative Solar 47, LLC, Solar Star California XLI, LLC.

Description: Joint Application for Authorization Under Section 203 of the Federal Power Act of Golden Fields Solar I, LLC, et al.

Filed Date: 8/9/22.

Accession Number: 20220809–5150.

Comment Date: 5 p.m. ET 8/30/22.

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG22–202–000.

Applicants: Appaloosa Run Wind, LLC.

Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Appaloosa Run Wind, LLC.
Filed Date: 8/10/22.
Accession Number: 20220810–5075.
Comment Date: 5 p.m. ET 8/31/22.
Docket Numbers: EG22–203–000.
Applicants: Young Wind, LLC.
Description: Young Wind, LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.
Filed Date: 8/10/22.
Accession Number: 20220810–5076.
Comment Date: 5 p.m. ET 8/31/22.
Docket Numbers: EG22–204–000.
Applicants: Lacy Creek Wind, LLC.
Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Lacy Creek Wind, LLC.
Filed Date: 8/10/22.
Accession Number: 20220810–5080.
Comment Date: 5 p.m. ET 8/31/22.
Docket Numbers: EG22–205–000.
Applicants: Inertia Wind Project, LLC.
Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Inertia Wind Project, LLC.
Filed Date: 8/10/22.
Accession Number: 20220810–5083.
Comment Date: 5 p.m. ET 8/31/22.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER22–2626–000.
Applicants: Avista Corporation.
Description: § 205(d) Rate Filing: Avista Corp OATT Errate Schedule 9 to be effective 3/2/2022.
Filed Date: 8/9/22.
Accession Number: 20220809–5113.
Comment Date: 5 p.m. ET 8/30/22.
Docket Numbers: ER22–2627–000.
Applicants: Niagara Mohawk Power Corporation, New York Independent System Operator, Inc.
Description: § 205(d) Rate Filing: Niagara Mohawk Power Corporation submits tariff filing per 35.13(a)(2)(iii: Section 205 SGIA among NYISO, National Grid, Dolan Solar (SA.2720) to be effective 7/27/2022.
Filed Date: 8/10/22.
Accession Number: 20220810–5021.
Comment Date: 5 p.m. ET 8/31/22.
Docket Numbers: ER22–2628–000.
Applicants: Elk Hill Solar 1, LLC.
Description: Tariff Amendment: Cancel Entire Rate Schedule Tariff to be effective 8/11/2022.
Filed Date: 8/10/22.
Accession Number: 20220810–5064.
Comment Date: 5 p.m. ET 8/31/22.
Docket Numbers: ER22–2629–000.
Applicants: Alabama Power Company, Georgia Power Company, Mississippi Power Company.
Description: § 205(d) Rate Filing: Alabama Power Company submits tariff filing per 35.13(a)(2)(iii: Newton Solar LGIA Filing to be effective 8/1/2022.
Filed Date: 8/10/22.
Accession Number: 20220810–5071.
Comment Date: 5 p.m. ET 8/31/22.
Docket Numbers: ER22–2630–000.
Applicants: Midcontinent Independent System Operator, Inc., Great River Energy.
Description: § 205(d) Rate Filing: Midcontinent Independent System Operator, Inc. submits tariff filing per 35.13(a)(2)(iii: 2022–08–10_SA 3668 GRE–WMU 1st Rev T–T & T–L to be effective 8/11/2022.
Filed Date: 8/10/22.
Accession Number: 20220810–5084.
Comment Date: 5 p.m. ET 8/31/22.

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: August 10, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–17691 Filed 8–16–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP22–1117–000.
Applicants: Sentinel Peak Resources California LLC, Seneca Resources Company, LLC.
Description: Joint Petition for Limited Waiver of Capacity Release Regulations, et al. of Seneca Resources Company, LLC and Sentinel Peak Resources California LLC.
Filed Date: 8/10/22.
Accession Number: 20220810–5086.
Comment Date: 5 p.m. ET 8/22/22.

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.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

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: August 11, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–17685 Filed 8–16–22; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EF22–2–000]

Western Area Power Administration; Notice of Filing

Take notice that on July 27, 2022, Western Area Power Administration submitted tariff filing: SNR_Washoe_WAPA201–20220608 to be effective 10/1/2022.

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. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

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 September 9, 2022.

Dated: August 10, 2022.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2022–17693 Filed 8–16–22; 8:45 am]

BILLING CODE 6717–01–P

FEDERAL ELECTION COMMISSION

Sunshine Act Meeting

TIME AND DATE: Tuesday, August 30, 2022 at 10 a.m. and its continuation at the conclusion of the open meeting on August 31, 2022.

PLACE: 1050 First Street NE, Washington, DC and virtual (this meeting will be a hybrid meeting).

STATUS: This meeting will be closed to the public.

MATTERS TO BE CONSIDERED: Compliance matters pursuant to 52 U.S.C. 30109. Matters concerning participation in civil actions or proceedings or arbitration.

* * * * *

CONTACT PERSON FOR MORE INFORMATION: Judith Ingram, Press Officer, Telephone: (202) 694–1220.

Authority: Government in the Sunshine Act, 5 U.S.C. 552b.

Laura E. Sinram,

Acting Secretary and Clerk of the Commission.

[FR Doc. 2022–17801 Filed 8–15–22; 4:15 pm]

BILLING CODE 6715–01–P

FEDERAL MARITIME COMMISSION

Notice of Request for Additional Information

The Commission gives notice that it has formally requested that the parties to the below listed agreement provide additional information pursuant to 46 U.S.C. 40304(d). This action prevents the agreement from becoming effective as originally scheduled. Interested parties may file comments within fifteen (15) days after publication of this notice appears in the **Federal Register**.

Agreement No.: 201391.

Title: South Atlantic Multiport Chassis Pool Agreement.

Parties: COSCO SHIPPING Lines Co., Ltd.; Georgia Ports Authority; Hamburg Sud; Hapag Lloyd AG; Hapag-Lloyd USA, LLC; Jacksonville Port Authority; Maersk A/S; Mediterranean Shipping Company S.A.; North Carolina State Ports Authority; Ocean Carrier Equipment Management Association; Ocean Network Express Pte. Ltd.; Wan Hai Lines Ltd.; ZIM Integrated Shipping Services Ltd.

By Order of the Federal Maritime Commission.

Dated: August 11, 2022

William Cody,

Secretary.

[FR Doc. 2022–17695 Filed 8–16–22; 8:45 am]

BILLING CODE 6730–02–P

FEDERAL RETIREMENT THRIFT INVESTMENT BOARD

Notice of Board Meeting

DATES: August 24, 2022 at 10:00 a.m.

ADDRESSES: Telephonic. Dial-in (listen only) information: Number: 1- 202–599–1426, Code: 272 550 417#; or via web:*https://teams.microsoft.com/l/meetup-join/19%3ameeting_MzZlNTRlZDYtNzRhZS00ZjhlLThmNWItNmIwZmE2ZmVkNzRl%40thread.v2/0?context=%7b%22Tid%22%3a%223f6323b7-e3fd-4f35-b43d-1a7afae5910d%22%2c%22Oid%22%3a%227c8d802c-5559-41ed-9868-8bfad5d44af9%22%7d.*

FOR FURTHER INFORMATION CONTACT: Kimberly Weaver, Director, Office of External Affairs, (202) 942–1640.

SUPPLEMENTARY INFORMATION:

Board Meeting Agenda

Open Session

1. Approval of the July 26, 2022 Board Meeting Minutes
2. Recordkeeper Annual Service Update: Accenture Federal Services (AFS)
3. Monthly Reports
   (a) Participant Activity Report
   (b) Investment Report
   (c) Legislative Report
4. Quarterly Report
   (d) Metrics
5. 2021 FISMA Results
6. CISO Update
7. FY 2023 Budget Review and Approval

Closed Session

8. Information covered under 5 U.S.C. 552b (c)(9)(B).

Authority: 5 U.S.C. 552b (e)(1).

Dated: August 11, 2022.

Dharmesh Vashee,

General Counsel, Federal Retirement Thrift Investment Board.

[FR Doc. 2022–17656 Filed 8–16–22; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–6765]

Replacement Reagent and Instrument Family Policy for In Vitro Diagnostic Devices; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled ''Replacement Reagent and Instrument Family Policy for In Vitro Diagnostic Devices.'' This guidance is intended to update and provide clarity on the replacement reagent and instrument family policy for manufacturers of in vitro diagnostic devices and FDA staff to promote consistent application of the concepts in this guidance. Specifically, it addresses a manufacturer's application of an assay that was previously cleared for use based on performance characteristics when used with a specified instrument

to an additional instrument that was previously cleared, or that is a member of an instrument family from which another member has been previously cleared. This document supersedes the final guidance ''Replacement Reagent and Instrument Family Policy'' issued on December 11, 2003.

DATES: The announcement of the guidance is published in the **Federal Register** on August 17, 2022.

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 Docket No. FDA–2017–D–6765 for ''Replacement Reagent and Instrument Family Policy for In Vitro Diagnostic Devices.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 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 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Replacement Reagent and Instrument Family Policy for In Vitro Diagnostic Devices'' to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Scott McFarland, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3572, Silver Spring, MD 20993–0002, 301–796–6217.

SUPPLEMENTARY INFORMATION:

I. Background

In 2003, FDA issued updated guidance on the ''Replacement Reagent and Instrument Family Policy'' for in vitro diagnostic (IVD) devices. The 2003 guidance described a mechanism for manufacturers to follow when applying an assay that was previously cleared based on performance characteristics when used with a specified instrument to an additional instrument that is either cleared or a member of an instrument family from which another instrument was previously cleared. Through the approach described in the 2003 guidance, manufacturers established sufficient control to maintain the level of safety and effectiveness demonstrated for the cleared device for these types of modified devices, when evaluated against predefined acceptance criteria using a proper validation protocol, without submission of a premarket notification (510(k)).

This guidance is intended to update and provide clarity on the replacement reagent and instrument family policy for manufacturers of IVD devices and FDA staff to promote consistent application of the concepts in this guidance. Specifically, it addresses a manufacturer's application of an assay that was previously cleared for use based on performance characteristics when used with a specified instrument to an additional instrument that was previously cleared, or that is a member of an instrument family from which another member has been previously cleared. This document supersedes the final guidance ''Replacement Reagent and Instrument Family Policy'' issued on December 11, 2003.

A notice of availability of the draft guidance appeared in the **Federal Register** of December 18, 2017 (82 FR 60024). FDA considered comments received and revised the guidance as appropriate in response to the comments, including changing the scope of the guidance such that, in certain limited situations, point of care IVD devices could be within the scope of the guidance rather than being expressly identified as outside the scope

of the guidance, the addition of flowcharts, updates to examples, and further clarification of terminology.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on the replacement reagent and instrument family policy for in vitro diagnostic devices. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov* and *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Persons unable to download an electronic copy of ''Replacement Reagent and Instrument Family Policy for In Vitro Diagnostic Devices'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 950 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. 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 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 and guidances have been approved by OMB as listed in the following table:

21 CFR part; guidance; or FDA form	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff''.	Q-submissions	0910–0756
800, 801, and 809	Medical Device Labeling Regulations	0910–0485
''Administrative Procedures for Clinical Laboratory Improvement Amendments (CLIA) of 1988 Categorization''.	CLIA Categorization	0910–0607
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation.	0910–0073

Dated: August 11, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–17643 Filed 8–16–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–2029]

Proposal To Withdraw Approval of MAKENA; Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of hearing.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) has granted a hearing on the Center for Drug Evaluation and Research's (CDER's) proposal to withdraw approval of MAKENA (hydroxyprogesterone caproate injection, 250 milligrams (mg) per milliliter (mL), once weekly), new drug application (NDA) 021945, held by Covis Pharma Group/Covis Pharma GmbH (Covis). This notice provides information and details regarding the hearing, including the time, date, and format of the hearing, as well as the questions to be posed to the advisory committee at the hearing.

DATES: The hearing will be held virtually October 17 to 19, 2022, beginning at 8 a.m. Eastern Time on each day and concluding at 4 p.m. on Days 1 and 2 and 12:30 p.m. on Day 3. Either electronic or written comments on the hearing must be submitted by November 3, 2022.

ADDRESSES: The docket number for this matter is FDA–2020–N–2029. The docket will close on November 3, 2022. Either electronic or written comments on this hearing must be submitted by November 3, 2022. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time on November 3, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date. Comments received on or before October 11, 2022, will be provided to the advisory committee for consideration.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked, and identified as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2020–N–2029 for ''Proposal to Withdraw Marketing Approval; Hearing.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 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 our 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.

FOR FURTHER INFORMATION CONTACT: Rachael Vieder Linowes, Office of Scientific Integrity, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4206, Silver Spring, MD 20993; 240–402–5931, *rachael.linowes@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 506 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 356) provides that a drug sponsor may request to expedite the review and approval of a drug intended to treat an unmet need related to a serious or life-threatening disease or condition. Under the accelerated approval pathway, FDA may grant accelerated approval based on the drug's effect on a surrogate or an intermediate clinical endpoint. FDA's regulations, at § 314.510 (21 CFR 314.510), require that accelerated approval be subject to a sponsor's engaging in further study ''to verify and describe [the drug's] clinical benefit, where there is uncertainty as to the relation of the surrogate endpoint to clinical benefit, or of the observed clinical benefit to ultimate outcome.''

Under section 506(c)(3) of the FD&C Act, FDA may withdraw approval of a drug approved under this pathway if, among other reasons, the required study fails to verify ''the predicted effect on irreversibility morbidity or mortality or other clinical benefit.'' Under § 314.530(a) (21 CFR 314.530(a)), FDA may withdraw accelerated approval of a drug when ''[a] postmarketing clinical study fails to verify clinical benefit'' or ''[o]ther evidence demonstrates that the drug product is not shown to be safe or effective under its conditions of use,'' among other circumstances.

To initiate the process for withdrawing accelerated approval of a drug, the Director of CDER must provide the applicant with notice of an opportunity for a hearing on the proposed grounds for withdrawal under § 314.530(b). To obtain a hearing, the applicant must, pursuant to § 314.530(c), request one within 15 days after receiving CDER's notice and submit ''the data and information upon which [it] intends to rely at the hearing'' within 30 days thereafter.

Pursuant to § 314.530(e)(1), FDA conducts hearings under § 314.530 in accordance with part 15 (21 CFR part 15), with certain modifications. The key modification under § 314.530(e)(1) is that an advisory committee is present at the hearing and provides advice and recommendations to the Commissioner. Under § 314.530(e)(2), the presiding officer, the members of the advisory committee, and up to three representatives from both the applicant and CDER may ask questions of the presenters at the hearing. The presiding officer, as a matter of discretion, may also permit questions of presenters posed by others participating in the hearing upon submission of such questions in writing. After receiving advice and recommendations from the advisory committee, the Commissioner of Food and Drugs makes the final decision on whether to withdraw accelerated approval of the drug product at issue (see § 314.530(f)).

On February 3, 2011, FDA approved the NDA for MAKENA under the accelerated approval pathway to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth. As described in CDER's proposal to withdraw approval, the MAKENA NDA ''relied on evidence from the Maternal Fetal Medicine Unit (MFMU) Network trial (referred to as 'Trial 002') for primary support of efficacy and safety.'' CDER granted accelerated approval based on the results for Trial 002. Consistent with section 506(c)(2) of the FD&C Act and § 314.510, CDER's approval letter required, *inter alia,* that the sponsor complete a postmarketing confirmatory study, described as ''a clinical trial of MAKENA in women with a singleton pregnancy who had a previous spontaneous preterm birth (Protocol #17P–ES–003)'' (Trial 003).

On October 5, 2020, CDER proposed withdrawing accelerated approval of MAKENA and provided Covis with an opportunity to request a hearing on the proposal.[1] In the proposal, CDER cited two grounds under section 506(c)(3) of the FD&C Act and § 314.530(a) for withdrawing approval: (1) the confirmatory study failed to verify clinical benefit of the drug and (2) the evidence does not establish that the drug is effective under its conditions of use. CDER's proposal to withdraw approval also provided notice to all holders of approved abbreviated new drug applications (ANDAs) referencing the NDA for MAKENA (NDA 021945) that, if the Agency withdraws

[1] AMAG Pharmaceuticals, Inc. (AMAG), the sponsor of NDA 021945 at the time, received this notice. After AMAG requested a hearing, Covis acquired AMAG, including NDA 021945. For efficiency, this notice refers to AMAG as ''Covis.''

accelerated approval of MAKENA, CDER would proceed to withdraw approval of the ANDAs under 21 CFR 314.151(b)(3).

On October 14, 2020, Covis timely requested a hearing and sought an additional 30 days in which to submit data and information in support. On December 4, 2020, after receiving an extension of time within which to do so, Covis further responded to CDER's proposal to withdraw accelerated approval of MAKENA. The response included data and information and incorporated other data and information in FDA's administrative files by reference.[2]

By letter to CDER and Covis dated August 18, 2021, FDA's Chief Scientist granted Covis's hearing request and appointed Celia M. Witten as presiding officer.

II. Notice of Hearing Under Part 15 and § 314.530

This public hearing will be held in accordance with part 15 and § 314.530. The presiding officer will conduct the hearing, and an advisory committee will be present at the hearing for purposes of considering the data and information presented by CDER and Covis with respect to CDER's proposal to withdraw accelerated approval of MAKENA and providing advice to the Commissioner of Food and Drugs on that proposal (see § 314.530(e)).

Under 21 CFR 15.30(f), the hearing is informal, and the rules of evidence do not apply. In accordance with § 314.530(e)(2), however, only the presiding officer, the members of the advisory committee, and up to three representatives from CDER and Covis may pose questions to the advisory committee at the hearing itself. The presiding officer may nonetheless exercise her discretion under § 314.530(e)(2) to allow others to propose questions by submitting them in writing for her consideration. In the interest of economy and efficiency, particularly given the virtual platform, the presiding officer has determined that only the holders of ANDAs referencing the NDA for MAKENA (ANDA holders) will be permitted to submit questions; that all proposed questions must be submitted to the docket for this proceeding in advance of the hearing; and that the questions selected will be posed to CDER and Covis at the close of their respective presentations (see section IV of this document).

III. Questions To Be Addressed at the Public Hearing

The questions to be posed to the advisory committee at the hearing are as follows:

1. For discussion and vote:

Do the findings from Trial 003 verify the clinical benefit of MAKENA on neonatal morbidity and mortality from complications of preterm birth?

2. For discussion and vote:

Does the available evidence demonstrate that MAKENA is effective for its approved indication of reducing the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth?

3. For discussion:

Should FDA allow MAKENA to remain on the market? As part of that discussion, you may discuss:

- whether the benefit-risk profile supports retaining the product on the market;
- what types of studies could provide confirmatory evidence to verify the clinical benefit of MAKENA on neonatal morbidity and mortality from complications of preterm birth?

For vote:

Considering your responses to the previous questions both in the discussions and votes, should FDA allow MAKENA to remain on the market while an appropriate confirmatory study is designed and conducted?

IV. Participating in the Public Hearing

Persons wishing to view the hearing may access the webcast at the following separate links on the respective days of the hearing:

Day 1: *https://youtu.be/EEm7pM_LgsM.*

Day 2: *https://youtu.be/Nt2bcDVgpag.*

Day 3: *https://youtu.be/Dal27hktzcg.*

Request for Oral Presentations: We currently expect public participation to occur from 2 p.m. to 4 p.m. Eastern Time on the first day of the hearing and from 8 a.m. to 10 a.m. on the second day. Persons interested in participating in the hearing by making an oral presentation during the 4 hours currently reserved for such presentations must submit requests by 11:59 p.m. Eastern Time on September 6, 2022, as further described below.

If you wish to make a formal presentation or present oral comments during the session for public participation, you must register at the following link by 5 p.m. Eastern Time on September 6, 2022: *https://www.surveymonkey.com/r/B72THCF.* When registering, please provide complete contact information, including name, title, affiliation, address, email, and telephone number. To complete your request for an opportunity to make a presentation at the hearing, you must also submit a comment to the docket for this hearing matter (see **ADDRESSES**) by 11:59 p.m. Eastern Time on September 6, 2022, and clearly indicate in the heading and/or cover page that your comment is a ''Request for Oral Presentation.''

In the ''Request for Oral Presentation'' submitted to the public docket, you must identify yourself and others who will join you for your presentation, list the affiliation (if any) of each individual participating in your presentation (including your own), and request a specific amount of time for your presentation. You must also include a summary of what you plan to present at the hearing and a copy of any slide deck, along with any data or information on which you intend to rely at the hearing that is not already referenced or included in the public docket for this hearing matter. No commercial or promotional material will be permitted to be presented or distributed at the public hearing.

We urge organizations with common interests to consolidate or coordinate their presentations. In accordance with 21 CFR 15.21(c), the presiding officer may require joint presentations by persons with common interests.

The presiding officer will determine the amount of time allotted to each presenter and the approximate time each presentation is to begin and will select and notify participants by September 30, 2022. If you are notified that you will be a presenter, we encourage you to be online well in advance of the approximate time provided in the notice. Actual presentation times may vary based on how the hearing progresses.

Proposed Questions: To propose a question to either CDER or Covis, an ANDA holder must submit a comment to the docket for this hearing matter (see **ADDRESSES**) by 11:59 p.m. Eastern Time on September 30, 2022; indicate in the heading and/or cover page that the comment includes ''Proposed Question(s)''; and state in the submission that the question or questions are being proposed by a specific ANDA holder or someone authorized to do so on that specific ANDA holder's behalf. The comment should also indicate whether each proposed question is intended for CDER, Covis, or both.

[2] The presiding officer has subsequently granted requests by Covis to submit additional data and information that were not included in its December 4, 2020, submission and may do so again based on a showing of good cause.

Transcripts: Please be advised that as soon as a transcript of the public hearing is available, it will be accessible at *https://www.regulations.gov.* It may also be viewed at the address where Dockets Management Staff is located (see **ADDRESSES**). A link to the transcript will also be available on the Agency's website.

Dated: August 12, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–17715 Filed 8–16–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0986]

Hydrogen Peroxide-Based Contact Lens Care Products: Consumer Labeling Recommendations—Premarket Notification (510(k)) Submissions; Draft Guidance for Industry and Food and Drug Administration Staff; 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 the draft guidance entitled ''Hydrogen Peroxide-Based Contact Lens Care Products: Consumer Labeling Recommendations—Premarket Notification (510(k)) Submissions.'' FDA is issuing this draft guidance to provide labeling recommendations for hydrogen peroxide-based contact lens care products (HPCPs) submitted in premarket notification (510(k)) submissions. The labeling recommendations in this draft guidance are intended to promote the safe and effective use of HPCPs and ensure that consumers receive and understand information regarding the benefits and risks associated with the use of the device. This draft guidance is not final nor is it for implementation at this time.

DATES: Submit either electronic or written comments on the draft guidance by October 17, 2022 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2022–D–0986 for ''Hydrogen Peroxide-Based Contact Lens Care Products: Consumer Labeling Recommendations—Premarket Notification (510(k)) Submissions.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 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 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Hydrogen Peroxide-Based Contact Lens Care Products: Consumer Labeling Recommendations—Premarket Notification (510(k)) Submissions'' to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Angelo Green, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1306, Silver Spring, MD 20993–0002, 301–796–6860.

SUPPLEMENTARY INFORMATION:

I. Background

The safety and effectiveness of HPCPs when used as directed has been well

established in the last few decades; however, FDA has become aware of an increase in the number of adverse event reports related to the misuse of these products. These reports led FDA to convene a meeting of the Ophthalmic Devices Panel of the Medical Devices Advisory Committee and the Risk Communication Advisory Committee on March 17, 2017, to discuss additional measures to mitigate the potential risk for misuse of these devices. The meeting covered a range of important issues, including appropriate labeling and packaging of these products and the importance of clearly communicating these concerns to the consumer public, which were incorporated into this draft guidance. When finalized, this guidance is intended to provide recommendations concerning the content and format of labeling for HPCPs. FDA believes that the labeling recommendations in this guidance may help manufacturers develop labeling with information about specific risks and directions for use of the HPCPs in conjunction with a user's prescribed contact lenses.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Hydrogen Peroxide-Based Contact Lens Care Products: Consumer Labeling Recommendations—Premarket Notification (510(k)) Submissions.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov* or *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.*

Persons unable to download an electronic copy of ''Hydrogen Peroxide-Based Contact Lens Care Products: Consumer Labeling Recommendations—Premarket Notification (510(k)) Submissions'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 18041 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. 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 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, guidance, and forms have been approved by OMB as listed in the following table:

21 CFR part	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
800, 801, and 809	Medical Device Labeling Regulations	0910–0485

Dated: August 11, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–17642 Filed 8–16–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Senior Executive Service Performance Review Board

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HRSA, an operating division of HHS, is publishing a list of individuals who may be named to serve on the Senior Executive Service Performance Review Board that oversees the evaluation of performance appraisals for Senior Executive Service members for the Fiscal Years 2022 and 2023.

FOR FURTHER INFORMATION CONTACT: Georgia Lyons, HRSA Executive Resources, Office of Human Resources, 5600 Fishers Lane, Rm 12N06C, Rockville, Maryland 20857, or (301) 443–4618.

SUPPLEMENTARY INFORMATION: Title 5, U.S.C. Section 4314(c)(4) of the Civil Service Reform Act of 1978, Public Law 95–454, requires that the appointment of Performance Review Board Members be published in the **Federal Register**. The following individuals may be named to serve on the Senior Executive Service Performance Review Board:

Onyekachukwu Anaedozie
Anthony Archeval
Cynthia Baugh
Tonya Bowers
Adriane Burton
Tina Cheatham
Laura Cheever
Christopher Coppenbarger
Natasha Coulouris
Cheryl Dammons
Elizabeth DeVoss
Tanette Downs
Diana Espinosa
Catherine Ganey
Alexandra Garcia
Jordan Grossman
Heather Hauck
Alexandra Huttinger
Carole Johnson
Laura Kavanagh
Martin Kramer
James Macrae
Maren McBride Kahn
Susan Monarez
Thomas Morris
Suma Nair
Luis Padilla
Nisha Patel
Krista Pedley
Wendy Ponton
Sheila Pradia Williams
Michael Warren

Carole Johnson,

Administrator.

[FR Doc. 2022–17657 Filed 8–16–22; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; Fasting Mimicking Diets and Peptides in Normal Aging and Alzheimer's Disease.

Date: October 19, 2022.

Time: 11:30 a.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Bita Nakhai, Ph.D., Chief, Basic and Translational Sciences Section (BTSS), Scientific Review Branch, National Institute on Aging, Gateway Bldg., 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20814, 301–402–7701, *nakhaib@nia.nih.gov.*

Information is also available on the Institute's/Center's home page: *www.nia.nih.gov/,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: August 11, 2022.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–17631 Filed 8–16–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; 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: NIGMS Initial Review Group Training and Workforce Development Study Section—C Training and Workforce Development Study Section C (TWD–C)—Review of MARC and U–RISE Applications.

Date: October 13–14, 2022.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute of General Medical Science, Natcher Bldg. 45, 45 Center Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Sonia Ivette Ortiz-Miranda, Ph.D., Scientific Review Officer, National Institute of General Medical Sciences, National Institutes of Health, Bethesda, MD 20892, (301) 594–0534, *sonia.ortiz-miranda@nih.gov.*

Information is also available on the Institute's/Center's home page: *www.nigms.nih.gov/,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: August 12, 2022.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–17701 Filed 8–16–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Arthritis and Musculoskeletal and Skin Diseases Advisory Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting website (*http://videocast.nih.gov/*).

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Arthritis and Musculoskeletal and Skin Diseases Advisory Council.

Date: September 14, 2022.

Open: 10:00 a.m. to 1:10 p.m.

Agenda: Discussion of Program Policies and Issues.

Place: National Institute of Arthritis and Musculoskeletal and Skin Diseases, 6701 Democracy Blvd., Democracy I, Suite 800, Bethesda MD 20892–4872, *https://videocast.nih.gov/* (Virtual Meeting).

Open: 2:00 p.m. to 2:30 p.m.

Agenda: Board of Scientific Counselors Report.

Place: National Institute of Arthritis and Musculoskeletal and Skin Diseases, 6701 Democracy Blvd., Democracy I, Suite 800, Bethesda MD 20892–4872, *https://videocast.nih.gov/* (Virtual Meeting).

Closed: 2:35 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Arthritis and Musculoskeletal and Skin Diseases, 6701 Democracy Blvd., Democracy I, Suite 800, Bethesda MD 20892–4872 (Virtual Meeting).

Contact Person: Kathy Salaita, SCD Chief, Scientific Review Branch, National Institute of Arthritis, Musculoskeletal and Skin Diseases, National Institutes of Health, 6701 Democracy Blvd., Rm 818, Bethesda, MD 20892, 301–594–5033, *kathy.salaita@nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: August 12, 2022.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–17705 Filed 8–16–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; Hearing Loss and Aging.

Date: October 3, 2022.

Time: 1 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Anita H. Undale, Ph.D., MD, Scientific Review Branch, National Institute on Aging, Gateway Building, Suite 2W200, 7201 Wisconsin Avenue, Bethesda, MD 20892, (301) 827–7428, *anita.undale@nih.gov.*

Information is also available on the Institute's/Center's home page: *www.nia.nih.gov/,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: August 11, 2022.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–17632 Filed 8–16–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Asthma Education Prevention Program Coordinating Committee, which was published in the **Federal Register** on July 08, 2022, 87 FR 40853.

The NAEPPC meeting is being amended to change the date to September 28th, 2022. The meeting is open to the public.

The Zoom Connection for public attendance is: *https://nih.zoomgov.com/j/1603194596?pwd=ZnhJV3BLcEFOVThvUUdhQnNGOG5xZz09.*

Dated: August 11, 2022.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–17704 Filed 8–16–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel; NIGMS Pathway to Independence (K99/R00).

Date: November 7–8, 2022.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute of General Medical Science, Natcher Bldg. 45, 45 Center Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Marc Rigas, Ph.D., Scientific Review Officer, National Institute of General Medical Science, Natcher Bldg. 45, 45 Center Drive, Bethesda, MD 20892, 301–402–1074, *rigasm@mail.nih.gov.*

Information is also available on the Institute's/Center's home page: *www.nigms.nih.gov/,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: August 12, 2022.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–17702 Filed 8–16–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental & Craniofacial RESEARCH; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Dental and Craniofacial Research Council.

The meeting will be held as a virtual meeting and is open to the public. Individuals who plan to view the virtual meeting and need special assistance or other reasonable accommodations to view the meeting, should notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting website (*http://videocast.nih.gov/*).

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/or 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 grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Dental and Craniofacial Research Council.

Date: September 13, 2022.

Open: 10:00 a.m. to 3:00 p.m.

Agenda: Report of the Director, NIDCR and concept clearances.

Place: National Institutes of Health, 6701 Democracy Blvd., Bethesda, MD 20892 (Virtual Meeting).

Closed: 3:15 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: National Institutes of Health, 6701 Democracy Blvd., Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Lynn M. King, Ph.D., Executive Secretary, Division of Extramural Activities, National Institute of Dental Craniofacial Research, 6701 Democracy

Blvd., Room 960, Bethesda, MD 20892–4878, (301) 594–5006, *Lynn.King@nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *https://www.nidcr.nih.gov/about-us,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program No. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: August 11, 2022.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–17629 Filed 8–16–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; Research Infrastructure Development and Utilization for Aging Studies.

Date: September 14, 2022.

Time: 10:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Rajasri Roy, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute on Aging, National Institutes of Health, Gateway Building 2W200, 7201 Wisconsin Avenue, Bethesda, MD 20892, (301) 496–6477, *rajasri.roy@nih.gov.*

Information is also available on the Institute's/Center's home page: *www.nia.nih.gov/,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: August 11, 2022.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–17630 Filed 8–16–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Time-Sensitive Obesity PAR Review.

Date: September 9, 2022.

Time: 4:00 p.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Two Democracy Plaza 6707, Democracy Boulevard, Bethesda, MD 20892 (Video Meeting).

Contact Person: Michele L. Barnard, Ph.D., Scientific Review Officer, Review Branch, Division of Extramural Activities, NIDDK, National Institutes of Health, Room 7353, 6707 Democracy Boulevard, Bethesda, MD 20892–2542, (301) 594–8898, *barnardm@extra.niddk.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: August 12, 2022.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–17703 Filed 8–16–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–0361.

Comments are invited on: (a) whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Program Evaluation for Prevention Contract (PEPC)—Strategic Prevention Framework for Prescription Drugs (SPF-Rx) Evaluation (OMB No. 0930–0377)—Revision

The Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Substance Abuse Prevention (CSAP) aims to complete a cross-site evaluation of SAMHSA's SPF-Rx grant program. SPF-Rx is designed to address nonmedical use of prescription drugs as well as opioid overdoses by raising awareness about the dangers of sharing medications and by working with pharmaceutical and medical communities on the risks of overprescribing. The SPF-Rx program aims to promote collaboration between states/tribes and pharmaceutical and

medical communities to understand the risks of overprescribing to youth ages 12–17 and adults 18 years of age and older. The program also aims to enhance capacity for, and access to, Prescription Drug Monitoring Program (PDMP) data for prevention purposes. This request for data collection includes a revision from previously approved Office of Management and Budget (OMB) instruments.

The SPF-Rx program's indicators of success are reductions in opioid overdoses, reduction in prescription drug misuse and improved use of PDMP data. Data collected through the tools described in this statement will be used for the national cross-site evaluation of SAMHSA's SPF-Rx program. This package covers continued data collection through 2023. The Program Evaluation for Prevention Control (PEPC) team will systematically collect and maintain an Annual Reporting Tool (ART) and Grantee and Community Level Outcomes data modules submitted by SPF-Rx grantees through the online Data Management System (DMS).

SAMHSA is requesting approval for data collection for the SPF-Rx cross-site evaluation with the following instruments:

Annual Reporting Tool (ART)—The ART is a survey instrument collected yearly to monitor state, tribal entity, and community-level performance, and to evaluate the effectiveness of the SPF-Rx program. This tool is completed by grantees and sub-recipient community project directors and provides process data related to funding use and effectiveness, organizational capacity, collaboration with community partners, data infrastructure, planned intervention targets, intervention implementation, evaluation, contextual factors, training and technical assistance (T/TA) needs, and sustainability.

Grantee-and Community-Level Outcomes Modules—These modules collect data on key SPF-Rx program outcomes, including opioid prescribing patterns and provider use of PDMP. Grantees will provide outcomes data at the grantee level for their state, tribal area, or jurisdiction, as well as at the community level for each of their sub-recipient communities.

Grantee-Level Interview—This qualitative interview will be administered at the end of the evaluation to obtain information from the grantee project directors on their programs, staffing, populations of focus, infrastructure, capacity, lessons learned, and collaboration.

Annualized Data Collection Burden by Year

Instrument	Number of respondents	Responses per respondent	Total number of responses	Hours per response	Total burden hours
Annual Reporting Tool	[a]110	1	110	4	440
	[b]21	1	21	3	63
Grantee-Level PDMP Outcomes Module	[b]21	1	21	2.5	52.5
Community-Level PDMP Outcomes Module	[b]21	5.2	110	1.25	137.5
Grantee-Level Interview	[b]21	1	21	1.5	31.5
FY2023	131		283		724.5

[a] Community subrecipient respondent.
[b] Grantee respondent.

Instrument	Number of respondents	Responses per respondent	Total number of responses	Hours per response	Total burden hours
Annual Reporting Tool	[a]110	1	110	4	440
	[b]21	1	21	3	63
Grantee-Level PDMP Outcomes Module	[b]21	1	21	2.5	52.5
Community-Level PDMP Outcomes Module	[b]21	5.2	110	1.25	137.5
Grantee-Level Interview	[b]0	N/A	N/A	1.5	N/A
FY2024	131		283		693

[a] Community subrecipient respondent.
[b] Grantee respondent.

Instrument	Number of respondents	Responses per respondent	Total number of responses	Hours per response	Total burden hours
Annual Reporting Tool	[a]110	1	110	4	440
	[b]21	1	21	3	63
Grantee-Level PDMP Outcomes Module	[b]21	1	21	2.5	52.5
Community-Level PDMP Outcomes Module	[b]21	5.2	110	1.25	137.5
Grantee-Level Interview	[b]21	1	21	1.5	31.5
FY2025	131		283		724.5

[a] Community subrecipient respondent.
[b] Grantee respondent.

Send comments to Carlos Graham, SAMHSA Reports Clearance Officer, 5600 Fishers Lane, Room 15E57–A, Rockville, Maryland 20857, *OR* email a copy to *carlos.graham@samhsa.hhs.gov.* Written comments should be received by October 17, 2022.

Carlos Graham,

Reports Clearance Officer.

[FR Doc. 2022–17720 Filed 8–16–22; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7063–N–01]

60-Day Notice of Proposed Information Collection: Memorandum of Understanding/Information Security Agreement Signature Page, OMB Control No.: Pending

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this Notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* October 17, 2022.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Anna Guido, Management Analyst, Department of Housing and Urban Development, 451 7th Street SW, Room 4176, Washington, DC 20410–5000; telephone 202–402–5535. This is not a toll-free number. Persons with hearing or speech impairments may access this number via TTY by calling the Federal Relay Service at (800) 877–8339. This is a toll-free number. Or email at *Anna.P.Guido@hud.gov* for a copy of the proposed forms or other available information.

FOR FURTHER INFORMATION CONTACT: Christopher Webber, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; telephone 202–402–5840. This is not a toll-free number. Persons with hearing or speech impairments may access this number via TTY by calling the Federal Relay Service at (800) 877–8339. This is a toll-free number. Copies of available documents submitted to OMB may be obtained from Anna Guido.

SUPPLEMENTARY INFORMATION: This Notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Memorandum of Understanding/ Information Security Agreement Signature page.

OMB Approval Number: Pending.

Type of Request: New collection.

Form Number: HUD–22015.

Description of the need for the information and proposed use: Federal policy requires agencies to develop Interconnection Security Agreements (ISAs) for federal information systems and networks that share or exchange information with external information systems and networks. Department of Housing and Urban Development (HUD) has developed its Memorandum of Understanding (MOU)/ISA template in accordance with practices outlined in Office of Management and Budget (OMB) Circular A–130, Managing Information as a Strategic Resource, and the National Institute of Standards and Technology (NIST) Special Publication (SP) 800–47, Security Guide for Interconnecting Information Technology Systems.

The information collected through this form is part of the MOU/ISA process. This process allows for HUD and external entities (people, businesses, PHAs, Tribes, etc.) to build and share application-level interfaces allowing for the exchange of data. This collection will ensure the privacy and security of data exchanged between HUD and an external entity as it will allow HUD to monitor and track who has access to HUD's data and ensure that any system requiring HUD data is internally authorized by HUD's OCIO and HUD's Office of Information Technology (IT) Security (OITS).

Estimated Number of Respondents: 30–50 per application.

Estimated Number of Responses: 60–100 per year (2 applications per year estimate).

Frequency of Response: One response every 3 years per respondent, per application.

Average Hours per Response: .5 hours.

Total Estimated Burdens: 30–50 hours per year.

B. Solicitation of Public Comment

This Notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 3507.

Dated: August 12, 2022.

Christopher Webber,

Principal Deputy Chief Information Officer.

[FR Doc. 2022–17717 Filed 8–16–22; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7062–N–13]

Privacy Act of 1974; System of Records

AGENCY: Office of Public and Indian Housing and Office of Housing, HUD.

ACTION: Notice of a modified system of records.

SUMMARY: The Enterprise Income Verification System (EIV) is used to verify program participants/tenants, reported income, identify unreported income sources and/or amounts and identify substantial annual income discrepancies amongst households that receive HUD provided rental assistance through programs administered by HUD's Office of Public and Indian Housing and Office of Housing Multifamily program. Under the Privacy Act of 1974, the Department of Housing and Urban Development, the Office of Public and Indian Housing proposes to update the system of records titled EIV. The EIV System has been modified replacing the Income Discrepancy Report with the Income Validation Tool built on the MicroStrategy platform.

DATES: This notice shall become valid September 16, 2022.

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

Federal e-Rulemaking Portal: http://www.regulations.gov. Follow the instructions provided on that site to submit comments electronically.

Fax: 202–619–8365.

Email: www.privacy@hud.gov.

Mail: Attention: Privacy Office; LaDonne White, Chief Privacy Officer; The Executive Secretariat; 451 Seventh Street SW, Room 10139; Washington, DC 20410–0001.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change to *http://ww.regulations.gov*. including any personal information provided.

Docket: For access to the docket to read background documents or comments received go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: LaDonne White; 451 Seventh Street SW, Room 10139; Washington, DC 20410–0001; telephone number 202–708–3054 (this is not a toll-free number). Individuals who are hearing- or speech-impaired may access this telephone number via TTY by calling the Federal Relay Service at 800–877–8339 (this is a toll-free number).

SUPPLEMENTARY INFORMATION: The EIV System is used to verify program participants/tenants, reported income, identify unreported income sources and/or amounts and identify substantial annual income discrepancies amongst households that receive HUD provided rental assistance through programs administered by HUD's Office of Public and Indian Housing and Office of Housing's Multifamily Housing Programs. The EIV System has been modified replacing the Income Discrepancy Report with the Income Validation Tool built on the MicroStrategy platform. This change was necessary to address OIG Audit #2014–FO–0004, Compliance with the Improper Payments and Elimination Recovery Act of 2010, findings and recommendations related to improper payments and the identification of tenant unreported and/or underreported income during mandatory reexaminations of family composition and income. The intended effect of this change is to eliminate false positives within EIV's Income Discrepancy Report which was estimated at approximately 50% of all income discrepancies, and to allow HUD to make better decisions for determination of rental subsidy and the degree of improper payments in HUD rental subsidy programs. Further, the IVT provides projections of discrepant income enabling users to analyze in detail, income, wage, and social security benefit information for a specific household and/or household member(s), detailing all captured income sources and dates of employment.

SYSTEM NAME AND NUMBER:

Enterprise Income Verification System, PIH–5.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

EIV data/servers is Stennis Space Center of NASA, John C. Stennis Space Center, MS 39529–0001.

SYSTEM MANAGER(S):

Rochelle Katz, PIH/EIV System Owner, U.S. Department of Housing, Office of Public and Indian Housing, 550 12th Street SW, First Floor, Washington, DC 20410–10001.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Section 453(j) of the Social Security Act as amended, now codified at 42 U.S.C. 653(j), Section 904 of the Stewart B. McKinney Homeless Assistance Amendments Act of 1988, as amended, now codified at 42 U.S.C. 3544, The Omnibus Budget Reconciliation Act of 1993 (Budget Reconciliation Act) 6103(l)(7) of title 26 of the United States Code (Internal Revenue Code).

PURPOSES OF THE SYSTEM:

The EIV System is a web-based Upfront income verification System that allows authorized Public Housing Agencies, Multifamily Housing Owners/Agents, and Contract Administrators to verify program participants/tenants, reported income, identify unreported income sources and/or amounts and identify substantial annual income discrepancies amongst households that receive HUD provided rental assistance through programs administered by HUD's Office of Public and Indian Housing and Office of Housing's Multifamily Housing Programs.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Families participating in housing programs administered by HUD's Office of Public and Indian Housing (current and former participants), including Tribally Designated Housing Entities, participating in the public housing program, Section 8 HCV program, Disaster Housing Assistance Programs and families currently participating in the Office of Housing, Multifamily Housing Division programs.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records consist of unit address (subsidized property address), family composition (names, dates of birth and SSNs of Household Members), financial data such as tenant-reported income to PHAs, O/As, and C/As, and wage, unemployment compensation, SS and SSI benefit data obtained from Department of Health and Human Services (HHS) and Social Security Administration (SSA).

RECORD SOURCE CATEGORIES:

Inventory Management System/Public Housing Information Center, Tenant Rental Assistance Certification System (IMS/PIC, TRACS), Social Security Administration and the Department of Health and Human Services.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

(A) To a congressional office from the record of an individual, in response to an inquiry from the congressional office made at the request of that individual.

(B) To appropriate Federal, State, and local governments, or persons, pursuant to a showing of compelling circumstances affecting the health or safety or vital interest of an individual or data subject, including assisting such agencies or organizations in preventing the exposure to or transmission of a communicable or quarantinable disease, or to combat other significant public health threats, if upon such disclosure appropriate notice was transmitted to the last known address of such individual to identify the health threat or risk.

(C) To Federal, State, and local agencies, their employees, and agents for the purpose of conducting computer matching programs as regulated by the Privacy Act of 1974, as amended (5 U.S.C. 552a).

(D) To Federal agencies, non-Federal entities, their employees, and agents (including contractors, their agents or employees; employees or contractors of the agents or designated agents); or contractors, their employees or agents with whom HUD has a contract, service agreement, grant, cooperative agreement, or computer matching agreement for the purpose of: (1) Detection, prevention, and recovery of improper payments; (2) detection and prevention of fraud, waste, and abuse in major Federal programs administered by a Federal agency or non-Federal entity; (3) detection of fraud, waste, and abuse by individuals in their operations and programs, but only to the extent that the information shared is necessary and relevant to verify pre-award and

prepayment requirements prior to the release of Federal funds, prevent and recover improper payments for services rendered under programs of HUD or of those Federal agencies and non-Federal entities to which HUD provides information under this routine use.

(E) To contractors, grantees, experts, consultants, students, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for the Federal Government when necessary to accomplish an agency function related to this system of records. Also, to a recipient who has provided the agency with advance, adequate written assurance that the record provided from the system of records will be used solely for statistical research or reporting purposes. Records under this condition will be disclosed or transferred in a form that does not identify an individual.

(F) To contractors, grantees, experts, consultants and their agents, or others performing or working under a contract, service, grant, or cooperative agreement with HUD, when necessary to accomplish an agency function related to a system of records. Disclosure requirements are limited to only those data elements considered relevant to accomplishing an agency function. Individuals provided information under these routine use conditions are subject to Privacy Act requirements and disclosure limitations imposed on the Department.

(G) To contractors, experts and consultants with whom HUD has a contract, service agreement, or other assignment of the Department, when necessary to utilize relevant data for the purpose of testing new technology and systems designed to enhance program operations and performance.

(H) To appropriate agencies, entities, and persons when (1) HUD suspects or has confirmed that there has been a breach of the system of records, (2) HUD has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, [the agency] (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the HUD's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm. To another Federal agency or Federal entity, when HUD determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

(I) To appropriate Federal, State, local, tribal, or governmental agencies or multilateral governmental organizations responsible for investigating or prosecuting the violations of, or for enforcing or implementing, a statute, rule, regulation, order, or license, where HUD determines that the information would assist in the enforcement of civil or criminal laws. To third parties during a law enforcement investigation, to the extent necessary to obtain information pertinent to the investigation, provided the disclosure of such information is appropriate to the proper performance of the official duties of the officer making the disclosure.

(J) To a court, magistrate, administrative tribunal, or arbitrator while presenting evidence, including disclosures to opposing counsel or witnesses during civil discovery, litigation, mediation, or settlement negotiations; or in connection with criminal law proceedings; or in response to a subpoena or to a prosecution request when such records to be released are specifically approved by a court provided order.

(K) To appropriate Federal, State, local, tribal, or governmental agencies or multilateral governmental organizations responsible for investigating or prosecuting the violations of, or for enforcing or implementing, a statute, rule, regulation, order, or license, where HUD determines that the information would assist in the enforcement of civil or criminal laws.

(L) To third parties during a law enforcement investigation to the extent necessary to obtain information pertinent to the investigation, provided disclosure is appropriate to the proper performance of the official duties of the officer making the disclosure.

(M) To another agency or to an instrumentality of any governmental jurisdiction within or under the control of the United States for a civil or criminal law enforcement activity if the activity is authorized by law, and if the head of the agency or instrumentality has made a written request to the agency that maintains the record, specifying the portion desired and the law enforcement activity for which the record is sought.

(N) To any component of the Department of Justice or other Federal agency conducting litigation or in proceedings before any court, adjudicative, or administrative body, when HUD determines that the use of such records is relevant and necessary to the litigation and when any of the following is a party to the litigation or have an interest in such litigation: (1) HUD, or any component thereof; or (2) any HUD employee in his or her official capacity; or (3) any HUD employee in his or her individual capacity where the Department of Justice or agency conducting the litigation has agreed to represent the employee; or (4) the United States, or any agency thereof, where HUD determines that litigation is likely to affect HUD or any of its components.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are maintained in paper and electronic storage media.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records are retrieved by Name, Date of Birth, and/or SSN.

POLICIES AND PRACTICIES FOR RETENTION AND DISPOSAL OF RECORDS:

Destroy one year after System of Records is placed on inactive list.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

EIV Physical controls include, key cards, security guards and Identification badges. HUD will secure downloaded reports on HUD secure SharePoint site. Public Housing Agencies, Multifamily Housing Owners/Agents, and Contract Administrators must secure downloaded data to a secure/locked space and/or cabinet. Computer terminals are secured in controlled areas which are locked when unoccupied. Access to automated records is limited to authorized personnel who must use a password to gain access to the system. Administrative controls include methods to ensure only authorized personnel access to PII. Each EIV user must first have access to HUD' Web Access Secure Systems. Each EIV User must be re-certified to use the EIV System every April and October of the calendar year. EIV Technical controls include, Encryption of Data at Rest, Firewall, Role-based Access Controls, VPN, Encryption of Data in Transit, User ID and Password, and PIV Card.

RECORD ACCESS PROCEDURES:

Individuals seeking notification of and access to their records in this system of records may submit a request in writing to the Department of Housing and Urban Development, Attn: FOIA Program Office, 451 7th Street SW, Suite

10139, Washington, DC 20410–0001 or by emailing *foia@hud.gov.* Individuals must furnish the following information for their records to be located:

1. Full name.
2. Signature.
3. The reason why the individual believes this system contains information about him/her.
4. The address to which the information should be sent.

CONTESTING RECORD PROCEDURES:

Same as the Notification Procedures Below.

NOTIFICATION PROCEDURES:

Any person wanting to know whether this system of records contains information about him or her should contact the System Manager. Such person should provide his or her full name, position title and office location at the time the accommodation was requested, and a mailing address to which a response is to be sent.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

74 FR 45235, September 1, 2009; FR E9–21087, August 31, 2009.

LaDonne White,

Chief Privacy Officer, Office of Administration.

[FR Doc. 2022–17710 Filed 8–16–22; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7062–N–11]

Privacy Act of 1974; System of Records

AGENCY: Office of Chief Financial Officer, HUD.

ACTION: Notice of a modified system of records.

SUMMARY: HUDCAPS is HUD's subsidiary ledger system, and provides the capability of capturing, recording, and summarizing HUD's financial results of operations across all business areas. Under the Privacy Act of 1974, the Department of Housing and Urban Development, the Office of the Chief Financial Officer proposes to update the system of records titled, ''HUD HUDCAPS CFO/FY.05.'' This system of records allows the Department of Housing and Urban Development OCFO's HUDCAPS to collect and maintain records on PIH Section 8 recipients and grantees for the Section 8 Voucher program.

DATES: Comments will be accepted on or before September 16, 2022. The SORN becomes effective immediately, while the routine uses become effective after the comment period.

ADDRESSES: You may submit comments, identified by docket number by one of these methods:

Federal e-Rulemaking Portal: http://www.regulations.gov. Follow the instructions provided on that site to submit comments electronically.

Fax: 202–619–8365.

Email: www.privacy@hud.gov.

Mail: Attention: Privacy Office; Ladonne L. White; The Executive Secretariat; 451 Seventh Street SW, Room 10139; Washington, DC 20410.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change to *http://www.regulations.gov.* including any personal information provided.

Docket: For access to the docket to read background documents or comments received go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: LaDonne White; 451 Seventh Street SW, Room 10139; Washington, DC 20410; telephone number 202–708–3054 (this is not a toll-free number). Individuals hearing- or speech-impaired may access this telephone number via TTY by calling the Federal Relay Service at 800–877–8339 (this is a toll-free number).

SUPPLEMENTARY INFORMATION: The following are amended from the SORN—

- Authority for Maintenance of the System: Replace ''Sec. 113 of the Budget and Accounting Act of 1951 (31 U.S.C.66a)'' with ''31 U.S.C. 3511''
- Remove instances of Program Accounting System (PAS) because it has been decommissioned.
- Updated Categories of Individuals Covered by System.
- Updated Policies and Practices for Retention and Disposal of Records.
- Routine uses previously included by reference are not explicitly listed in the SORN. This change adds no new routine uses, but merely reorganizes them. The routine uses included by reference to HUD's Appendix I are now explicitly listed.

SYSTEM NAME AND NUMBER:

HUD Central Accounting and Program System (HUDCAPS, A75).

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

HUD Headquarters, 451 7th Street, SW, Washington, DC 20410–1001 and National Center for Critical Information Processing and Storage (NCCIPS), Stennis Space Center, MS 39529. The backup data center is at Mid-Atlantic Data Center in Clarksville, VA 23927.

SYSTEM MANAGER(S):

Assistant Chief Financial Officer for Systems, Office of the Chief Financial Officer, Department of Housing and Urban Development, 451 Seventh Street SW, Room 3100, Washington, DC 20410.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

31 U.S.C. 3511 The Chief Financial Officers Act of 1990 (31 U.S.C. 901, *et seq.*) Executive Order 9397, as amended by Executive Order 13478 Housing and Community Development Act of 1987, 42 U.S.C. 3543.

PURPOSES OF THE SYSTEM:

A75 HUDCAPS is an Office of the Chief Financial Officer (OCFO) system that serves as a sub-ledger financial system for HUD.

HUDCAPS provides the capability of capturing, recording, and summarizing HUD's financial results of operations across all business areas.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

PIH Section 8 recipients and grantees.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records collected and/or stored in HUDCAPS includes grantee/recipient name, Business Tax-ID (can be EIN, SSN, and/or TIN), Business address, Data Universal Numbering System (DUNS), business banking account and routing numbers, and financial data.

RECORD SOURCE CATEGORIES:

PIH Section 8 recipients/grantees provide data to the Ft. Worth Accounting Center to enter into HUDCAPS.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

(A) To a congressional office from the record of an individual, in response to an inquiry from the congressional office made at the request of that individual.

(B) To appropriate agencies, entities, and persons when: (I) HUD suspects or has confirmed that there has been a breach of the system of records; (II) HUD has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, HUD (including its information systems, programs, and operations), the Federal Government, or national security; and (III) The disclosure made to such agencies, entities, and persons is reasonably necessary to assist in

connection with HUD's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

(C) To another Federal agency or Federal entity, when HUD determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (I) responding to a suspected or confirmed breach or (II) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

(D) To a court, magistrate, administrative tribunal, or arbitrator in the course of presenting evidence, including disclosures to opposing counsel or witnesses in the course of civil discovery, litigation, mediation, or settlement negotiations; or in connection with criminal law proceedings; when HUD determines that use of such records is relevant and necessary to the litigation and when any of the following is a party to the litigation or have an interest in such litigation: (1) HUD, or any component thereof; or (2) any HUD employee in his or her official capacity; or (3) any HUD employee in his or her individual capacity where HUD has agreed to represent the employee; or (4) the United States, or any agency thereof, where HUD determines that litigation is likely to affect HUD or any of its components.

(E) To any component of the Department of Justice or other Federal agency conducting litigation or in proceedings before any court, adjudicative, or administrative body, when HUD determines that the use of such records is relevant and necessary to the litigation and when any of the following is a party to the litigation or have an interest in such litigation: (1) HUD, or any component thereof; or (2) any HUD employee in his or her official capacity; or (3) any HUD employee in his or her individual capacity where the Department of Justice or agency conducting the litigation has agreed to represent the employee; or (4) the United States, or any agency thereof, where HUD determines that litigation is likely to affect HUD or any of its components.

(G) To appropriate Federal, State, local, tribal, or other governmental agencies or multilateral governmental organizations responsible for investigating or prosecuting the violations of, or for enforcing or implementing, a statute, rule, regulation, order, or license, where HUD determines that the information would assist in the enforcement of civil or criminal laws when such records, either alone or in conjunction with other information, indicate a violation or potential violation of law.

(F) To Federal agencies, non-Federal entities, their employees, and agents (including contractors, their agents or employees; employees or contractors of the agents or designated agents); or contractors, their employees or agents with whom HUD has a contract, service agreement, grant, cooperative agreement, or computer matching agreement for the purpose of: (I) Detection, prevention, and recovery of improper payments; (II) detection and prevention of fraud, waste, and abuse in major Federal programs administered by a Federal agency or non-Federal entity; (III) for the purpose of establishing or verifying the eligibility of, or continuing compliance with statutory and regulatory requirements by, applicants for, recipients or beneficiaries of, participants in, or providers of services with respect to, cash or in-kind assistance or payments under Federal benefits programs or recouping payments or delinquent debts under such Federal benefits programs; (IV) detection of fraud, waste, and abuse by individuals in their operations and programs. Records under this routine use may be disclosed only to the extent that the information shared is necessary and relevant to verify pre-award and prepayment requirements prior to the release of Federal funds or to prevent and recover improper payments for services rendered under programs of HUD or of those Federal agencies and non-Federal entities to which HUD provides information under this routine use.

(G) To contractors, grantees, experts, consultants, Federal agencies, and non-Federal entities, including, but not limited to, State and local governments and other research institutions or their parties, and entities and their agents with whom HUD has a contract, service agreement, grant, cooperative agreement, or other agreement for the purposes of statistical analysis and research in support of program operations, management, performance monitoring, evaluation, risk management, and policy development, or to otherwise support the Department's mission. Records under this routine use may not be used in whole or in part to make decisions that affect the rights, benefits, or privileges of specific individuals. The results of the matched information may not be disclosed in identifiable form.

(H) To contractors, grantees, experts, consultants and their agents, or others performing or working under a contract, service, grant, or cooperative agreement with HUD, when necessary to accomplish an agency function related to a system of records. Disclosure requirements are limited to only those data elements considered relevant to accomplishing an agency function.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are maintained in Electronic and paper formats

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records can be retrieved by the Business Tax ID (this is called the Vendor ID in the system, and it can be the SSN/TIN/EIN depending on the grantee).

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Destroy 6 years after final payment or cancellation, but longer retention is authorized if required for business use.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

All HUD employees have undergone background investigations. HUD buildings are guarded and monitored by security personnel, cameras, ID checks, and other physical security measures. Access is restricted to authorized personnel or contractors whose responsibilities require access. System users must take the mandatory security awareness training annually as mandated by the Federal Information Security Management Act (FISMA). Users must also sign a Rules of Behavior form certifying that they agree to comply with the requirements before they are granted access to the system. HUDCAPS resides on the P207 IBM Mainframe general support system, which is at NASA's Stennis Space Center. The physical security controls for P207 IBM Mainframe is the responsibility of OCIO. OCIO handles the backups and encryption of backups on the P207 IBM Mainframe. OCIO is also responsible for the mainframe/LAN-based security controls (*e.g.,* VPN, encryption of data in transit, IDS). All users authenticate to the HUD LAN with PIV cards before they can access HUDCAPS. OCFO limits access to records that contain PII data on a need to know basis, user recertification is performed, audit logs are reviewed, security assessments are performed, and background checks are performed prior to granting access. Not all employees and contractors have access to the vendor table that includes the PII.

Updates to HUDCAPS vendor data is limited to those with specific roles.

RECORD ACCESS PROCEDURES:

Individuals seeking notification of and access to their records in this system of records may submit a request in writing to the Department of Housing and Urban Development, Attn: FOIA Program Office, 451 7th Street SW, Suite 10139, Washington, DC 20410–0001. or by emailing *foia@hud.gov.* Individuals must furnish the following information for their records to be located:

1. Full name.
2. Signature.
3. The reason why the individual believes this system contains information about him/her.
4. The address to which the information should be sent.

NOTIFICATION PROCEDURES:

Any person wanting to know whether this system of records contains information about him or her should contact the System Manager. Such person should provide his or her full name, position title and office location at the time the accommodation was requested, and a mailing address to which a response is to be sent.

CONTESTING RECORD PROCEDURES:

Same as the Notification Procedures above.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

Docket No. FR–7009–N–04; 83 FR 11240 (March 14, 2018).

LaDonne White,

Chief Privacy Officer, Office of Administration.

[FR Doc. 2022–17709 Filed 8–16–22; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7062–N–12]

Privacy Act of 1974; System of Records

AGENCY: Office of Chief Financial Officer, HUD.

ACTION: Notice of a modified system of records.

SUMMARY: Financial Data Mart (FDM) is a warehouse of data extracted from various HUD systems and is supported by several query tools for improved financial and program data reporting. FDM facilitated the viewing understanding and reporting of financial data. FDM is the primary reporting tool used to generate internal ad-hoc reports, scheduled event-driven reports, and queries.

DATES: Comments will be accepted on or before September 16, 2022. This proposed action will be effective. The SORN becomes effective immediately, while the routine uses become effective after the comment period immediately upon publication except for the routine uses, which will become effective on the date following the end of the comment period unless comments are received which result in a contrary determination

ADDRESSES: You may submit comments, identified by docket number by one method:

Federal e-Rulemaking Portal: http://www.regulations.gov. Follow the instructions provided on that site to submit comments electronically.

Fax: 202–619–8365.

Email: www.privacy@hud.gov.

Mail: Attention: Privacy Office, Mr. LaDonne White; The Executive Secretariat; 451 Seventh Street SW, Room 10139; Washington, DC 20410–1000.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change to *http://www.regulations.gov.* including any personal information provided.

Docket: For access to the docket to read background documents or comments received go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: LaDonne White; 451 Seventh Street SW, Room 10139; Washington, DC 20410; telephone number 202–708–3054 (this is not a toll-free number). Individuals hearing- or speech-impaired may access this telephone number via TTY by calling the Federal Relay Service at 800–877–8339 (this is a toll-free number).

SUPPLEMENTARY INFORMATION: The following are amended from the previous SORN—

- Authority for Maintenance of the System: Updated legal citation by replacing ''Sec. 113 of the Budget and Accounting Act of 1951 (31 U.S.C.66a)'' with ''31 U.S.C. 3511.''
- Updated Categories of Individuals Covered by System to reflect the collections of the system.
- Updated Categories of Records in the System to reflect the collections of the system. Non-substantive changes were made.
- Updated Policies and Practices for Storage of Records to be more specific on how records are stored in FDM.
- Updated Policies and Practices for Retention and Disposal of Records to reflect the correct General Records Schedule.
- Updated Administrative, Technical, and Physical Safeguards to reflect additional safeguards identified for FDM.
- Updated the Routine Use section to explicitly include HUD's Routine Uses that were included by reference only.
- Added Routine Use 14–16 to follow Routine Uses for A75 HUDCAPS and A67 LOCCS, which transmit data to FDM.
- Updated Record Access Procedures, Contesting Record Procedures, and Notification Procedures to comply with HUD Privacy Office's procedures and format.

SYSTEM NAME AND NUMBER:

Financial Data Mart (FDM, A75R).

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

HUD Headquarters, 451 7th Street SW, Washington, DC 20410 and National Center for Critical Information Processing and Storage (NCCIPS), Stennis Space Center, MS 39529–6000. The backup data center is at Mid-Atlantic Data Center in Clarksville, VA 23927–3201.

SYSTEM MANAGER(S):

Sairah R. Ijaz, Assistant Chief Financial Officer for Systems, Office of the Chief Financial Officer, Department of Housing and Urban Development, 451 Seventh Street SW, Room 3100, Washington, DC 20410–0001.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

31 U.S.C. 3511, The Chief Financial Officers Act of 1990 (31 U.S.C. 901, *et seq.*), Executive Order 9397, as amended by Executive Order 13478, Housing and Community Development Act of 1987, 42 U.S.C. 3543.

PURPOSE(S) OF THE SYSTEM:

A75R Financial Data Mart (FDM) is a warehouse of data extracted from a variety of HUD's financial systems and is supported by several query tools for the purpose of improved financial and program data reporting. A75R FDM was designed to facilitate the viewing, understanding, and reporting of financial data. FDM is the primary reporting tool used to generate internal ad-hoc reports, scheduled event-driven reports, and queries. The FDM provides HUD:

- Timely and comparable financial management information
- Improved accounting processing control to detect, prevent and mitigate mistakes,

- fraud, waste, and mismanagement of funds
- Uniformity in financial information and reporting
- Quality assurance processes resulting in improved data integrity
- Improved timeliness of ad-hoc financial analyses
- Financial and programmatic reporting and dashboards for all HUD staff
- Application support for Open Obligation Review and user recertification processing

The system is used to summarize financial activity provided by HUD's critical financial systems.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Federal Employees, Contractors, and grant/subsidy/loan recipients.

CATEGORIES OF RECORDS IN THE SYSTEM:

The system contains Names, SSN, Tax-IDs (which may include SSNs for sole-proprietors), addresses, user-id, and financial information (*e.g.,* deposit account number, bank routing number).

RECORD SOURCE CATEGORIES:

FDM receives records from other HUD information systems such as A75 HUD Central Accounting and Program Systems (HUDCAPS), A67 Line of Credit Control System (LOCCS), and P162 HUD Integrated Human Resources and Training System (HIHRTS). FDM also receives records from Department of Treasury, Administrative Resource Center (ARC)'s Oracle Federal Financials.

ROUTINE USES MAINTINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

(A) To a congressional office from the record of an individual, in response to an inquiry from the congressional office made at the request of that individual.

(B) To appropriate agencies, entities, and persons when: (I) HUD suspects or has confirmed that there has been a breach of the system of records; (II) HUD has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, HUD (including its information systems, programs, and operations), the Federal Government, or national security; and (III) The disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with HUD's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

(C) To another Federal agency or Federal entity, when HUD determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (I) responding to a suspected or confirmed breach or (II) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

(D) To a court, magistrate, administrative tribunal, or arbitrator in the course of presenting evidence, including disclosures to opposing counsel or witnesses in the course of civil discovery, litigation, mediation, or settlement negotiations; or in connection with criminal law proceedings; when HUD determines that use of such records is relevant and necessary to the litigation and when any of the following is a party to the litigation or have an interest in such litigation: (1) HUD, or any component thereof; or (2) any HUD employee in his or her official capacity; or (3) any HUD employee in his or her individual capacity where HUD has agreed to represent the employee; or (4) the United States, or any agency thereof, where HUD determines that litigation is likely to affect HUD or any of its components.

(E) To any component of the Department of Justice or other Federal agency conducting litigation or in proceedings before any court, adjudicative, or administrative body, when HUD determines that the use of such records is relevant and necessary to the litigation and when any of the following is a party to the litigation or have an interest in such litigation: (1) HUD, or any component thereof; or (2) any HUD employee in his or her official capacity; or (3) any HUD employee in his or her individual capacity where the Department of Justice or agency conducting the litigation has agreed to represent the employee; or (4) the United States, or any agency thereof, where HUD determines that litigation is likely to affect HUD or any of its components.

(F) To appropriate Federal, State, local, tribal, or other governmental agencies or multilateral governmental organizations responsible for investigating or prosecuting the violations of, or for enforcing or implementing, a statute, rule, regulation, order, or license, where HUD determines that the information would assist in the enforcement of civil or criminal laws when such records, either alone or in conjunction with other information, indicate a violation or potential violation of law.

(G) To Federal agencies, non-Federal entities, their employees, and agents (including contractors, their agents or employees; employees or contractors of the agents or designated agents); or contractors, their employees or agents with whom HUD has a contract, service agreement, grant, cooperative agreement, or computer matching agreement for the purpose of: (I) Detection, prevention, and recovery of improper payments; (II) detection and prevention of fraud, waste, and abuse in major Federal programs administered by a Federal agency or non-Federal entity; (III) for the purpose of establishing or verifying the eligibility of, or continuing compliance with statutory and regulatory requirements by, applicants for, recipients or beneficiaries of, participants in, or providers of services with respect to, cash or in-kind assistance or payments under Federal benefits programs or recouping payments or delinquent debts under such Federal benefits programs; (IV) detection of fraud, waste, and abuse by individuals in their operations and programs. Records under this routine use may be disclosed only to the extent that the information shared is necessary and relevant to verify pre-award and prepayment requirements prior to the release of Federal funds or to prevent and recover improper payments for services rendered under programs of HUD or of those Federal agencies and non-Federal entities to which HUD provides information under this routine use.

(H) To contractors, grantees, experts, consultants and their agents, or others performing or working under a contract, service, grant, cooperative agreement, or other agreement with HUD, when necessary to accomplish an agency function related to a system of records. Disclosure requirements are limited to only those data elements considered relevant to accomplishing an agency function.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are maintained in electronic format only.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records are retrieved by name, social security number, home address,

POLICIES AND PRACTICIES FOR RETENTION AND DISPOSAL OF RECORDS:

Destroy 6 years after final payment or cancellation, but longer retention is authorized if required for business use.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

All HUD employees have undergone background investigations. HUD buildings are guarded and monitored by security personnel, cameras, ID checks,

and other physical security measures. Access is restricted to authorized personnel or contractors whose responsibilities require access. System users must take the mandatory security awareness training annually as mandated by the Federal Information Security Management Act (FISMA). Users must also sign a Rules of Behavior form certifying that they agree to comply with the requirements before they are granted access to the system.

FDM resides on the HUD OCIO Local Area Network (LAN). The HUD OCIO Infrastructure and Operations Office (IOO) secures the Stennis and Clarksville Data Centers where the LAN resides, and for backing up and encrypting FDM data. FDM sends and receives data through HUD SFTP (Security File Transfer Protocol), which encrypts the data. SSNs are encrypted in the database.

Supervisors determine and authorize FDM access for their employees, and OCFO checks their suitability by ensuring the user's investigation record is appropriate. The majority of FDM users are read-only and cannot enter data into FDM. An annual system user recertification is conducted to ensure each FDM user requires access to the system.

NOTIFICATION PROCEDURES:

Any person wanting to know whether this system of records contains information about him or her should contact the System Manager. Such person should provide his or her full name, position title and office location at the time the accommodation was requested, and a mailing address to which a response is to be sent.

RECORD ACCESS PROCEDURES:

Individuals seeking notification of and access to their records in this system of records may submit a request in writing to the Department of Housing and Urban Development, Attn: FOIA Program Office, 451 7th Street SW, Suite 10139, Washington, DC 20410–0001 or by emailing *foia@hud.gov.* Individuals must furnish the following information for their records to be located:

1. Full name.
2. Signature.
3. The reason why the individual believes this system contains information about him/her.
4. The address to which the information should be sent.

CONTESTING RECORD PROCEDURES:

Same as the Notification Procedures above.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

Docket No. FR–5763–N–03; 79 FR 16805 (March 26, 2014).

LaDonne White,

Chief Privacy Officer, Office of Administration.

[FR Doc. 2022–17708 Filed 8–16–22; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLNV9120000.L18200000.XX0000. LXSS006F0000.223.241A MO:4500164356.]

Second Call for Nominations for the Mojave-Southern Great Basin Resource Advisory Council, Nevada

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of call for nominations.

SUMMARY: The purpose of this notice is to request public nominations for the Bureau of Land Management's (BLM) Mojave-Southern Great Basin Resource Advisory Council (RAC) to fill existing vacancies as well as member terms that are scheduled to expire. The Council provides advice and recommendations to the BLM on land use planning and management of the public land resources located within the BLM's Battle Mountain, Ely, and Southern Nevada Districts.

DATES: All nominations must be received no later than September 16, 2022.

ADDRESSES: Nominations and completed applications should be sent to Kirsten Cannon, Public Affairs Specialist, BLM Southern Nevada District Office, 4701 North Torrey Pines, Las Vegas, NV 89130; phone: (702) 515–5057; email: *k1cannon@blm.gov.*

FOR FURTHER INFORMATION CONTACT: Rita Henderson, Public Affairs Specialist, BLM Nevada State Office, 1340 Financial Boulevard, Reno, Nevada 89502; phone: (775) 461–6753; email: *ritahenderson@blm.gov.*

Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: The Federal Land Policy and Management Act (FLPMA) directs the Secretary of the Interior to involve the public in planning and issues related to management of lands administered by the BLM. Section 309 of FLPMA (43 U.S.C. 1739) directs the Secretary to establish 10- to 15-member citizen-based advisory councils that are consistent with the Federal Advisory Committee Act (FACA). As required by FACA, RAC membership must be balanced, and representative of the various interests concerned with the management of the public lands. The BLM's regulations governing RACs are found at 43 CFR 1784 and include the following three membership categories:

Category One—Holders of Federal grazing permits or leases within the area for which the RAC is organized; represent interests associated with transportation or rights-of-way; represent developed outdoor recreation, off-highway vehicle users, or commercial recreation activities; represent the commercial timber industry; or represent energy and mineral development.

Category Two—Representatives of nationally or regionally recognized environmental organizations; dispersed recreational activities; archaeological and historical interests; or nationally or regionally recognized wild horse and burro interest groups.

Category Three—Hold State, county, or local elected office; are employed by a State agency responsible for the management of natural resources, land, or water; represent Indian tribes within or adjacent to the area for which the RAC is organized; are employed as academicians in natural resource management or the natural sciences; or represent the affected public-at-large.

Individuals may nominate themselves or others. Nominees must be residents of the State of Nevada. The BLM will evaluate nominees based on their education, training, experience, and knowledge of the geographic area of the RAC. Nominees should demonstrate a commitment to collaborative resource decision-making.

The following must accompany all nominations:

—A completed RAC application, which can either be obtained through your local BLM office or online at: *https://www.blm.gov/sites/blm.gov/files/1120-019_0.pdf.*
—Letters of reference from represented interests or organizations; and
—Any other information that addresses the nominee's qualifications.

Simultaneous with this notice, BLM Nevada will issue a press release providing additional information for submitting nominations.

(Authority: 43 CFR 1784.4–1)

Angelita Bulletts,

BLM Southern Nevada District Manager.

[FR Doc. 2022–17638 Filed 8–16–22; 8:45 am]

BILLING CODE 4310–HC–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[L14400000/LLAZ920000/ET0000/AZA–18465]

Notice of Application for Extension and Opportunity for Public Meeting; Federal Correctional Institution—Phoenix, Arizona

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of application.

SUMMARY: The United States Department of Justice, Federal Bureau of Prisons (BOP) has filed an application with the Bureau of Land Management (BLM) for the Secretary of the Interior to extend the withdrawal created by Public Land Order (PLO) No. 6493, as extended by PLO No. 7474, for an additional 20-year term. PLO No. 6493, which as extended by PLO 7474 will currently expire on December 23, 2023, withdrew 70 acres of public lands from settlement, sale, location, or entry under the general land laws, including the United States mining laws, but not from leasing under the mineral leasing laws, subject to valid existing rights, and reserved the land for use by the BOP for support facilities at the Federal Correctional Institution—Phoenix, in Maricopa County, Arizona. This notice provides for the public to comment and request a public meeting for the 20-year withdrawal extension application.

DATES: Comments and requests for a public meeting must be received by November 15, 2022.

ADDRESSES: All comments and meeting requests should be sent to the BLM Arizona State Office, 1 North Central Avenue, Suite 800, Phoenix, AZ 85004; faxed to (602) 417–9452; or sent by email to *BLM_AZ_Withdrawal_Comments@blm.gov.* The BLM will not consider comments via telephone calls.

FOR FURTHER INFORMATION CONTACT: Michael Ouellett, Realty Specialist, BLM Arizona State Office, 1 North Central Avenue, Suite 800, Phoenix, AZ 85004, telephone: (602) 417–9561, email: *mouellett@blm.gov;* or you may contact the BLM office at the address listed above. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: The BOP has filed an application requesting the extension of the withdrawal and reservation of 70 acres established by PLO No. 6493 (48 FR 56227), as extended by PLO No. 7474 (65 FR 80907), which are incorporated herein by reference. The BOP has requested that the withdrawal be extended for an additional 20-year term and the land reserved for use by the BOP for support facilities at the Federal Correctional Institution-Phoenix, subject to valid existing rights.

There are no suitable alternative sites available.

No water rights would be needed to fulfill the purpose of this withdrawal extension.

Notice is hereby given that comments or request for an opportunity for a public meeting is afforded in connection with this withdrawal extension. All interested persons who desire a public meeting for the purpose of being heard on the requested withdrawal extension must submit a written request to the State Director, BLM Arizona State Office at the address in the **ADDRESSES** section no later than November 15, 2022. If the BLM authorized officer determines that a public meeting will be held, a notice of the date, time, and place will be published in the **Federal Register** and a local newspaper at least 30 days before the scheduled date of the meeting.

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 BLM in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

A decision of the Secretary of the Interior to extend a withdrawal as requested is subject to compliance with the National Environmental Policy Act (NEPA). The BLM established a categorical exclusion (CX), developed pursuant to NEPA, and found at 516 Departmental Manual 11.9(E)(1), that addresses extensions such as the one requested, which consists merely of an extension of time, without any other changes. The BLM anticipates reliance on the referenced CX, subject to extraordinary circumstances review, should the Secretary elect to extend the withdrawal, and anticipates that neither preparation of an environmental impact statement nor an environmental assessment will be necessary.

This application will be processed in accordance with the regulations at 43 CFR 2310.4.

(Authority: 43 U.S.C. 1714(f))

Raymond Suazo,

State Director.

[FR Doc. 2022–17712 Filed 8–16–22; 8:45 am]

BILLING CODE 4310–32–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLCA930000–L14400000–ET0000; CACA–054374]

Notice of Withdrawal Application and Opportunity for Public Meeting, California

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of withdrawal application.

SUMMARY: The United States Forest Service (USFS) filed an application with the Bureau of Land Management (BLM) requesting that the Secretary of the Interior withdraw 2,841 acres of National Forest System lands from location and entry under the United States mining laws, but not from leasing under the mineral or geothermal leasing laws or disposal under the Mineral Materials Act of 1947, for up to 50 years, subject to valid existing rights, to maintain, protect, and conserve critical habitat for listed threatened and endangered plant species in the San Bernardino National Forest, California. This notice segregates the lands from location and entry under the United States mining laws, but not from leasing under the mineral or geothermal leasing laws or disposal under the Mineral Materials Act of 1947, subject to valid existing rights for up to two years, while the application is being considered. The application also includes 280 acres of non-Federal lands within the boundaries of the San Bernardino National Forest that, if acquired, would be subject to this notice. The land described in this notice would remain open to such forms of disposition allowed by law on National Forest System land. This notice also gives the public an opportunity to comment on the withdrawal application and to request a public meeting.

DATES: Comments and public meeting requests must be received by November 15, 2022.

ADDRESSES: All comments and meeting requests should be sent to the BLM California State Director, 2800 Cottage Way W–1928, Sacramento, CA 95825–1886. Records, maps, and copies of the legal descriptions relating to the application are available through mailed request by contacting the BLM Public Room at: Bureau of Land Management California State Office, Public Room, 2800 Cottage Way W–1928, Sacramento, CA 95825–1886.

FOR FURTHER INFORMATION CONTACT: Heather Daniels, BLM California State Office, telephone: (916) 978–4674, email: *hdaniels@blm.gov*; or Zareen Ali, Forest Service Regional Office, telephone: (707) 562–8964 during regular business hours, 8:00 a.m. to 4:30 p.m. Monday through Friday, except holidays. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: The USFS filed an application with the BLM requesting that the Secretary of the Interior withdraw the following described lands from location and entry under the United States mining laws, but not from leasing under the mineral or geothermal leasing laws or disposal under the Mineral Materials Act of 1947, for up to 50 years, subject to valid existing rights, to maintain, protect, and conserve critical habitat for listed threatened and endangered plant species in the San Bernardino National Forest, California.

National Forest System Lands

San Bernardino National Forest

San Bernardino Meridian, California

T. 3 N., R. 1 E.,
Sec. 13, SE¼;
Sec. 14, W½NE¼SW¼, W½SE¼NE¼SW¼, NW¼NW¼SW¼, NW¼SW¼NW¼SW¼, E½SW¼NW¼SW¼, E½NW¼SW¼, NE¼SW¼SW¼, NE¼NW¼SW¼SW¼, E½SE¼SW¼SW¼, and SE¼SW¼;
Sec. 19, lot 4 and SE¼SW¼;
Sec. 23, NE¼NE¼NE¼;
Sec. 24, NE¼ and NW¼;
Sec. 30, lots 1 and 2, NE¼, and E½NW¼.
T. 3 N., R. 2 E.,

A parcel of land within Protracted Blocks 39, 40, 45, and 46 of Township 3 North, Range 2 East, San Bernardino Meridian, San Bernardino County, California adjoining the southeast quarter of section 13 and the northeast quarter of section 24 in Township 3 North, Range 1 East, San Bernardino Meridian, and being more particularly described as follows:

Beginning at the east quarter section corner of said section 13;

Thence along the easterly line of said section, South 1°30′20″ East, 2935.53 feet to the easterly section corner of said sections 13 and 24;

Thence along the easterly line of said section 24, South 1°27′50″ East, 2594.76 feet, to the east quarter section corner of said section 24;

Thence along the following 5 courses in the unsurveyed portion of Township 3 North, Range 2 East, San Bernardino Meridian:

1. North 90°00′00″ East, 2441.85 feet;
2. North 1°27′50″ West, 2594.76 feet;
3. North 90°00′00″ East, 2308.15 feet;
4. North 1°30′20″ West, 2935.53 feet;
5. South 90°00′00″ West, 4750.00 feet to the Point Of Beginning;

Excepting therefrom any portion within Mineral Survey 5679A as patented August 8th, 1924 to Voorhies, et al (Patent Number 942560);

Containing 430 acres, more or less.

T. 2 N., R. 3 E.,
Sec. 17, N½SW¼.
T. 3 N., R. 1 W.,
Sec. 10, SE¼;
Sec. 14, W½NW¼ and W½SW¼;
Sec. 15, NE¼;
Sec. 22, SE¼;
Sec. 23, W½NW¼, W½NE¼SW¼, S½SE¼NE¼SW¼, NW¼SW¼, S½SW¼, S½SW¼NE¼SE¼, S½SE¼NE¼SE¼, S½SW¼NW¼SE¼, S½SE¼NW¼SE¼, and S½SE¼;
Sec. 26, NW¼NW¼;
Sec. 27, lot 1, NE¼, N½NW¼, and SW¼NW¼.

The area described aggregates 2,841 acres of National Forest System lands in San Bernardino County.

The following described non-Federal lands are within the boundaries of the San Bernadino National Forest. If title to these non-Federal lands is subsequently acquired by the United States, the lands will become subject to the terms and conditions of the withdrawal.

Non-Federal Lands

San Bernardino Meridian, California

T. 3 N., R. 1 E.,
Sec. 13, SW¼;
Sec. 14, NE¼SE¼ and S½SE¼.

The area described aggregates 280 acres in San Bernadino County.

The use of a rights-of-way, interagency, or cooperative agreement would not adequately constrain non-discretionary uses that may result in disturbance of the lands embraced within the San Bernadino National Forest.

There are no suitable alternative sites as the described lands contain the resource values to be protected.

No additional water rights will be needed to fulfill the purpose of the requested withdrawal.

For a period until November 15, 2022, all persons who wish to submit comments, suggestions, objections, or request a public meeting in connection with the proposed withdrawal may present their views in writing to the BLM State Director at the address indicated above.

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. Individuals that submit written comments may request confidentiality by asking us in your comment to withhold your personal identifying information from public review; however, we cannot guarantee that we will be able to do so.

Notice is hereby given that the opportunity for a public meeting is afforded in connection with the withdrawal application. All interested parties who desire a public meeting for the purpose of being heard on the withdrawal application must submit a written request to the Bureau of Land Management California State Director at the address indicated above by November 15, 2022. If the Authorized Officer determines that the BLM will hold a public meeting, the BLM will publish a notice of the time and place in the **Federal Register** and a local newspaper at least 30 days before the scheduled date of the meeting.

For a period until August 17, 2024, subject to valid existing rights, the National Forest System lands described in this notice will be segregated from location and entry under the United States mining laws, but not from leasing under the mineral or geothermal leasing laws or disposal under the Mineral Materials Act of 1947, while the withdrawal application is being processed, unless the application is denied, canceled, or the withdrawal is approved prior to that date. Publication of this notice shall also serve to segregate the 280 acres of non-Federal lands described in this notice for up to two years if during this time they are acquired by the United States.

The land described in this notice would remain open to such forms of disposition allowed by law on National Forest System land. Licenses, permits, cooperative agreements, or discretionary land use authorizations of a temporary nature and that would not significantly impact the values to be protected by the requested withdrawal may be allowed

with the approval of the authorized officer of the USFS during the temporary segregation period.

The application will be processed in accordance with the regulations set forth in 43 CFR part 2300.

Karen E. Mouritsen,

California State Director.

[FR Doc. 2022–17706 Filed 8–16–22; 8:45 am]

BILLING CODE 4311–15–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRNHL–DTS#–34350; PPWOCRADI0, PCU00RP14.R50000]

National Register of Historic Places; Notification of Pending Nominations and Related Actions

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The National Park Service is soliciting electronic comments on the significance of properties nominated before August 6, 2022, for listing or related actions in the National Register of Historic Places.

DATES: Comments should be submitted electronically by September 1, 2022.

ADDRESSES: Comments are encouraged to be submitted electronically to *National_Register_Submissions@nps.gov* with the subject line ''Public Comment on <property or proposed district name, (County) State>.'' If you have no access to email you may send them via U.S. Postal Service and all other carriers to the National Register of Historic Places, National Park Service, 1849 C Street NW, MS 7228, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Sherry A. Frear, Chief, National Register of Historic Places/National Historic Landmarks Program, 1849 C Street NW, MS 7228, Washington, DC 20240, *sherry_frear@nps.gov,* 202–913–3763.

SUPPLEMENTARY INFORMATION: The properties listed in this notice are being considered for listing or related actions in the National Register of Historic Places. Nominations for their consideration were received by the National Park Service before August 6, 2022. Pursuant to Section 60.13 of 36 CFR part 60, comments are being accepted concerning the significance of the nominated properties under the National Register criteria for evaluation.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Nominations Submitted by State or Tribal Historic Preservation Officers

ARKANSAS

Greene County

Standard Oil Company Oil Station Garage Building, (Truscon Buildings in Arkansas, c.1915–1937 MPS), 202 West Vine St., Paragould, MP100008154

Independence County

Dry Run Bridge, (New Deal Recovery Efforts in Arkansas MPS), AR 106 over Dry Run, Bethesda vicinity, MP100008153

Mississippi County

Jonesboro, Lake City & Eastern Railroad Steam Locomotive #34 and Associated, Rolling Stock, Southwest of jct. of AR 158 and Park Ave., Victoria, SG100008168

Ouachita County

Standard Oil Company Oil Station Pumphouse, (Truscon Buildings in Arkansas, c.1915–1937 MPS), 505 East Washington St., Camden, MP100008150

Camden Commercial Historic District, Roughly Washington St. between Harrison and Madison Sts., and Adams Ave. between Washington and Jefferson Sts., Camden, SG100008151

Pulaski County

Burns Park Golf Center, 28 Championship Dr., North Little Rock, SG100008148

White County

Carmichael, Leslie and Anamiece, House, 712 Randall Dr., Searcy, SG100008145

Department of Labor Employment Security Division Office, 501 West Arch Ave., Searcy, SG100008146

DISTRICT OF COLUMBIA

District of Columbia

Founding Church of Scientology, Washington, DC, 1812 19th St. NW, Washington, SG100008142

IDAHO

Ada County

South Municipal Pool, 921 South Shoshone St., Boise, SG100008162

Lowell Municipal Pool, 1601 North 28th St., Boise, SG100008169

MAINE

Cumberland County, Orr's Island Meeting House, 1579 Harpswell Islands Rd., Orr's Island, Harpswell, SG100008122

Waldo County

Pilley House, 11 Moosehead Trail, Brooks, SG100008124

MICHIGAN

Wayne County

Sojourner Truth Homes, (The Civil Rights Movement and the African American Experience in 20th Century Detroit MPS), 4525 and 4801 East Nevada St., Detroit, MP100008140

MISSISSIPPI

Hinds County

Upper Midtown Historic District (Boundary Increase), Roughly bounded by Duncan Ave., North West, Livingston, & North Mill Sts., Jackson, BC100008164

Griffith Memorial Baptist Church, 519 West Silas Brown St., Jackson, SG100008165

East Midtown Historic District, Roughly bounded by Adelle, North West, Nearview, and Blair Sts., Jackson, SG100008166

Jones County

Bynum-Anderson House, 701 Holly St., Ellisville, SG100008163

PENNSYLVANIA

Lawrence County

New Castle Hospital, 1000 South Mercer Street, New Castle, SG100008138

Lehigh County

Hokendauqua Thomas Iron Company Town Historic District, Roughly bounded by Front, Center, Carbon, Vine, and South Sts., Whitehall, SG100008170

Monroe County

Frantz School, (Educational Resources of Pennsylvania MPS), 485 Church Rd., Kunkletown, MP100008137

Shrawder-Sittig House, 553 River Rd., Smithfield Township, SG100008144

TEXAS

El Paso County

Colmenero, Damacio, Site, (Historic Properties of Ysleta del Sur Pueblo, El Paso County, Texas MPS), 151 Irma Rd., El Paso, MP100008126

Granillo, Trinidad, Site, (Historic Properties of Ysleta del Sur Pueblo, El Paso County, Texas MPS), 139 Palla Pl., El Paso, MP100008127

House at 124 North Old Pueblo Road, (Historic Properties of Ysleta del Sur Pueblo, El Paso County, Texas MPS), 124 North Old Pueblo Rd., El Paso, MP100008128

Ysleta del Sur Pueblo Tuhla District, (Historic Properties of Ysleta del Sur Pueblo, El Paso County, Texas MPS), 117 Juno Pl., El Paso, MP100008129

Salida de los Santos Site, (Historic Properties of Ysleta del Sur Pueblo, El Paso County, Texas MPS), 8817 Old Country Dr., El Paso, MP100008130

Pakitu (Pumpkin Village) Housing District, (Historic Properties of Ysleta del Sur Pueblo, El Paso County, Texas MPS), Roughly bounded by Socorro Rd., US-Mexico border, agricultural fields, and Bernardo Holguin St., El Paso, MP100008131

Ysleta del Sur Pueblo Iye-Kitu (Corn Village) Housing District, (Historic Properties of

Ysleta del Sur Pueblo, El Paso County, Texas MPS), 200–333, 9303 Alton Griffon St., 9301–9425 Juanchido Ln., 9300–9392 Nakitu Dr., 291–341 Granillo St., El Paso, MP100008132
Ysleta del Sur Pueblo Hueco Mountain Property, (Historic Properties of Ysleta del Sur Pueblo, El Paso County, Texas MPS), Hueco Tanks Rd., approx. 5 mi. north of US 62/180, El Paso, MP100008133

Lubbock County

In Town Inn, 1212 Main St., Lubbock, SG100008171

VIRGINIA

Nelson County

Ryan Hall Elementary School, 71 Braddock Ln., Shipman, SG100008135
Winchester Independent City, Virginia Apple Storage Warehouse, 1955 Valley Ave., Winchester, SG100008136

York County

Oak Grove Baptist Church Historic District, 529 Waller Mill Rd., Airport Rd., Rochambeau Ave., Williamsburg vicinity, SG100008134

WISCONSIN

Dane County

Kohl's Food Store, 4207 Monona Dr., Monona, SG100008139

An owner objection received for the following resource:

ARKANSAS

Desha County

McGehee Bank, 301 West 2nd St, McGehee, SG100008156

A request for removal has been made for the following resources:

ARKANSAS

Chicot County

Chicot County Training School, Jct. of Hazel and North School Sts., Dermott, OT04000490

Clark County

McNeely Creek Bridge, (Historic Bridges of Arkansas MPS), Cty. Rd. 12, Beirne, OT04000495

Craighead County

Home Ice Company, 700 Cate Ave., Jonesboro, OT100001005

Cross County

Deadrick, Capt. Isaac N., House, Northwest of jct. of US 64 and AR 163, Levesque, OT93000964

Fulton County

AR 289 Bridge Over English Creek, (Historic Bridges of Arkansas MPS), AR 289 over English Cr., Mammoth Spring vicinity, OT08001338

Miller County

Foulke, Claude, House, 501 Pecan St., Texarkana, OT82002125

Pulaski County

Amboy Overpass, (Historic Bridges of Arkansas MPS), AR 365 over Union-Pacific RR tracks, north of jct. of AR 365 and AR 176, North Little Rock, OT95000608

MICHIGAN

Kent County

Grand Rapids Cycle Company Factory, 514 Butterworth St. SW, Grand Rapids, OT04000600

Wayne County

Tiger Stadium, 2121 Trumbull Ave., Detroit, OT88003236

A request to move has been received for the following resource:

ARKANSAS

Columbia County

Mt. Prospect Methodist Church, Jct. of Cty. Rds. 446 and 61, Richland, MV90000428

Additional documentation has been received for the following resources:

MAINE

Cumberland County

Mechanics' Hall (Additional Documentation), 519 Congress St., Portland, AD73000118

Sagadahoc County

Bath Historic District (Additional Documentation), Roughly bounded by Beacon St., the Kennebec R., Vine and Court Sts., and a line parallel to the Kennebec R., Bath, AD73000261

Nominations submitted by Federal Preservation Officers:

The State Historic Preservation Officer reviewed the following nomination(s) and responded to the Federal Preservation Officer within 45 days of receipt of the nomination(s) and supports listing the properties in the National Register of Historic Places.

FLORIDA

Alachua County

Federal Building, United States Post Office, and Court House, 401 SE 1st Ave., Gainesville, SG100008118

Hillsborough County

Federal Office Building, 500 East Zack St., Tampa, SG100008119

Marion County

Federal Building, United States Post Office, and Court House, 207 NW 2nd St., Ocala, SG100008120

MONTANA

Rosebud County

Poker Jim Butte Fire Lookout, FS Rd. 4801, Ashland vicinity, SG100008167

Authority: Section 60.13 of 36 CFR part 60.

Dated: August 9, 2022.

Sherry A. Frear,

Chief, National Register of Historic Places/National Historic Landmarks Program.

[FR Doc. 2022–17649 Filed 8–16–22; 8:45 am]

BILLING CODE 4312–52–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1317]

Notice of a Commission Determination Not To Review an Initial Determination Terminating the Investigation Based on a Settlement; Termination of the Investigation; Certain Barcode Scanners, Scan Engines, Mobile Computers With Barcode Scanning Functionalities, Products Containing the Same, and Components Thereof

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission (''Commission'') has determined not to review an initial determination (''ID'') (Order No. 3) of the presiding administrative law judge (''ALJ''), terminating the investigation based on a settlement agreement.

FOR FURTHER INFORMATION CONTACT: Ronald A. Traud, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–3427. Copies of non-confidential documents filed in connection with this investigation 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 this investigation on June 3, 2022, based on a complaint filed on behalf of Honeywell International Inc. of Charlotte, North Carolina, and Hand Held Products, Inc. of Charlotte, North Carolina (collectively, ''Honeywell''). 87 FR 33833 (June 3, 2022). The complaint alleged a violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain barcode scanners, scan engines, mobile computers with barcode scanning functionalities, products containing the same, and components thereof by reason of the infringement of certain claims of U.S. Patent Nos. 9,465,970, 10,956,695, and 11,238,252.

Id. The complaint further alleged that an industry in the United States exists as required by section 337. *Id.* The Commission's notice of investigation named as respondents Zebra Technologies Corporation of Lincolnshire, Illinois, and Symbol Technologies, Inc. of Holtsville, New York (collectively, ''Zebra''). *Id.* The Office of Unfair Import Investigations was not named as a party in this investigation. *Id.*

On July 11, 2022, pursuant to Commission Rule 210.21(b) (19 CFR 210.21(b)), Honeywell and Zebra filed a joint motion to terminate this investigation in its entirety based on a settlement agreement. On July 12, 2022, the ALJ issued Order No. 3, the subject ID, which granted the motion. The ID found that the motion complied with the Commission's Rules and that terminating the investigation would not be contrary to the public interest. No petitions for review of the ID were filed.

The Commission has determined not to review the subject ID.

This investigation is hereby terminated in its entirety.

The Commission vote for this determination took place on August 11, 2022.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: August 11, 2022.

Katherine Hiner,

Acting Secretary to the Commission.

[FR Doc. 2022–17640 Filed 8–16–22; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1121 (Advisory Opinion Proceeding)]

Certain Earpiece Devices and Components Thereof; Notice of a Commission Determination Not To Review an Initial Determination Granting a Joint Motion To Terminate the Advisory Opinion Proceeding Based on Settlement; Termination of the Advisory Opinion Proceeding

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review the presiding administrative law judge's (''ALJ'') initial determination (''ID'') (Order No. 6), granting a joint motion to terminate the advisory opinion proceeding based on settlement. The advisory opinion proceeding is terminated.

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 June 29, 2018, based on a complaint filed on behalf of Bose Corporation (''Bose'') of Framingham, Massachusetts. 83 FR 30776 (Jun. 29, 2018). The complaint alleged violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain earpiece devices and components thereof by reason of infringement of one or more claims of U.S. Patent Nos. 9,036,852 (''the '852 patent''); 9,036,853 (''the '853 patent''); 9,042,590 (''the '590 patent''); 8,249,287 (''the '287 patent''); 8,311,253 (''the '253 patent''); and 9,398,364 (''the '364 patent''). The notice of investigation named fourteen respondents. The Office of Unfair Import Investigations was also named as a party in the original investigation.

On October 31, 2019, the Commission issued a general exclusion order (''GEO''), a limited exclusion order (''LEO''), and cease and desist orders with respect to certain claims of the asserted patents other than the '364 patent. 84 FR 59838–840 (Nov. 6, 2019). The GEO prohibits the unlicensed importation of certain earpiece devices and components thereof that infringe claims 1 and 7 the '852 patent; claims 1 and 8 of the '853 patent; claims 1 and 6 of the '590 patent; and claims 1, 7, and 8 of the '287 patent. The LEO covers the '253 patent. The Commission also imposed a bond in the amount of one hundred percent (100%) of the entered value of the imported articles during the period of Presidential review. The Commission remanded certain issues to the ALJ and thereafter the '364 patent was withdrawn from the investigation and the investigation was terminated in its entirety. 84 FR 72382–383 (Dec. 31, 2019).

On February 4, 2022, Fantasia Trading, LLC (''Fantasia''), the importer of record, filed a request for an advisory opinion that Anker's Soundcore Liberty 2 Pro (''A3909''), Soundcore Liberty Neo (''A3911''), and Soundcore Life Dot 2 (''A3922'') products (collectively, the ''Anker Earphones'') do not infringe claims 1 and 7 of the '852 patent; claims 1 and 8 of the '853 patent; claims 1 and 6 of the '590 patent; and claims 1, 7, and 8 of the '287 patent, and thus are not covered by the GEO issued in this investigation.

On March 8, 2022, the Commission determined to institute an advisory opinion proceeding under Commission Rule 210.79 to ascertain whether the Anker Earphones infringe claims 1 and 7 of the '852 patent; claims 1 and 8 of the '853 patent; claims 1 and 6 of the '590 patent; and claims 1, 7, and 8 of the '287 patent, and are covered by the GEO issued in this investigation. 87 FR 14287 (Mar. 14, 2022). The Commission further determined to refer the matter to the Chief ALJ for assignment to an ALJ for appropriate proceedings and to issue an initial advisory opinion (''IAO'') at the earliest practicable time, preferably within 120 days of institution, but no later than 7 months after institution. The ALJ was directed to set a target date at two months following the date of issuance of the IAO. The following entities were named as parties to the proceeding: (1) Bose; and (2) Fantasia.

On July 1, 2022, Fantasia and Bose filed a joint motion to terminate the advisory opinion proceeding based on a settlement agreement. ID at 1. The joint motion attached redacted public and confidential versions of the settlement agreement. *Id.* at 3.

On July 14, 2022, the ALJ issued the subject ID (Order No. 6), granting the joint motion to terminate the advisory opinion proceeding. The ID found that the motion to terminate complies with Commission Rule 210.21(a), 19 CFR 210.21(a), and there is no evidence that terminating this investigation based on the settlement agreement would be contrary to the public interest. *Id.* at 2–4. No petition for review of the ID was filed.

The Commission has determined not to review the subject ID. The advisory opinion proceeding is terminated.

The Commission vote for this determination took place on August 11, 2022.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and in Part 210 of the Commission's Rules of Practice and Procedure, 19 CFR part 210.

By order of the Commission.
Issued: August 11, 2022.

Katherine Hiner,

Acting Secretary to the Commission.

[FR Doc. 2022–17660 Filed 8–16–22; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1321]

Certain Barcode Scanners, Scan Engines, Mobile Computers With Barcode Scanning Functionalities, Products Containing the Same, and Components Thereof II; Notice of a Commission Determination Not To Review an Initial Determination Terminating the Investigation Due to a Settlement Agreement; Termination of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission (''Commission'') has determined not to review an initial determination (''ID'') (Order No. 3) issued by the presiding administrative law judge (''ALJ'') terminating the above-captioned investigation based on a settlement agreement. The investigation is hereby terminated.

FOR FURTHER INFORMATION CONTACT: Carl P. Bretscher, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2382. 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 this investigation on March 11, 2022, based on a complaint, as supplemented, filed by Honeywell International Inc. of Charlotte, North Carolina and Hand Held Products, Inc. of Charlotte, North Carolina (collectively, ''Honeywell''). 87 FR 38423–24 (June 28, 2022). The complaint, as supplemented, alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, in the importation into the United States, sale for importation, or sale in the United States after importation of certain barcode scanners, scan engines, mobile computers with barcode scanning functionalities, products containing the same, and components thereof by reason of infringement of certain claims of U.S. Patent Nos. 11,323,949; 11,323,650; 7,852,519; and 9,258,188. *Id.* The complaint further alleges that a domestic industry exists. *Id.*

The Commission's notice of investigation named the following respondents: Zebra Technologies Corp. of Lincolnshire, Illinois and Symbol Technologies, LLC of Holtsville, New York (collectively, ''Zebra''). The Office of Unfair Import Investigations is not participating as a party in this investigation.

On July 11, 2022, Honeywell and Zebra jointly moved to terminate the investigation based on a settlement agreement.

On July 12, 2022, the presiding ALJ issued the subject ID (Order No. 3) granting the joint motion to terminate the investigation. The ID finds that, pursuant to Commission Rules 210.21(a), (b) (19 CFR 210.21(a), (b)), Honeywell and Zebra represent that there are no other agreements, express or implied, oral or written, between them regarding the subject matter of this investigation. The ID further finds that termination is proper because it would not be contrary to the public health and welfare, competitive conditions in the U.S. economy, the production of like or directly competitive conditions in the United States, or U.S. consumers. The ID further finds that termination is in the public interest, and it will conserve public and private resources.

No party filed a petition for review of the subject ID.

The Commission has determined not to review the subject ID. Accordingly, the investigation is hereby terminated.

The Commission vote for this determination took place on August 11, 2022.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: August 11, 2022.

Katherine Hiner,

Acting Secretary to the Commission.

[FR Doc. 2022–17639 Filed 8–16–22; 8:45 am]

BILLING CODE 7020–02–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95473; File No. SR–NYSE–2022–35]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Extending the Expiration Date of the Temporary Amendments to Rules 9261 and 9830

August 11, 2022.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that on July 29, 2022, 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 extending the expiration date of the temporary amendments to Rules 9261 and 9830 as set forth in SR–NYSE–2020–76 from July 31, 2022, to October 31, 2022, in conformity with recent changes by the Financial Industry Regulatory Authority, Inc. (''FINRA''). The proposed rule change would not make any changes to the text of NYSE Rules 9261 and 9830. 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.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes extending the expiration date of the temporary amendments as set forth in SR–NYSE–2020–76 [4] to Rules 9261 (Evidence and Procedure in Hearing) and 9830 (Hearing) from July 31, 2022, to October 31, 2022 to harmonize with recent changes by FINRA to extend the expiration date of the temporary amendments to its Rules 9261 and 9830. SR–NYSE–2020–76 temporarily granted to the Chief or Deputy Chief Hearing Officer the authority to order that hearings be conducted by video conference if warranted by public health risks posed by in-person hearings during the ongoing COVID–19 pandemic. The proposed rule change would not make any changes to the text of Exchange Rules 9261 and 9830.[5]

Background

In 2013, the NYSE adopted disciplinary rules that are, with certain exceptions, substantially the same as the FINRA Rule 8000 Series and Rule 9000 Series, and which set forth rules for conducting investigations and enforcement actions.[6] The NYSE disciplinary rules were implemented on July 1, 2013.[7]

In adopting disciplinary rules modeled on FINRA's rules, the NYSE adopted the hearing and evidentiary processes set forth in Rule 9261 and in Rule 9830 for hearings in matters involving temporary and permanent cease and desist orders under the Rule 9800 Series. As adopted, the text of Rule 9261 is identical to the counterpart FINRA rule. Rule 9830 is substantially the same as FINRA's rule, except for conforming and technical amendments.[8]

In response to the COVID–19 global health crisis and the corresponding need to restrict in-person activities, on August 31, 2020, FINRA filed with the Commission a proposed rule change for immediate effectiveness, SR–FINRA–2020–027, which allowed FINRA's Office of Hearing Officers (''OHO'') to conduct hearings, on a temporary basis, by video conference, if warranted by the current COVID–19-related public health risks posed by an in-person hearing. Among the rules FINRA amended were Rules 9261 and 9830.[9]

Given that FINRA and OHO administers disciplinary hearings on the Exchange's behalf, and that the public health concerns addressed by FINRA's amendments apply equally to Exchange disciplinary hearings, on September 15, 2020, the Exchange filed to temporarily amend Rule 9261 and Rule 9830 to permit FINRA to conduct virtual hearings on its behalf.[10] In December 2020, FINRA filed a proposed rule change, SR–FINRA–2020–042, to extend the expiration date of the temporary amendments in SR–FINRA–2020–027 from December 31, 2020, to April 30, 2021.[11] On December 22, 2020, the Exchange similarly filed to extend the temporary amendments to Rule 9261 and Rule 9830 to April 30, 2021.[12] On April 1, 2021, FINRA filed a proposed rule change, SR–FINRA–2021–006, to extend the expiration date of the temporary rule amendments to, among other rules, FINRA Rule 9261 and 9830 from April 30, 2021, to August 31, 2021.[13] On April 20, 2021, the Exchange filed to extend the temporary amendments to Rule 9261 and Rule 9830 to August 31, 2021.[14] On August 13, 2021, FINRA filed a proposed rule change, SR–FINRA–2021–019, to extend the expiration date of the temporary amendments to, among other rules, FINRA Rule 9261 and 9830 from August 31, 2021, to December 31, 2021.[15] On August 27, 2021, the Exchange filed to extend the temporary amendments to Rule 9261 and Rule 9830 to December 31, 2021.[16] On December 7, 2021, FINRA filed a proposed rule change, SR–FINRA–2021–031, to extend the expiration date of the temporary amendments to, among other rules, FINRA Rule 9261 and 9830 from December 31, 2021, to March 31, 2022.[17] On December 27, 2021, the Exchange filed to extend the temporary amendments to Rule 9261 and Rule 9830 to March 31, 2022, after which the temporary amendments will expire absent another proposed rule change filing by the Exchange.[18] On March 7, 2022, FINRA filed to extend the expiration date of the temporary rule amendments to, among other rules, FINRA Rule 9261 and 9830 from March 31, 2022, to July 31, 2022.[19] On March 29, 2022, the Exchange filed to extend the temporary amendments to Rule 9261 and Rule 9830 to July 31, 2022, after which the temporary amendments will expire absent another proposed rule change filing by the Exchange.[20]

Even though it has been more than two years since the World Health Organization declared COVID–19 a pandemic, FINRA has determined that uncertainty still remains around this disease. The continued presence of COVID–19 variants including the quickly emerging Omicron BA.4 and BA.5 subvariants, dissimilar vaccination rates throughout the United States, and

[4] *See* Securities Exchange Act Release No. 90024 (September 28, 2020), 85 FR 62353 (October 2, 2020) (SR–NYSE–2020–76) (''SR–NYSE–2020–76'').

[5] The Exchange may submit a separate rule filing to extend the expiration date of the proposed extension beyond October 31, 2022 if the Exchange requires additional temporary relief from the rule requirements identified in NYSE–SR–2020–76. The amended NYSE rules will revert back to their original state at the conclusion of the temporary relief period and any extension thereof.

[6] *See* Securities Exchange Act Release No. 68678 (January 16, 2013), 78 FR 5213 (January 24, 2013) (SR–NYSE–2013–02) (''2013 Notice''), 69045 (March 5, 2013), 78 FR 15394 (March 11, 2013) (SR–NYSE–2013–02) (''2013 Approval Order''), and 69963 (July 10, 2013), 78 FR 42573 (July 16, 2013) (SR–NYSE–2013–49).

[7] *See* NYSE Information Memorandum 13–8 (May 24, 2013).

[8] *See* 2013 Approval Order, 78 FR at 15394, n.7 & 15400; 2013 Notice, 78 FR at 5228 & 5234.

[9] *See* Securities Exchange Act Release No. 89737 (September 2, 2020), 85 FR 55712 (September 9, 2020) (SR–FINRA–2020–027) (the ''August 31 FINRA Filing'').

[10] *See* note 4, *supra.*

[11] *See* Securities Exchange Act Release No. 90619 (December 9, 2020), 85 FR 81250 (December 15, 2020) (SR–FINRA–2020–042).

[12] *See* Securities Exchange Act Release No. 90821 (December 30, 2020), 86 FR 644 (January 6, 2021) (SR–NYSE–2020–107).

[13] *See* Securities Exchange Act Release No. 91495 (April 7, 2021), 86 FR 19306 (April 13, 2021) (SR–FINRA–2021–006).

[14] *See* Securities Exchange Act Release No. 91629 (April 22, 2021), 86 FR 22505 (April 28, 2021) (SR–NYSE–2020–27).

[15] *See* Securities Exchange Act Release No. 92685 (August 17, 2021), 86 FR 47169 (August 23, 2021) (SR–FINRA–2021–019).

[16] *See* Securities Exchange Act Release No. 92907 (September 9, 2021), 86 FR 51421 (September 15, 2021) (SR–NYSE–2021–47).

[17] *See* Securities Exchange Act Release No. 93758 (December 13, 2021), 86 FR 71695 (December 17, 2021) (SR–FINRA–2021–31).

[18] *See* Securities Exchange Act Release No. 93920 (January 6, 2022), 87 FR 1794 (January 12, 2022) (SR–NYSE–2021–78).

[19] *See* Securities Exchange Act Release No. 94430 (March 16, 2022), 87 FR 16262 (March 22, 2022) (SR–FINRA–2022–004).

[20] *See* Securities Exchange Act Release No. 94585 (April 1, 2022), 87 FR 20479 (April 7, 2022) (SR–NYSE–2022–18).

the current medium to high COVID–19 community levels in many states indicate that COVID–19 remains an active and real public health concern.[21] Due to the uncertainty and the lack of a clear timeframe for a sustained and widespread abatement of COVID–19-related health concerns and corresponding restrictions,[22] FINRA believes that there is a continued need for temporary relief beyond July 31, 2022.[23] On July 8, 2022, FINRA accordingly filed to extend the expiration date of the temporary rule amendments to, among other rules, FINRA Rule 9261 and 9830 from July 31, 2022, to October 31, 2022.[24]

Proposed Rule Change

Consistent with FINRA's recent proposal, the Exchange proposes to extend the expiration date of the temporary rule amendments to NYSE Rules 9261 and 9830 as set forth in SR–NYSE–2020–76 from July 31, 2022, to October 31, 2022.

As set forth in SR–FINRA 2022–018, even though it has been more than two years since the World Health Organization declared COVID–19 a pandemic, uncertainty still remains around this disease. The continued presence of COVID–19 variants including the quickly emerging Omicron BA.4 and BA.5 subvariants, dissimilar vaccination rates throughout the United States, and the current medium to high COVID–19 community levels in many states indicate that COVID–19 remains an active and real public health concern.[25] Due to the uncertainty and the lack of a clear timeframe for a sustained and widespread abatement of COVID–19-related health concerns and corresponding restrictions,[26] FINRA believes that there is a continued need for temporary relief beyond July 31, 2022.[27] FINRA accordingly proposed to extend the expiration date of the temporary rule amendments from July 31, 2022, to October 31, 2022.

The Exchange proposes to similarly extend the expiration date of the temporary rule amendments to NYSE Rules 9261 and 9830 as set forth in SR–NYSE–2020–76 from July 31, 2022, to October 31, 2022. The Exchange agrees with FINRA that, even though it has been more than two years since the World Health Organization declared COVID–19 a pandemic, uncertainty still remains around this disease. The Exchange also agrees that, due to the uncertainty and the lack of a clear timeframe for a sustained and widespread abatement of COVID–19-related health concerns and corresponding restrictions, for the reasons set forth in SR–FINRA–2022–018, there is a continued need for this temporary relief beyond July 31, 2022. The proposed change would permit OHO to continue to assess, based on critical COVID–19 data and criteria and the guidance of health and security consultants, whether an in-person hearing would compromise the health and safety of the hearing participants such that the hearing should proceed by video conference. As noted in SR–FINRA–2022–018, in deciding whether to schedule a hearing by video conference, OHO may consider a variety of other factors in addition to COVID–19 trends. Similarly, as noted in SR–FINRA–2022–018, in SR–FINRA–2020–027, FINRA provided a non-exhaustive list of other factors OHO may take into consideration, including a hearing participant's individual health concerns and access to the connectivity and technology necessary to participate in a video conference hearing.[28] The Exchange believes that this is a reasonable procedure to continue to follow for hearings under Rules 9261 and 9830 chaired by a FINRA employee.

As noted below, the Exchange has filed the proposed rule change for immediate effectiveness and has requested that the SEC waive the requirement that the proposed rule change not become operative for 30 days after the date of the filing, so the Exchange can implement the proposed rule change immediately.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,[29] in general, and furthers the objectives of Section 6(b)(5),[30] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to, and perfect the mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is designed to provide a fair procedure for the disciplining of members and persons associated with members, consistent with Sections 6(b)(7) and 6(d) of the Act.[31]

The Exchange believes that the proposed rule change supports the objectives of the Act by providing greater harmonization between Exchange rules and FINRA rules of similar purpose, resulting in less burdensome and more efficient regulatory compliance. As such, the proposed rule change will foster cooperation and coordination with persons engaged in facilitating transactions in securities and will remove impediments to and perfect the mechanism of a free and open market and a national market system.

The proposed rule change, which extends the expiration date of the temporary amendments to Exchange rules consistent with FINRA's extension to its Rules 9261 and 9830 as set forth in SR–FINRA–2022–018, will permit the Exchange to continue to effectively conduct hearings during the COVID–19 pandemic. Given the current and frequently changing COVID–19 conditions and the uncertainty around when those conditions will see meaningful, widespread and sustained improvement, without this relief allowing OHO to proceed by video conference, some or all hearings may have to be postponed.

The ability to conduct hearings by video conference will permit the adjudicatory functions of the Exchange's

[21] *See* Securities Exchange Act Release No. 95281 (July 14, 2022), 87 FR 43335 (July 20, 2022) (SR–FINRA–2022–018) (''SR–FINRA–2022–018''). FINRA noted that, for example, there has been a notable upward trend in the number of daily COVID–19 cases in the United States since April 1, 2022. *See https://covid.cdc.gov/covid-data-tracker/#trends_dailycases.* In addition, on June 9, 2022, the Biden Administration announced its operational plan for COVID–19 vaccinations for children under the age of five. *See https://www.whitehouse.gov/briefing-room/statements-releases/2022/06/09/fact-sheetbiden-administration-announces-operational-plan-for-covid-19-vaccinations-for-children-under-5/. See* SR–FINRA–2022–018, 87 FR at 43335, n. 6.

[22] For instance, FINRA noted that the Centers for Disease Control and Prevention (''CDC'') recommends that people wear a mask in public indoor settings in areas with a high COVID–19 community level regardless of vaccination status or individual risk. *See https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/about-face-coverings.html.* The CDC also recommends that people wear a mask in indoor areas of public transportation and transportation hubs to protect themselves and those around them and help keep travel and public transportation safer for everyone. *See https://www.cdc.gov/coronavirus/2019-ncov/travelers/masks-public-transportation.html.* Furthermore, numerous states currently have mask mandates in certain settings, such as healthcare and correctional facilities. *See* SR–FINRA–2022–018, 87 FR at 43335, n.7.

[23] *See* SR–FINRA–2022–018, 87 FR 43335.

[24] *See* SR–FINRA–2022–018, 87 FR at 43335–36.

[25] *See* note 21, *supra.*

[26] *See* note 22, *supra.*

[27] *See* SR–FINRA–2022–018, 87 FR at 87 FR at 43337.

[28] *See* SR–FINRA–2022–018, 87 FR at 43336, n. 16.

[29] 15 U.S.C. 78f(b).

[30] 15 U.S.C. 78f(b)(5).

[31] 15 U.S.C. 78f(b)(7) & 78f(d).

disciplinary rules to continue unabated, thereby avoiding protracted delays. The Exchange believes that this is especially important in matters where temporary and permanent cease and desist orders are sought because the proposed rule change would enable those hearings to continue to proceed without delay, thereby enabling the Exchange to continue to take immediate action to stop significant, ongoing customer harm, to the benefit of the investing public.

As set forth in detail in the SR–NYSE–2020–76, the temporary relief to permit hearings to be conducted via video conference maintains fair process and will continue to provide fair process consistent with Sections 6(b)(7) and 6(d) of the Act [32] while striking an appropriate balance between providing fair process and enabling the Exchange to fulfill its statutory obligations to protect investors and maintain fair and orderly markets while avoiding the COVID–19-related public health risks for hearing participants. The Exchange notes that this proposal, like SR–NYSE–2020–76, provides only temporary relief. As proposed, the changes would be in place through October 31, 2022. As noted in SR–NYSE–2020–76 and above, the amended rules will revert back to their original state at the conclusion of the temporary relief period and, if applicable, any extension thereof.

Accordingly, the proposed rule change extending this temporary relief is in the public interest and consistent with the Act's purpose.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed temporary rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not intended to address competitive issues but is rather intended solely to extend temporary relief necessitated by the continued impacts of the COVID–19 pandemic and the related health and safety risks of conducting in-person activities. The Exchange believes that the proposed rule change will prevent unnecessary impediments to critical adjudicatory processes and its ability to fulfill its statutory obligations to protect investors and maintain fair and orderly markets that would otherwise result if the temporary amendments were to expire on July 31, 2022.

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 Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [33] and Rule 19b–4(f)(6) thereunder.[34] Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.

A proposed rule change filed under Rule 19b–4(f)(6) [35] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b4(f)(6)(iii),[36] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange has indicated that there is a continued need to extend the temporary relief because the Exchange agrees with FINRA that the COVID–19 related health concerns necessitating this relief will not meaningfully subside by July 31, 2022.[37] The Exchange also states that extending the temporary relief provided in SR–NYSE–2020–76 immediately upon filing and without a 30-day operative delay will allow the Exchange to continue critical adjudicatory and review processes so that the Exchange may continue to operate effectively and meet its critical investor protection goals, while also protecting the health and safety of hearing participants.[38] The Commission also notes that this proposal extends without change the temporary relief previously provided by SR–NYSE–2020–76.[39] As proposed, the temporary changes would be in place through October 31, 2022 and the amended rules will revert back to their original state at the conclusion of the temporary relief period and, if applicable, any extension thereof.[40] For these reasons, the Commission believes that waiver of the 30-day operative delay for this proposal is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposal operative upon filing.[41]

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) [42] 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–2022–35 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.

[32] 15 U.S.C. 78f(b)(7) & 78f(d).

[33] 15 U.S.C. 78s(b)(3)(A)(iii).

[34] 17 CFR 240.19b–4(f)(6).

[35] 17 CFR 240.19b–4(f)(6).

[36] 17 CFR 240.19b–4(f)(6)(iii).

[37] *See supra* Item II; *see also* SR–FINRA–2022–018, 87 FR 43335, at 43336.

[38] *See* 87 FR 43335, at 43337–38 (noting the same in granting FINRA's request to waive the 30-day operative delay so that SR–FINRA–2022–018 would become operative immediately upon filing).

[39] *See supra* note 4.

[40] *See supra* note 5. As noted above, the Exchange states that if it requires temporary relief from the rule requirements identified in this proposal beyond October 31, 2022, it may submit a separate rule filing to extend the effectiveness of the temporary relief under these rules.

[41] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule change's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[42] 15 U.S.C. 78s(b)(2)(B).

All submissions should refer to File Number SR–NYSE–2022–35. 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–2022–35 and should be submitted on or before September 7, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[43]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–17663 Filed 8–16–22; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95479; File No. SR–Phlx–2022–33]

Self-Regulatory Organizations; Nasdaq PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Options 7, Section 4

August 11, 2022.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 1, 2022, Nasdaq PHLX LLC (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Phlx's Pricing Schedule at Options 7, Section 4, ''Multiply Listed Options Fees (Includes options overlying equities, ETFs, ETNs and indexes which are Multiply Listed) (Excludes SPY and broad-based index options symbols listed within Options 7, Section 5.A).''

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/phlx/rules,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Phlx proposes to amend its Pricing Schedule at Options 7, Section 4, ''Multiply Listed Options Fees (Includes options overlying equities, ETFs, ETNs and indexes which are Multiply Listed) (Excludes SPY and broad-based index options symbols listed within Options 7, Section 5.A).'' Specifically, Phlx proposes to remove the maximum Qualified Contingent Cross (''QCC'') rebate that will be paid by the Exchange in a given month. The Exchange believes that removing this rebate will permit Phlx to compete more effectively with other options exchange for QCC Orders by incentivizing market participants to transact a greater amount of QCC Orders on Phlx in order to receive a QCC Rebate.[3]

Today, the Exchange assesses a $.20 per contract QCC Transaction Fee for a Lead Market Maker,[4] Market Maker,[5] Firm [6] and Broker-Dealer.[7] Customers [8] and Professionals [9] are not assessed a QCC Transaction Fee. QCC Transaction Fees apply to electronic QCC Orders [10] and Floor QCC Orders.[11] Rebates are paid on all qualifying executed electronic QCC Orders and Floor QCC Orders based on the following six tier rebate schedule:[12]

[43] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Phlx will monitor the impact of this proposal on QCC Order volumes, and may in the future impose a maximum on the amount of QCC Rebate it would pay to members and member organizations that execute qualifying QCC Orders.

[4] The term ''Lead Market Maker'' applies to transactions for the account of a Lead Market Maker (as defined in Options 2, Section 12(a)). A Lead Market Maker is an Exchange member who is registered as an options Lead Market Maker pursuant to Options 2, Section 12(a). An options Lead Market Maker includes a Remote Lead Market Maker which is defined as an options Lead Market Maker in one or more classes that does not have a physical presence on an Exchange floor and is approved by the Exchange pursuant to Options 2, Section 11. *See* Options 7, Section 1(c). The term ''Floor Lead Market Maker'' is a member who is registered as an options Lead Market Maker pursuant to Options 2, Section 12(a) and has a physical presence on the Exchange's trading floor. *See* Options 8, Section 2(a)(3).

[5] The term ''Market Maker'' is defined in Options 1, Section 1(b)(28) as a member of the Exchange who is registered as an options Market Maker pursuant to Options 2, Section 12(a). A Market Maker includes SQTs and RSQTs as well as Floor Market Makers. *See* Options 7, Section 1(c). The term ''Floor Market Maker'' is a Market Maker who is neither an SQT or an RSQT. A Floor Market Maker may provide a quote in open outcry. *See* Options 8, Section 2(a)(4).

[6] The term ''Firm'' applies to any transaction that is identified by a member or member organization for clearing in the Firm range at The Options Clearing Corporation. *See* Options 7, Section 1(c).

[7] The term ''Broker-Dealer'' applies to any transaction which is not subject to any of the other transaction fees applicable within a particular category. *See* Options 7, Section 1(c).

[8] The term ''Customer'' applies to any transaction that is identified by a member or member organization for clearing in the Customer range at The Options Clearing Corporation (''OCC'') which is not for the account of a broker or dealer or for the account of a ''Professional'' (as that term is defined in Options 1, Section 1(b)(45)). *See* Options 7, Section 1(c).

[9] The term ''Professional'' applies to transactions for the accounts of Professionals, as defined in Options 1, Section 1(b)(45) 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). *See* Options 7, Section 1(c).

[10] Electronic QCC Orders are described in Options 3, Section 12.

[11] Floor QCC Orders are described in Options 8, Section 30(e).

[12] Volume resulting from all executed electronic QCC Orders and Floor QCC Orders, including Customer-to-Customer, Customer-to-Professional, and Professional-to-Professional transactions and

Tier	Threshold	Rebate per contract
Tier 1	0 to 99,999 contracts in a month	$0.00
Tier 2	100,000 to 299,999 contracts in a month	0.05
Tier 3	300,000 to 499,999 contracts in a month	0.07
Tier 4	500,000 to 699,999 contracts in a month	0.08
Tier 5	700,000 to 999,999 contracts in a month	0.09
Tier 6	Over 1,000,000 contracts in a month	0.11

The Exchange does not pay a QCC Rebate where the transaction is either: (i) Customer-to-Customer; (ii) Customer-to-Professional; (iii) Professional-to-Professional; or (iv) a dividend, merger, short stock interest or reversal or conversion strategy execution (as defined in Options 7, Section 4). The Exchange will continue to pay rebates on QCC Orders as described above.

Today, the maximum QCC Rebate to be paid in a given month may not exceed $750,000. The Exchange proposes to remove the limit on the amount of QCC Rebate that will be paid in a given month. With this proposal, members and member organizations will be paid QCC Rebates for all qualifying executed QCC Orders without limitation.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[13] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[14] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Commission and the courts have repeatedly expressed their preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, while adopting a series of steps to improve the current market model, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [15]

Likewise, in *NetCoalition* v. *Securities and Exchange Commission* [16] (''NetCoalition'') the D.C. Circuit upheld the Commission's use of a market-based approach in evaluating the fairness of market data fees against a challenge claiming that Congress mandated a cost-based approach.[17] As the court emphasized, the Commission ''intended in Regulation NMS that 'market forces, rather than regulatory requirements' play a role in determining the market data . . . to be made available to investors and at what cost.'' [18]

Further, ''[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers'. . . . '' [19] Although the court and the SEC were discussing the cash equities markets, the Exchange believes that these views apply with equal force to the options markets.

The Exchange believes that it is reasonable to remove the limit on the amount of QCC Rebate that will be paid in a given month because it would allow members and member organizations to be paid QCC Rebates, for all qualifying executed QCC Orders, without limitation. Further, removing the limit on the amount of QCC Rebate that would be paid in a given month will permit Phlx to compete more effectively with other options exchange for QCC Orders by incentivizing market participants to transact a greater amount of QCC Orders on Phlx in order to receive a QCC Rebate.

The Exchange believes that it is equitable and not unfairly discriminatory to remove the limit on the amount of QCC Rebate that will be paid in a given month because all qualifying market participants are eligible to transact QCC Orders, either electronically or on the Trading Floor, and would, therefore, be eligible to receive QCC Rebates for all qualifying executed QCC Orders, without limitation.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

Inter-Market Competition

The proposal does not impose an undue burden on inter-market competition. The Exchange believes its proposal remains competitive with other options markets and will offer market participants with another choice of where to transact options. The Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or rebate opportunities available at other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges. Because competitors are free to modify their own fees in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited.

Intra-Market Competition

The proposed amendments do not impose an undue burden on intra-market competition. The Exchange believes that removing the limit on the amount of QCC Rebate that will be paid in a given month does not impose an undue burden on competition because all qualifying market participants are eligible to transact QCC Orders, either

excluding dividend, merger, short stock interest or reversal or conversion strategy executions, is aggregated in determining the applicable volume tier.

[13] 15 U.S.C. 78f(b).

[14] 15 U.S.C. 78f(b)(4) and (5).

[15] Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (''Regulation NMS Adopting Release'').

[16] *NetCoalition* v. *SEC,* 615 F.3d 525 (D.C. Cir. 2010).

[17] *See NetCoalition,* at 534–535.

[18] *Id.* at 537.

[19] *Id.* at 539 (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSEArca–2006–21)).

electronically or on the Trading Floor, and would, therefore, be eligible to receive QCC Rebates for all qualifying executed QCC Orders, without limitation.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[20]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–Phlx–2022–33 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–Phlx–2022–33. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–Phlx–2022–33 and should be submitted on or before September 7, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[21]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–17669 Filed 8–16–22; 8:45 am]

BILLING CODE 8011–01–P

[20] 15 U.S.C. 78s(b)(3)(A)(ii).

[21] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 34671; 812–15360]

Pacific Funds Series Trust, et al.

August 11, 2022.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice.

Notice of an application under Section 6(c) of the Investment Company Act of 1940 (''Act'') for an exemption from Section 15(c) of the Act.

SUMMARY OF APPLICATION: The requested exemption would permit a Trust's board of trustees (the ''Board'') to approve new sub-advisory agreements and material amendments to existing sub-advisory agreements without complying with the in-person meeting requirement of Section 15(c) of the Act.

APPLICANT: Pacific Funds Series Trust and Pacific Select Fund (each a ''Trust'' and collectively the ''Trusts''), and Pacific Life Fund Advisors LLC (''PLFA'' or the ''Adviser'').

FILING DATES: The application was filed on June 27, 2022.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing on any application by emailing the SEC's Secretary at *Secretarys-Office@sec.gov* and serving the relevant applicant with a copy of the request by email, if an email address is listed for the relevant applicant below, or personally or by mail, if a physical address is listed for the relevant applicant below.

Hearing requests should be received by the Commission by 5:30 p.m. on September 7, 2022, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by emailing the Commission's Secretary.

ADDRESSES: The Commission: *Secretarys-Office@sec.gov.* Applicants: Audrey L. Cheng, Esq., *Audrey.Cheng@PacificLife.com* and Anthony Zacharski, Esq., *Anthony.Zacharski@Dechert.com.*

FOR FURTHER INFORMATION CONTACT: Terri Jordan, Branch Chief, at (202) 551–6825 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: For Applicants' representations, legal analysis, and condition, please refer to Applicants' application, dated June 27, 2022, which may be obtained via the Commission's website by searching for the file number at the top of this document, or for an Applicant using the Company name search field, on the SEC's EDGAR system. The SEC's EDGAR system may be searched at, at *http://www.sec.gov/edgar/searchedgar/legacy/companysearch.html.* You may also call the SEC's Public Reference Room at (202) 551–8090.

For the Commission, by the Division of Investment Management, under delegated authority.

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–17658 Filed 8–16–22; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95470]

Order Determining That the Financial Industry Regulatory Authority Conditionally May Access Certain Security-Based Swap Data Obtained by Security-Based Swap Data Repositories

AGENCY: Securities and Exchange Commission.

ACTION: Data access determination order.

SUMMARY: Pursuant to section 13(n)(5)(G)(v) of the Securities Exchange Act of 1934 (''Exchange Act''), and rule 13n–4(b)(9)(x) thereunder, the Securities and Exchange Commission (''Commission'') is issuing an order determining that it would be appropriate to require security-based swap data repositories to make security-based swap data available to Financial Industry Regulatory Authority (''FINRA'').

DATES: This data access determination order is effective September 16, 2022.

FOR FURTHER INFORMATION CONTACT: Carol McGee, Associate Director, Office of Derivatives Policy and Trading Practices, at (202) 551–5870, Division of Trading and Markets, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

SUPPLEMENTARY INFORMATION:

I. Background

A. Exchange Act Data Access Framework

Two entities currently are registered with the Commission as security-based swap data repositories (''SDRs'').[1] Among other responsibilities, SDRs are required to make security-based swap data available to certain recipients upon request.[2] Recipients may include certain specified entities,[3] as well as ''[a]ny other person that the Commission determines to be appropriate, conditionally or unconditionally, by order'' (including foreign authorities).[4] Access further is conditioned on there being in effect an arrangement between the Commission and the entity seeking access to address the confidentiality of the security-based swap data made available,[5] and on the Commission being notified of the request.[6]

Pursuant to this data access framework, FINRA has requested that the Commission issue an order determining that it would be appropriate to require SDRs to make security-based swap data available to FINRA.[7] For the reasons discussed below, the Commission is issuing the order. In connection with this order, the Commission and FINRA also are entering into an arrangement addressing the parameters of FINRA's access to security-based swap data held by SDRs, and the protections afforded to the data.[8]

B. Criteria for Making Access Determinations

The Commission has stated that it expects to consider a variety of factors in making access determinations, and that it may impose conditions in connection with those determinations. Relevant factors include whether the data provided ''would be subject to robust confidentiality safeguards, such as safeguards set forth in the relevant jurisdiction's statutes, rules or regulations with regard to disclosure of confidential information by an authority or its personnel, and/or safeguards set forth in the authority's internal policies and procedures.'' [9]

The Commission also may consider ''the relevant authority's interest in access to security-based swap data based on the relevant authority's regulatory mandate or legal responsibility or authority.'' [10] In addition, the Commission may take into account ''any other factors that are appropriate to the determination, including whether such a determination would be in the public interest, and whether the relevant authority agrees to provide the Commission and other U.S. authorities with reciprocal assistance in matters within their jurisdiction.'' [11]

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[1] *See* Exchange Act Release No. 91798, (May 7, 2021), 86 FR 26115, 26116 n.14 (May 12, 2021) (approving registration application of DTCC Data Repository (U.S.), LLC; Exchange Act Release No. 92189 (Jun. 16, 2021), 86 FR 32703 (Jun. 22, 2021) (approving registration application of ICE Trade Vault, LLC).

[2] Exchange Act section 13(n)(5)(G); 17 CFR 240.13n–4(b)(9). Those provisions in part require that the SBSDR provide notice of the data request to the Commission, and specifies that access be ''on a confidential basis pursuant to [Exchange Act] section 24.'' Exchange Act section 24, 15 U.S.C. 78x, generally addresses disclosures of information by the Commission and its personnel. In relevant part section 24 provides that the Commission may, ''in its discretion and upon a showing that such information is needed,'' provide all records and other information ''to such persons, both domestic and foreign, as the Commission by rule deems appropriate if the person receiving such records or information provides such assurances of confidentiality as the Commission deems appropriate.'' *See* Exchange Act section 24(c); *see also* 17 CFR 240.24c–1(b) (providing that the Commission may, upon ''such assurances of confidentiality as the Commission deems appropriate,'' provide non-public information to persons such as domestic and foreign governments or their political subdivisions, authorities, agencies or instrumentalities, self-regulatory organizations and foreign financial authorities).

[3] The following entities may access security-based swap data without the need for an additional Commission order: (i) the Board of Governors of the Federal Reserve System (''Board'') and any Federal Reserve Bank; (ii) the Office of the Comptroller of the Currency; (iii) the Federal Deposit Insurance Corporation; (iv) the Farm Credit Administration; (v) the Federal Housing Finance Agency; (vi) the Financial Stability Oversight Council (''FSOC''); (vii) the Commodity Futures Trading Commission (''CFTC''); (viii) the Department of Justice (''DOJ''); and (ix) the Office of Financial Research (''OFR''). *See* 17 CFR 240. 13n–4(b)(9); *see also* Exchange Act section 13(n)(5)(G)(v) (in part identifying ''each appropriate prudential regulator'' as well as FSOC, CFTC and DOJ). For those entities, data access still is predicated on other conditions, including the required confidentiality arrangement.

[4] 17 CFR 240.13n–4(b)(9)(x); *see also* Exchange Act section 13(n)(5)(G)(v).

[5] 17 CFR 240.13n–4(b)(10) (also stating that the arrangement shall be deemed to satisfy the Exchange Act section 13(n)(5)(H) requirement that the SBSDR receive a written agreement from the entity stating that the entity shall abide with the section 24 confidentiality requirements relating to the security-based swap information provided).

[6] Exchange Act section 13(n)(5)(G); 17 CFR 240. 13–4(b)(9). 17 CFR 240.13nc–4(d) further provides that the SBSDR shall satisfy the notification requirement by informing the Commission of its receipt of the first request for security-based swap data from a particular entity, and to maintain records of all information related to the initial and subsequent requests for data access from that entity.

[7] Letter from Stephanie Dumont, FINRA, to Vanessa Countryman, Secretary, Commission, dated August 11, 2022 (''FINRA request'').

[8] *See* Confidentiality Arrangement Between the U.S. Securities and Exchange Commission and the Financial Industry Regulatory Authority Concerning Access to Security-Based Swap Data Obtained by Registered Security-Based Swap Data Repositories, dated August 11, 2022 (available at [URL]) (''Confidentiality Arrangement'').

[9] Exchange Act Release No. 78716 (Aug. 29, 2016), 81 FR 60585 (Sep. 2, 2016) (adopting relevant amendments to 17 CFR 240.13n–4) (''Adopting Release''). The Commission also noted that it expected to consider whether there is a memorandum of understanding or other arrangement between the Commission and the relevant authority designed to protect the confidentiality of the security-based swap data provided to the authority (further noting that such a memorandum of understanding or other arrangement also would satisfy the statutory requirement that a security-based swap data repository obtain a confidentiality agreement from the authority). *See id.* at 60589 & n.60.

[10] Accordingly, determination orders ''typically would incorporate conditions that specify the scope of a relevant authority's access to data, and that limit this access in a manner that reflects the relevant authority's regulatory mandate or legal responsibility or authority,'' including conditions that address factors such as the domiciles of the counterparties to the security-based swap or of the underlying reference entities. Limiting access to information in this manner ''should be expected to help minimize the risk of unauthorized disclosure, misappropriation or misuse of security-based swap data, as each relevant authority will only have access to information within its regulatory mandate, or legal responsibility or authority.'' *Id.* at 60589. The Commission separately stated that the confidentiality arrangement between the Commission and the authority also may ''incorporate conditions that specify the scope of the relevant authority's access to data, and that limit this access in a manner that reflects the relevant authority's regulatory mandate or legal responsibility or authority.'' *Id.* at 60592.

[11] *Id.* at 60589.

C. Additional Aspects to the Determinations

The Commission has explained that it may take various approaches in deciding whether to impose additional conditions in connection with determination orders, such as issuing orders of limited duration.[12] The Commission also has stated that it may revoke a determination at any time (such as if an authority fails to maintain the confidentiality of the security-based swap data it has been provided), and that, even absent a revocation, an authority's access to data would cease upon the termination of the arrangements used to satisfy the confidentiality condition.[13]

The Commission has expressed the expectation that SDRs would provide relevant authorities with access to security-based swap data in accordance with the determination orders, and that the Commission generally does not expect to be involved in reviewing, signing-off on or otherwise approving relevant authorities' requests for security-based swap data from repositories that are made in accordance with a determination order.[14] The Commission also has stated that it has not prescribed any specific processes to govern a repository's treatment of requests for access.[15]

II. FINRA'S Data Access Request

FINRA is a self-regulatory organization that is registered with the Commission as a national securities association pursuant to Exchange Act section 15A. As such, the Exchange Act in part requires that FINRA be organized and have the capacity to enforce the compliance of member firms (and of persons associated with members) with requirements under the Exchange Act and with FINRA's own rules.[16]

A. Use of the Data

FINRA states that access to security-based swap data will enhance its ability to conduct effective reviews, examinations and investigations into potential violations of rules by FINRA members with respect to their security-based swap activities. Access would allow FINRA to incorporate security-based swap data into cross-market and cross-product surveillance, which would enhance FINRA's ability to detect practices such as manipulation and insider trading.[17] FINRA also anticipates using the security-based swap data in additional ways, including monitoring of member firms' compliance with financial responsibility requirements.[18]

B. Confidentiality Considerations

FINRA's request describes policies and procedures governing data privacy and data security that promote the appropriate safeguarding of data. Those include policies and procedures related to data classification guidelines, end-user practices and procedures for safeguarding data, reporting loss, and ensuring that only authorize users gain access. Those also include data security policies establishing technical security controls for systems and applications.[19]

For purposes of those privacy policies and procedures, FINRA states that it will treat the security-based swap data as ''Restricted Confidential Information,'' and that FINRA will implement special handling guidelines that will address access to the data and its use, handling and storage.[20] The confidentiality arrangement that the Commission is entering into with FINRA incorporates related safeguards.[21]

III. Determination and Associated Terms and Conditions

The Commission concludes that it is appropriate to require SDRs to make security-based swap data available to FINRA, subject to there being in effect a confidentiality arrangement between FINRA and the Commission. In reaching this conclusion, the Commission recognizes that FINRA plays an important role in promoting member firms' (and their associated persons') compliance with the federal securities laws, and the Commission concludes that access to security-based swap data will facilitate effective cross-market surveillance involving security-based swap activity.[22] FINRA's confidentiality framework and the confidentiality arrangement between the Commission and FINRA further will help ensure that FINRA will afford the security-based swap data appropriate protections—once FINRA has implemented special handling guidelines for the data.

Taking these factors as a whole, the Commission concludes that such a determination is in the public interest. By virtue of this order, the Exchange Act places an affirmative obligation upon SBSDRs to provide FINRA with access to security-based swap data consistent with the scope of the order, subject to the applicable terms and conditions, including a confidentiality arrangement between the Commission and FINRA being in effect, and FINRA implementing special handling guidelines, following consultation with Commission staff, to address access to the data and its use, handling and storage.[23]

IV. Conclusion

For the reasons discussed above, the Commission determines that it would be appropriate to require security-based swap data repositories to make security-based swap data available to FINRA.

It is hereby ordered, pursuant to Exchange Act section 13(n)(5)(G)(v) and

[12] *Id.*

[13] *Id.*

[14] *Id.*

[15] *Id.*

[16] *See* Exchange Act section 15A(b)(2); *see also* section 19(g)(1)(B) (in part requiring securities associations' compliance with Exchange Act requirements and association rules).

[17] FINRA request at 4–5.

[18] *Id.* at 6.

[19] *Id.*

[20] *Id.*

[21] As noted above, *see* note 8, *supra,* and accompanying text, the Commission is entering into a confidentiality arrangement with FINRA, addressing the parameters of FINRA's access to security-based swap data maintained by SDRs, as well as the confidentiality protections that FINRA will afford to the security-based swap data. These include provisions stating that FINRA will afford security-based swap data the highest level of protection under its policy framework for confidentiality procedures, and that, to the maximum extent practicable, FINRA will afford the security-based swap data confidentiality protections that are not less rigorous than applicable confidentiality protections afforded to Consolidated Audit Trail data. Confidentiality Arrangement para. 19. The Confidentiality Arrangement further provides that FINRA may disclose security-based swap information as required by FINRA rules related to disciplinary complaints or disciplinary decisions, and actions related to statutory disqualifications, suspensions, cancellations, expulsions or bars, subject to prior written consent by the Commission. Confidentiality Arrangement para. 20. In addition, FINRA conducts surveillance and exercises regulatory services on behalf of other self-regulatory organizations pursuant to Regulatory Services Agreements (''RSAs''). The Confidentiality Arrangement provides that FINRA may share confidential information pursuant to an RSA only if the client itself has entered into a separate confidentiality arrangement with the Commission, in connection with access to the information, that specifically provides that FINRA may share the information with the client. Confidentiality Arrangement para. 21.

[22] In reaching this conclusion, the Commission has considered the possibility of using more focused scopes of access, such as by limiting FINRA's access to data involving security-based swaps in which a member firm or associated person is a counterparty, guarantor or underlier to a security-based swaps. The Commission concludes, however, that this type of more limited access to security-based swap data would not sufficiently facilitate cross-market surveillance of improper activities such as insider trading and front-running, particularly given the possibility that wrongdoers may seek to avoid surveillance by using third-parties to engage in transactions in the security-based swap market.

[23] The Commission anticipates providing notice to SDRs in the event the relevant confidentiality arrangement no longer is in effect. Consistent with 17 CFR 240.13n–4(b)(10), this would terminate the SDRs' obligation to provide data access pursuant to the arrangement.

Exchange Act rule 13n–4(b)(9)(x), that FINRA may access security-based swap data obtained by security-based swap data repositories. Such access is conditioned on there being in effect an arrangement between the Commission and FINRA to address the confidentiality of the security-based swap information made available to FINRA. Such access further is conditioned on FINRA developing and implementing special handling guidelines as described above, following consultation with Commission staff, to promote the confidentiality afforded to the security-based swap data, prior to FINRA accessing the data.

By the Commission.

Dated: August 11, 2022.

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–17641 Filed 8–16–22; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95478; File No. SR–MIAX–2022–27]

Self-Regulatory Organizations; Miami International Securities Exchange LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Fee Schedule To Amend Certain Fees and Rebates for Transactions in SPIKES Options

August 11, 2022.

Pursuant to the provisions of Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 29, 2022, Miami International Securities Exchange LLC (''MIAX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing a proposal to amend the MIAX Options Fee Schedule (the ''Fee Schedule'') to amend the MIAX Options Exchange Fee Schedule (the ''Fee Schedule'') to amend certain fees and rebates for transactions in SPIKES options (defined below).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

The text of the proposed rule change is available on the Exchange's website at *http://www.miaxoptions.com/rule-filings,* at MIAX's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Section (1)(b)(i) of the Fee Schedule to: (1) amend certain fees and rebates for Simple and Complex transactions in SPIKES options; [3] (2) adopt a new ''Routing EEM Rebate Program'' [4] for certain SPIKES option orders routed to the Exchange; (3) remove the Market Turner Incentive Program; and (4) amend certain PRIME [5] and cPRIME [6] fees for orders in SPIKES options.

Background

On October 12, 2018, the Exchange received approval from the Commission to list and trade on the Exchange options on the SPIKES® Index, a new index that measures expected 30-day volatility of the SPDR S&P 500 ETF Trust (commonly known and referred to by its ticker symbol, ''SPY'').[7] The Exchange adopted its initial SPIKES options transaction fees on February 15, 2019 and adopted a new section of the Fee Schedule—Section 1)a)xi), SPIKES—for those fees.[8] SPIKES options began trading on the Exchange on February 19, 2019.

Proposed Changes to the Table of Fees for Simple and Complex Orders in SPIKES Options

The Exchange proposes to amend Section (1)(b)(i) of the Fee Schedule to amend the table of Simple and Complex Fees for transactions in SPIKES options. The Exchange charges Simple and Complex fees by origin type to each market participant that places resting liquidity in SPIKES options, *i.e.,* quotes or orders on the MIAX System,[9] which are assessed the ''maker'' fee (each a ''Maker''). The Exchange also charges Simple and Complex fees by origin type to each market participant that executes against (remove) resting liquidity in SPIKES options, which are assessed a higher ''taker'' fee (each a ''Taker'').

Currently, with respect to Simple and Complex Maker fees, the Exchange charges the following, regardless of the contra-side origin: (i) $0.00 per contract for SPIKES options orders for Priority Customers,[10] Market Makers,[11] and Firm Proprietary quotes or orders; and (ii) $0.10 per contract for SPIKES options orders for Non-MIAX Market Makers, Broker-Dealers, and Public Customers that are not Priority

[3] SPIKES is a ''Proprietary Product.'' The term ''Proprietary Product'' means a class of options that is listed exclusively on the Exchange. *See* Fee Schedule, Section (1)(b)(i), note ''Δ'' and Exchange Rule 100.

[4] An ''Electronic Exchange Member'' or ''EEM'' means the holder of a Trading Permit who is not a Market Maker. Electronic Exchange Members are deemed ''members'' under the Exchange Act. *See* Exchange Rule 100.

[5] The Price Improvement Mechanism (''PRIME'') is a process by which a Member may electronically submit for execution (''Auction'') an order it represents as agent (''Agency Order'') against principal interest, and/or an Agency Order against solicited interest. *See* Exchange Rule 515A(a).

[6] ''cPRIME'' is the process by which a Member may electronically submit a ''cPRIME Order'' (as defined in Rule 518(b)(7)) it represents as agent (a ''cPRIME Agency Order'') against principal or solicited interest for execution (a ''cPRIME Auction''), subject to the conditions set forth in Exchange Rule 515A, Interpretation and Policy .12. *See* Exchange Rule 515A, Interpretation and Policy .12.

[7] *See* Securities Exchange Act Release No. 84417 (October 12, 2018), 83 FR 52865 (October 18, 2018) (SR–MIAX–2018–14) (Order Granting Approval of a Proposed Rule Change by Miami International Securities Exchange, LLC to List and Trade on the Exchange Options on the SPIKES® Index).

[8] *See* Securities Exchange Release No. 85283 (March 11, 2019), 84 FR 9567 (March 15, 2019) (SR–MIAX–2019–11). The Exchange initially filed the proposal on February 15, 2019 (SR–MIAX–2019–04). That filing was withdrawn and replaced with SR–MIAX–2019–11. On September 30, 2020, the Exchange filed its proposal to, among other things, reorganize the Fee Schedule to adopt new Section (1)(b), Proprietary Products Exchange Fees, and moved the fees and rebates for SPIKES options into new Section (1)(b)(i). *See* Securities Exchange Act Release No. 90146 (October 9, 2020), 85 FR 65443 (October 15, 2020) (SR–MIAX–2020–32).

[9] The term ''System'' means the automated trading system used by the Exchange for the trading of securities. *See* Exchange Rule 100.

[10] A ''Priority Customer'' means a person or entity that (i) is not a broker or dealer in securities, and (ii) does not place more than 390 orders in listed options per day on average during a calendar month for its own beneficial accounts(s). A ''Priority Customer Order'' means an order for the account of a Priority Customer. *See* Exchange Rule 100.

[11] The term ''Market Makers'' refers to ''Lead Market Makers'', ''Primary Lead Market Makers'' and ''Registered Market Makers'' collectively. *See* Exchange Rule 100.

Customers.[12] Currently, with respect to Simple and Complex Taker fees, the Exchange charges the following, regardless of the contra-side origin: (i) $0.00 per contract for SPIKES options orders for Priority Customers; (ii) $0.20 per contract for SPIKES options orders for Market Makers and Firm Proprietary orders; and (iii) $0.25 per contract for SPIKES options orders for Non-MIAX Market Makers, Broker-Dealers, and Public Customers that are not Priority Customers.[13] The Exchange notes that it charges Simple and Complex Taker fees of $0.05 per contract for SPIKES options with a premium price of $0.10 or less for Market Makers and Firm Proprietary quotes or orders, which is denoted by the symbol ''*''.

The Exchange proposes to add two new columns to the table of Simple and Complex Fees to provide for different Maker and Taker fees depending on whether the contra-side origin is a Priority Customer or not. The Exchange proposes that the first fee column in the table of Simple and Complex Fees will now be titled ''Simple/Complex¥ Maker when trading contra to origins Not Priority Customer.'' The Exchange proposes to keep the current Maker fee rates in place for that column. Accordingly, with the proposed changes, the Exchange will charge Simple and Complex Maker fees when trading contra to origins not Priority Customer as follows: (i) $0.00 per contract for SPIKES options orders for Priority Customers, Market Makers, and Firm Proprietary orders; and (ii) $0.10 per contract for SPIKES options orders for Non-MIAX Market Makers, Broker-Dealers, and Public Customers that are not Priority Customers.

Next, the Exchange proposes to add a new second fee column titled ''Simple/Complex¥ Maker when trading contra to Priority Customer.'' The Exchange proposes to charge the following Simple and Complex Maker fees when trading contra to Priority Customer orders: (i) $0.00 per contract for SPIKES options orders for Priority Customers; (ii) $0.10 per contract for SPIKES options orders for Market Makers and Firm Proprietary orders; and (iii) $0.25 per contract for SPIKES options orders for Non-MIAX Market Makers, Broker-Dealers, and Public Customers that are not Priority Customers.

The Exchange proposes that the third fee column in the table of Simple and Complex Fees will now be titled ''Simple/Complex¥ Taker when trading contra to origins Not Priority Customer.'' The Exchange proposes to keep the current Taker fee rates in place for that column. Accordingly, with the proposed changes, the Exchange will charge Simple and Complex Taker fees when trading contra to origins not Priority Customer as follows: (i) $0.00 per contract for SPIKES options orders for Priority Customers; (ii) $0.20 per contract for SPIKES options orders for Market Makers and Firm Proprietary orders; and (iii) $0.25 per contract for SPIKES options orders for Non-MIAX Market Makers, Broker-Dealers, and Public Customers that are not Priority Customers.

Next, the Exchange proposes to add a new fourth fee column titled ''Simple/Complex¥ Taker when trading contra to Priority Customer.'' The Exchange proposes to charge the following Simple and Complex Taker fees when trading contra to Priority Customer orders: (i) $0.00 per contract for SPIKES options orders for Priority Customers; (ii) $0.30 per contract for SPIKES options orders for Market Makers and Firm Proprietary orders; and (iii) $0.35 per contract for SPIKES options orders for Non-MIAX Market Makers, Broker-Dealers, and Public Customers that are not Priority Customers. The Exchange notes that it will continue charge Simple and Complex Taker fees of $0.05 per contract for SPIKES options with a premium price of $0.10 or less for Market Makers and Firm Proprietary orders, which will be denoted by the symbol ''*'' in the new column of Taker fees for trading contra to Priority Customer orders.

Next, the Exchange proposes to amend the fee for Simple Opening orders in SPIKES options listed in the table of Simple and Complex Fees in Section (1)(b)(i) of the Fee Schedule. Currently, the Exchange charges the following Simple Opening fees: (i) $0.00 per contract for SPIKES options orders for Priority Customers; and (ii) $0.15 per contract for SPIKES options orders for Market Makers, Non-MIAX Market Makers, Broker-Dealers, Firm Proprietary quotes or orders, and Public Customers that are not Priority Customers. The Exchange now proposes to increase the fee for Simple Opening orders in SPIKES options from $0.15 per contract to $0.25 per contract for all market participants except Priority Customers.

The Exchange does not propose any changes to the fees for Combination Orders,[14] the Simple Large Trade Discount Threshold or the Complex Large Trade Discount Threshold.

The purpose of all these changes is for business and competitive reasons.

Proposal To Adopt the Routing EEM Rebate Program

Next, the Exchange proposes to adopt the ''Routing EEM Rebate Program'' following the footnotes for the table of Simple and Complex Fees for SPIKES options in Section (1)(b)(i) of the Fee Schedule. Pursuant to this program, the Exchange proposes to provide a ($0.25) rebate per executed Priority Customer origin SPIKES options contract to the EEM that routed the order to the Exchange. The Exchange proposes that the following Priority Customer SPIKES options orders would be eligible to participate in the Routing EEM Rebate Program: (a) Simple Orders of 250 contracts or less (including during the Opening Process); (b) for Complex Orders, the lesser of (i) 250 strategies or less, or (ii) orders for a total of 1,000 contracts or less; (c) PRIME Agency Orders of 250 contracts or less; and (d) for cPRIME Agency Orders, the lesser of (i) 250 strategies or less, or (ii) orders for a total of 1,000 contracts or less. The Exchange proposes that the following Priority Customer SPIKES options orders would not be eligible to participate in the Routing EEM Rebate Program: (a) PRIME contra-side orders; (b) cPRIME contra-side orders; and (c) for Combination Orders, (i) a Combination Order, (ii) Combination Orders as part of a larger strategy, and (iii) Combination Orders as part of a cPRIME order. The Exchange also proposes to exclude from the Routing EEM Rebate Program orders that are broken up in order to qualify for the 250 contracts (strategies) size limit described above. The purpose of the change to adopt the Routing EEM Rebate Program is to attract more Priority Customer order flow in SPIKES options, thereby improving the overall marketplace for SPIKES options on the Exchange.

Removal of the Market Turner Incentive Program

Next, the Exchange proposes to amend Section (1)(b)(i) of the Fee Schedule to remove the Market Turner[15] Incentive Program. The Exchange adopted the Market Turner Incentive Program beginning June 1,

[12] *See* Fee Schedule, Section (1)(b)(i).

[13] *See id.*

[14] A ''SPIKES Combination'' is a purchase (sale) of a SPIKES call option and sale (purchase) of a SPIKES put option having the same expiration date and strike price. *See* Fee Schedule, Section (1)(b)(i), note ''~''.

[15] The term ''Market Turner'' means a Market Maker simple quote (not eQuote) that establishes and maintains the new MIAX best bid (the ''MBB'') or the MIAX best offer (''MBO'') in a SPIKES option. *See* Fee Schedule, Section (1)(b)(i).

2019.[16] Pursuant to the Market Turner Incentive Program, the Exchange provides a per contract rebate to the Market Turner for each SPIKES options contract that executes as the MBB (MBO). The amount of the rebate is as follows: (i) $0.20 per executed contract, for options having a premium price greater than $0.10, or (ii) $0.05 per executed contract, for options having a premium price of $0.10 or less.[17] The Market Turner Incentive Program was adopted to incentivize Market Makers to quote aggressively in SPIKES options on the Exchange, which the Exchange believed would strengthen its market quality for all market participants in SPIKES options. The Market Turner Incentive Program was also designed to attract additional market makers (both existing MIAX Market Makers as well as non-members to join MIAX) to quote in SPIKES options. The Exchange believes that the Market Turner Incentive Program has fulfilled its intended purpose and that the Exchange's other fee changes related to SPIKES options, including the changes described herein, will continue to strengthen the market quality for all market participants in SPIKES options. Accordingly, the Exchange proposes to remove the text for the Market Turner Incentive Program from the Fee Schedule.

Proposed Changes to PRIME and cPRIME Fees for SPIKES Options

Next, the Exchange proposes to amend the table of PRIME and cPRIME fees for SPIKES options in Section (1)(b)(i) of the Fee Schedule. Currently, for SPIKES options orders entered into PRIME or cPRIME, the Exchange charges a contra-side fee for all origin types in the amount of $0.20 and a responder fee in the amount of $0.25. The Exchange now proposes to increase the contra-side and responder fees for SPIKES options orders entered into PRIME or cPRIME for all origin types. In particular, the Exchange proposes to charge a contra-side fee for all origin types in the amount of $0.25 and a responder fee in the amount of $0.50. The purpose of these changes is for business and competitive reasons.

The proposed changes described in this filing will become effective August 1, 2022.

2. Statutory Basis

The Exchange believes that its proposal to amend its Fee Schedule is consistent with Section 6(b) of the Act[18] in general, and furthers the objectives of Section 6(b)(4) of the Act[19] in particular, in that it is an equitable allocation of reasonable fees and other charges among its members and issuers and other persons using its facilities.

Simple and Complex Fee Changes

The Exchange believes the proposed changes to the Simple and Complex fees for transactions in SPIKES option are reasonable, equitable and not unfairly discriminatory because the Exchange will continue to assess lower transaction fees to its Makers as compared to its Takers as an incentive for market participants to provide liquidity on the Exchange. The Exchange believes this will encourage greater order flow from all market participants, which will in turn bring greater volume and liquidity to the Exchange, which benefits all market participants by providing more trading opportunities and tighter spreads. The Exchange believes it is reasonable, equitable and not unfairly discriminatory to charge slightly higher fees for market participants trading contra to Priority Customer SPIKES options orders because there is a history in the options markets of providing preferential treatment to Priority Customers and Priority Customer order flow attracts additional liquidity to the Exchange. The Exchange believes the added Priority Customer SPIKES options order flow will provide all market participants with more trading opportunities and encourage an increase in Market Maker activity, which facilitates tighter spreads. This may cause an additional corresponding increase in order flow from other market participants, contributing overall towards a robust and well-balanced market ecosystem, particularly in a newer product such as SPIKES options.

The Exchange believes that it is equitable and not unfairly discriminatory that Firm Proprietary orders will continue to be assessed lower Maker and Taker fees for Simple and Complex orders than other origin types because the Exchange believes that Firm Proprietary order flow enhances liquidity on the Exchange for the benefit of all market participants. Firm Proprietary order flow liquidity benefits all market participants by providing more robust trading opportunities, which attract Market Makers. An increase in the activity of those market participants in turn facilitates tighter spreads, which may cause an additional corresponding increase in order flow from other market participants. The Maker and Taker fees offered to Firm Proprietary orders are intended to attract more Firm Proprietary order volume to the Exchange.

The Exchange further believes that it is equitable and not unfairly discriminatory to continue to assess lower Maker and Taker fees to Market Makers for Simple and Complex orders as compared to other market participants because Market Makers, unlike other market participants, take on a number of obligations, including quoting obligations that other market participants do not have.[20] Further, Market Makers have added market making and regulatory requirements, which normally do not apply to other market participants. For example, Market Makers have obligations to maintain continuous markets, engage in a course of dealings reasonably calculated to contribute to the maintenance of a fair and orderly market, and to not make bids or offers or enter into transactions that are inconsistent with a course of dealing. Further, the proposed lower Maker and Taker fees offered to Market Makers are intended to incent Market Makers to quote and trade more in SPIKES options on the Exchange, thereby providing more liquidity and trading opportunities for all market participants in SPIKES options. Additionally, the proposed Maker and Taker fees for Market Makers will be applied equally to all Market Makers in SPIKES options.

Moreover, the Exchange believes that assessing all other market participants that are not Priority Customers a higher transaction fee for orders in SPIKES options, including for Simple Opening orders, is reasonable, equitable, and not unfairly discriminatory because these types of market participants are more sophisticated and have higher levels of order flow activity and system usage. This level of trading activity draws on a greater amount of system resources than that of Priority Customers. Further, the Exchange believes it is equitable and not unfairly discriminatory to assess all other market participants that are not Priority Customers, Market Makers, or Firm Proprietary orders higher Simple and Complex Maker fees for orders in SPIKES options (including Simple Opening orders) because Priority Customers, Market Makers, and Firm Proprietary orders bring valuable liquidity to the market. An increase in the activity of these market participants in turn facilitates tighter spreads, which may cause an additional corresponding increase in order flow from other market

[16] *See* Securities Exchange Act Release No. 86110 (June 14, 2019), 84 FR 28864 (June 20, 2019) (SR–MIAX–2019–29).

[17] *See* Fee Schedule, Section (1)(b)(i).

[18] 15 U.S.C. 78f(b).

[19] 15 U.S.C. 78f(b)(4) and (5).

[20] *See, generally,* Chapter VI of the Exchange's Rulebook.

participants, which in turn benefits the market as a whole.

The Exchange also believes the proposed changes for SPIKES options Simple and Complex transaction fees are reasonably designed because the proposed fees are within the range of fees assessed by other exchanges employing similar fee structures for singly-listed competing options products. For example, Cboe Exchange, Inc. (''Cboe'') assesses Customers VIX [21] simple order fees based on tiered premium price which ranges from base prices of $0.10 to $0.45 per contract and complex order fees based on tiered premium price which ranges from base prices $0.05 to $0.45 per contract.[22] Further, a Clearing Trading Permit Holder Proprietary is assessed a VIX fee based on a VIX sliding scale which ranges from $0.25 to $0.01 per contract.[23] A Cboe Options Market-Maker/DPM/LMM are assessed fees based on tiered premium price which ranges from $0.05 to $0.23 per contract. Joint Back Office, Non-Trading Permit Holder Market Makers, and Professionals are assessed a VIX $0.40 per contract fee.[24] VIX transactions are assessed a Surcharge Fee/Index License of $0.10 ($0.00 for capacity codes F and L for VIX transactions where the VIX Premium is ≤ $0.10 and the related series has an expiration of seven (7) calendar days or less).[25] Similarly, Nasdaq ISE, LLC (''ISE'') charges all market participants, except priority customers, a $0.75 per contract fee for all regular orders in NDX Index options.[26] For complex orders in NDX Index options, ISE, similar to the Exchange, charges a different Maker fee depending on whether the contra-side is a priority customer or not. For complex orders in NDX Index options, ISE charges a Maker fee of $0.20 per contract for all market participants, except priority customers, when trading contra to origins that are not priority customer.[27] For complex orders in NDX Index options when trading contra to priority customer, ISE charges a Maker fee of $0.86 per contract to market makers and $0.88 per contract to all other market participants, except priority customers.[28] Further, for complex orders in NDX Index options, ISE charges a Taker fee of $0.86 per contract for market makers and $0.88 per contract for all other market participants, except priority customers.[29]

Routing EEM Rebate Program

The Exchange believes the proposal to adopt the Routing EEM Rebate Program is reasonable, equitably allocated and not unfairly discriminatory because it would apply equally to all of the Exchange's EEMs that send Priority Customer SPIKES options orders to the Exchange. The Exchange believes the Routing EEM Rebate Program is reasonable because it is designed to incentivize increased SPIKES options order flow, which should strengthen the market quality for SPIKES options for all market participants, leading to more trading opportunities and tighter spreads. To the extent Priority Customer SPIKES options order flow is increased by the proposal, market participants will increasingly compete for the opportunity to trade on the Exchange including sending more orders and providing narrower and larger-sized quotations in the effort to trade with such Priority Customer order flow.

Removal of Market Turner Incentive Program

The Exchange believes that the proposed change to discontinue the Market Turner Incentive Program and remove that language from the Fee Schedule is reasonable, equitable and not unfairly discriminatory because the elimination of the Market Turner Incentive Program will uniformly apply to all Market Makers in SPIKES options. The Exchange initially adopted the Market Turner Incentive Program to attract additional market makers (both existing MIAX Market Makers as well as non-members to join MIAX) to quote in SPIKES options. The Exchange believes that the Market Turner Incentive Program is no longer necessary and that the Exchange's fees and rebates for transactions in SPIKES options will continue to strengthen the market quality for all market participants in SPIKES options.

Contra-Side and Responder Fee Increases in PRIME and cPRIME Auctions for SPIKES Options

The Exchange believes that the proposed increases to contra-side and responder fees for SPIKES options in PRIME and cPRIME are equitable and not unfairly discriminatory because the proposed fees will apply equally to all origins. The Exchange believes that the application of these fees are equitable and not unfairly discriminatory because the fees are identical for all market participants for contra-side orders or for market participants that respond to PRIME and cPRIME Auctions for SPIKES options orders.

The Exchange believes its proposal to amend its contra-side and responder fees for all origins in PRIME and cPRIME Auctions for SPIKES options is reasonable, equitably allocated and not unfairly discriminatory because these changes are for business and competitive reasons. In order to attract SPIKES options order flow, the Exchange initially set low fees for contra-side and responders for its PRIME and cPRIME Auctions for SPIKES options. The Exchange now believes that it is appropriate to increase these fees but believes they will remain competitive and should enable the Exchange to continue to attract SPIKES options order flow to PRIME and cPRIME Auctions.

The Exchange also believes the proposed contra-side and responder fees are similar to fees charged by competing options exchanges in singly-listed products. The Exchange notes that Cboe assesses Automated Improvement Mechanism (''AIM'') [30] contra-side fees to Customers for VIX transactions based on tiered premium price, which ranges from base prices of $0.10 to $0.45 per contract and complex order fees based on tiered premium price which ranges from base prices of $0.05 to $0.45 per contract.[31] Cboe Options Market-Makers/DPMs/LMMs are assessed VIX AIM contra-side fees based on tiered premium price, which ranges from $0.05 to $0.23 per contract. Joint Back Office, Non-Trading Permit Holder Market Makers, and Professionals are assessed a VIX AIM contra-side fee $0.40 per contract fee.[32] In addition, Cboe assesses a variety of surcharges for VIX transactions, including an AIM Agency/Primary Surcharge fee of $0.04

[21] ''VIX'' refers to options on the The Cboe Volatility Index (the ''VIX Index''). The VIX Index is an up-to-the-minute market estimate of expected volatility that is calculated by using real-time S&P 500® Index (''SPX'') option bid/ask quotes. *See* VIX Options Product Specifications, *available at https://www.cboe.com/tradable_products/vix/vix_options/specifications/* (last visited July 25, 2022).

[22] *See* Cboe Fee Schedule, Rate Table—Underlying Symbol List A, Page 2, *available at https://www.cboe.com/us/options/membership/fee_schedule/cone/* (last visited July 25, 2022).

[23] *See id.*

[24] *See id.*

[25] *See id.* The Exchange notes that it is continuing to waive the ''Index License Surcharge'' for SPIKES options of $0.075 per contract. *See* Fee Schedule, Section (1)(b)(i), note ''#''.

[26] *See* ISE Fee Schedule, Options 7 Pricing schedule, Section 5. Index Options Fees and Rebates, Section A, NDX Index Options Fees for Regular Orders, *available at https://listingcenter.nasdaq.com/rulebook/ise/rules/ISE%20Options%207* (last visited July 25, 2022).

[27] *See id.,* Section 4. Complex Order Fees and Rebates.

[28] *See id.*

[29] *See id.*

[30] *See* Cboe Rule 5.37.

[31] *See supra* note 22.

[32] *See id.*

per contract.[33] Similarly, ISE charges all market participants, except priority customers, a $0.75 per contract fee for all originating and contra side of Crossing Orders and Responses to Crossing Orders in NDX Index options.[34] Accordingly, the Exchange believes the proposed changes to contra-side and responder fees for transactions in SPIKES options in PRIME and cPRIME are similar to fees charged by competing options exchanges in singly-listed competing products.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

Intra-Market Competition

The Exchange does not believe that the proposed rule changes will impose any burden on intra-market competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that the proposed changes will enhance the competitiveness of the Exchange relative to other exchanges that offer their own singly-listed products. The Exchange notes that there are other volatility products available today on other options markets, such as VIX and VOLQ,[35] which allow investors to gauge volatility. As noted above, the Exchange believes that the proposed pricing for transactions in SPIKES options is comparable to and within the range of fees and rebates charged by the Exchange's competitors offering singly-listed products.[36] In sum, if the changes proposed herein are unattractive to market participants, it is likely that the Exchange will receive no market share as a result. The Exchange believes that the proposed changes to the fees and rebates for transactions in SPIKES options are not going to have an impact on intra-market competition based on the total cost for participants to transact in such order types versus the cost for participants to transact in other order types available for trading on the Exchange.

Inter-Market Competition

The Exchange does not believe that the proposed rule changes will impose any burden on inter-market competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges and to attract order flow to the Exchange. The Exchange believes that the proposed rule change reflects this competitive environment because it is adjusting its fees in a manner that encourages market participants to provide liquidity in SPIKES options, and to attract additional transaction volume to the Exchange.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act,[37] and Rule 19b–4(f)(2)[38] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–MIAX–2022–27 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–MIAX–2022–27. 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–MIAX–2022–27 and should be submitted on or before September 7, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[39]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–17668 Filed 8–16–22; 8:45 am]

BILLING CODE 8011–01–P

[33] *See id.*

[34] *See supra* note 26.

[35] ''VOLQ'' refers to options on the Nasdaq-100® volatility Index (the ''VOLQ Index''). The VOLQ Index measures changes in 30-day implied volatility as expressed by options on the Nasdaq-100® Index (''NDX''), a modified market capitalization- weighted index composed of securities issued by 100 of the largest non-financial companies listed on The Nasdaq Stock Market LLC. *See* Nasdaq-100® Volatility Index Option Description, *available at https://indexes.nasdaqomx.com/Index/Overview/VOLQ* (last visited July 25, 2022).

[36] *See supra* notes 22 and 26.

[37] 15 U.S.C. 78s(b)(3)(A)(ii).

[38] 17 CFR 240.19b–4(f)(2).

[39] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95471; No. SR–NYSEARCA–2022–50]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Modify the NYSE Arca Options Fee Schedule

August 11, 2022.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on August 5, 2022, NYSE Arca, Inc. (''NYSE Arca'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to modify the NYSE Arca Options Fee Schedule (''Fee Schedule'') regarding credits for Floor Broker Qualified Contingent Cross (''QCC'') transactions. The Exchange proposes to implement the fee change effective August 5, 2022.[4] 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.

[4] The Exchange originally filed to amend the Fee Schedule on August 1, 2022 (SR–NYSEArca–2022–48) and withdrew such filing on August 5, 2022.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this filing is to amend the Fee Schedule to modify the credits offered to Floor Brokers for QCC transactions.[5] The Exchange proposes to implement the rule change on August 5, 2022.

Currently, Floor Brokers earn a credit for executed QCC orders of ($0.07) per contract for the first 300,000 contracts or ($0.10) per contract in excess of 300,000.[6] QCC executions in which a Customer is on both sides of the QCC trade are not be eligible for a Floor Broker credit, and the maximum Floor Broker credit is $375,000 per month per Floor Broker firm.[7] A Floor Broker that meets a certain minimum level of average daily volume (''ADV'') may also earn an additional ($0.02) per contract credit (the ''Enhanced Credit'') on the first 300,000 eligible QCC contracts. Specifically, a Floor Broker is currently entitled to the Enhanced Credit if the Floor Broker executes the greater of (1) at least 150% of the Floor Broker's First Quarter 2019 billable contract sides ADV; or (2) at least 30,000 billable contract sides ADV.[8]

The Exchange now proposes to increase the amount of the credits available to Floor Brokers for executed QCC orders. Specifically, the Exchange proposes that Floor Brokers may earn a credit of ($0.22) on Non-Customer vs. Non-Customer QCC transactions and a credit of ($0.11) on Customer vs. Non-Customer QCC transactions.[9] The Exchange also proposes to eliminate the Enhanced Credit, as the proposed increased credits of ($0.11) and ($0.22) would exceed the credit amount that Floors Brokers previously could have earned with the Enhanced Credit.[10]

[5] A QCC Order is defined as an originating order to buy or sell at least 1,000 contracts that is identified as being part of a qualified contingent trade coupled with a contra-side order or orders totaling an equal number of contracts. *See* Rule 6.62P–O(g)(1)(A).

[6] *See* Fee Schedule, Qualified Contingent Cross (''QCC'') Transaction Fees and Credits, *available at: https://www.nyse.com/publicdocs/nyse/markets/arca-options/NYSE_Arca_Options_Fee_Schedule.pdf.*

[7] *See id.* at Endnote 13.

[8] *See id.*

[9] The Exchange also proposes to delete text in Endnote 13 providing that the Floor Broker credit is paid on volume within a given tier and is not retroactive to the first contract traded. This language relates to the current structure of the Floor Broker credits, which is based on the number of contracts executed, and would not be applicable to the proposed credits.

[10] To effect this change, the Exchange proposes to delete the text from Endnote 13 setting forth the qualifying criteria for the Enhanced Credit as well as accompanying text in Endnote 13 describing the calculation of the Enhanced Credit.

Although the Exchange cannot predict with certainty whether the proposed change would encourage Floor Brokers to increase their QCC volume, the proposed change is intended to continue to incentivize additional QCC executions by Floor Brokers by increasing the credits available on such orders, and all Floor Brokers are eligible to qualify for the proposed credits.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[11] in general, and furthers the objectives of Sections 6(b)(4) and (5) of the Act,[12] 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 Rule Change Is Reasonable

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.'' [13]

There are currently 16 registered options exchanges competing for order flow. Based on publicly-available information, and excluding index-based options, no single exchange has more than 16% of the market share of executed volume of multiply-listed equity and ETF options trades.[14] Therefore, no exchange possesses significant pricing power in the execution of multiply-listed equity and ETF options order flow. More specifically, in June 2022, the Exchange had less than 13% market share of

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(4) and (5).

[13] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (S7–10–04) (''Reg NMS Adopting Release'').

[14] The OCC publishes options and futures volume in a variety of formats, including daily and monthly volume by exchange, available here: *https://www.theocc.com/Market-Data/Market-Data-Reports/Volume-and-Open-Interest/Monthly-Weekly-Volume-Statistics.*

executed volume of multiply-listed equity and ETF options trades.[15]

The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can shift order flow, or discontinue or reduce use of certain categories of products, in response to fee changes. Accordingly, competitive forces constrain options exchange transaction fees. Stated otherwise, modifications to exchange transaction fees can have a direct effect on the ability of an exchange to compete for order flow.

To respond to this competitive marketplace, the Exchange has established incentives to assist Floor Brokers in attracting more business to the Exchange—including credits on QCC transactions—as such participants serve an important function in facilitating the execution of orders on the Exchange (including via open outcry), thereby promoting price discovery on the public markets.

The Exchange believes that the proposed modification of the credits offered to Floor Brokers on QCC transactions is reasonable because it is designed to continue to incent Floor Brokers to increase the number of QCC transactions sent to the Exchange and would offer Floor Brokers incentives on QCC transactions similar to those provided by other options exchanges.[16] The Exchange further believes that it is reasonable to offer a ($0.22) credit for QCC transactions involving a Non-Customer vs. Non-Customer and a ($0.11) credit on QCC transactions involving a Customer vs. Non-Customer because Non-Customer vs. Non-Customer QCC transactions are billable on both sides of the transaction, whereas Customer vs. Non-Customer QCC transactions are billable on one side. To the extent that the proposed change attracts more volume to the Exchange, this increased order flow would continue to make the Exchange a more competitive venue for order execution, which, in turn, promotes just and equitable principles of trade and removes impediments to and perfects the mechanism of a free and open market and a national market system. The Exchange notes that all market participants stand to benefit from any increase in volume by Floor Brokers, which could promote market depth, facilitate tighter spreads and enhance price discovery to the extent the proposed change encourages Floor Brokers to utilize the Exchange as a primary trading venue, and may lead to a corresponding increase in order flow from other market participants. In addition, any increased liquidity on the Exchange would result in enhanced market quality for all participants.

Finally, to the extent the proposed change continues to attract greater volume and liquidity, the Exchange believes the proposed change would improve the Exchange's overall competitiveness and strengthen its market quality for all market participants. In the backdrop of the competitive environment in which the Exchange operates, the proposed rule change is a reasonable attempt by the Exchange to increase the depth of its market and improve its market share relative to its competitors. The Exchange's fees are constrained by intermarket competition, as Floor Brokers may direct their order flow to any of the 16 options exchanges, including those offering rebates on QCC orders.[17] Thus, Floor Brokers have a choice of where they direct their order flow, including their QCC transactions. The proposed rule change is designed to continue to incent Floor Brokers to direct liquidity to the Exchange and, in particular, QCC orders, thereby promoting market depth, price discovery and improvement, and enhanced order execution opportunities for market participants, particularly to the extent Floor Brokers are incentivized to aggregate their trading activity at the Exchange.

The Exchange cannot predict with certainty whether the proposed change would encourage Floor Brokers to increase their QCC order flow to the Exchange, but believes that the proposed increased credits would continue to incent Floor Brokers to do so.

The Proposed Rule Change Is an Equitable Allocation of Credits and Fees

The Exchange believes the proposed rule change is an equitable allocation of its fees and credits. The proposal is based on the amount and type of business transacted on the Exchange, and Floor Brokers can attempt to trade QCC orders to earn the increased credits or not. In addition, the proposed credits are available to all Floor Brokers equally. The Exchange further believes that the proposed change, which would provide a ($0.22) credit for Non-Customer vs. Non-Customer QCC transactions and a ($0.11) credit on Customer vs. Non-Customer QCC transactions, represents an equitable allocation of credits because Non-Customer vs. Non-Customer QCC transactions are billable on both sides of the transaction, whereas Customer vs. Non-Customer QCC transactions are billable on one side. The Exchange also believes that the proposed credits are an equitable allocation of fees and credits because they would encourage and support Floor Brokers' role in facilitating the execution of orders on the Exchange, and to the extent the proposed credits incent Floor Brokers to direct increased liquidity to the Exchange, all market participants would benefit from enhanced opportunities for price improvement and order execution.

Moreover, the proposed credits are designed to incent Floor Brokers to encourage OTP Holders to aggregate their executions—particularly QCC transactions—at the Exchange as a primary execution venue. To the extent that the proposed changes attract more QCC volume to the Exchange, this increased order flow would continue to make the Exchange a more competitive venue for, among other things, order execution. Thus, the Exchange believes the proposed rule change would improve market quality for all market participants on the Exchange and, as a consequence, attract more order flow to the Exchange, thereby improving market-wide quality and price discovery.

The Proposed Rule Change Is not Unfairly Discriminatory

The Exchange believes it is not unfairly discriminatory to modify the credits offered to Floor Brokers on QCC orders because the proposed credits would be available to all similarly-situated Floor Brokers on an equal and non-discriminatory basis. The proposed credits are also not unfairly discriminatory to non-Floor Brokers because Floor Brokers serve an important function in facilitating the execution of orders on the Exchange (including via open outcry), which the Exchange wishes to encourage and support to promote price improvement opportunities for all market participants.

[15] Based on a compilation of OCC data for monthly volume of equity-based options and monthly volume of equity-based ETF options, *see id.,* the Exchange's market share in equity-based options increased from 9.07% for the month of June 2021 to 12.23% for the month of June 2022.

[16] *See, e.g.,* EDGX Options Exchange Fee Schedule, QCC Initiator/Solicitation Rebate Tiers (applying ($0.22) per contract rebate up to 999,999 contracts for QCC transactions with non-customers on both sides); BOX Options Fee Schedule at Section IV.D.1. (QCC Rebate) (providing for ($0.22) per contract rebate up to 1,499,999 contracts for QCC transactions when both parties are a broker-dealer or market maker); *see also* Nasdaq ISE, Options 7, Section 6.A. (QCC and Solicitation Rebate) (offering rebates on QCC transactions of up to ($0.11) on 1,000,000 or more contract sides in a month).

[17] *See id.*

The proposal is based on the amount and type of business transacted on the Exchange, and Floor Brokers are not obligated to execute QCC orders. Rather, the proposal is designed to encourage Floor Brokers to utilize the Exchange as a primary trading venue for all transactions (if they have not done so previously) and increase QCC volume sent to the Exchange. To the extent that the proposed change attracts more QCC orders to the Exchange, this increased order flow would continue to make the Exchange a more competitive venue for order execution. Thus, the Exchange believes the proposed rule change would improve market quality for all market participants on the Exchange and, as a consequence, attract more order flow to the Exchange, thereby improving market-wide quality and price discovery. The resulting increased volume and liquidity would provide more trading opportunities and tighter spreads to all market participants and thus would promote just and equitable principles of trade, remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, protect investors and the public interest.

Finally, the Exchange believes that it is subject to significant competitive forces, as described below in the Exchange's statement regarding the burden on competition.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act, the Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Instead, as discussed above, the Exchange believes that the proposed change 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 all market participants. 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.'' [18]

Intramarket Competition. The proposed increased credits are designed to attract additional order flow to the Exchange (particularly in Floor Brokers' QCC transactions), which may increase the volumes of contracts traded on the Exchange. Greater liquidity benefits all market participants on the Exchange, and increased QCC transactions would increase opportunities for execution of other trading interest. The proposed credits would be available to all similarly-situated Floor Brokers that execute QCC trades, and to the extent that there is an additional competitive burden on non-Floor Brokers, the Exchange believes that any such burden would be appropriate because Floor Brokers serve an important function in facilitating the execution of orders (including via open outcry) and price discovery for all market participants.

Intermarket Competition. The Exchange operates in a highly competitive market in which market participants can readily favor one of the 16 competing option exchanges if they deem fee levels at a particular venue to be excessive. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges and to attract order flow to the Exchange. Based on publicly-available information, and excluding index-based options, no single exchange has more than 16% of the market share of executed volume of multiply-listed equity and ETF options trades.[19] Therefore, currently no exchange possesses significant pricing power in the execution of multiply-listed equity and ETF options order flow. More specifically, in June 2022, the Exchange had less than 13% market share of executed volume of multiply-listed equity and ETF options trades.[20]

The Exchange believes that the proposed rule change reflects this competitive environment because it modifies the Exchange's fees in a manner designed to incent Floor Brokers to direct trading interest (particularly QCC transactions) to the Exchange, to provide liquidity and to attract order flow. To the extent that Floor Brokers are incentivized to utilize the Exchange as a primary trading venue for all transactions, all of the Exchange's market participants should benefit from the improved market quality and increased opportunities for price improvement.

The Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues. In such an environment, the Exchange must continually review, and consider adjusting, its fees and credits to remain competitive with other exchanges. For the reasons described above, the Exchange believes that the proposed rule change reflects this competitive environment. The Exchange further believes that the proposed change could promote competition between the Exchange and other execution venues, including those that currently offer rebates on QCC transactions, by encouraging additional orders (and, in particular, QCC orders) to be sent to the Exchange for execution.[21]

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) [22] of the Act and subparagraph (f)(2) of Rule 19b–4 [23] 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) [24] 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:

[18] *See* Reg NMS Adopting Release, *supra* note 13, at 37499.

[19] The OCC publishes options and futures volume in a variety of formats, including daily and monthly volume by exchange, available here: *https://www.theocc.com/Market-Data/Market-Data-Reports/Volume-and-Open-Interest/Monthly-Weekly-Volume-Statistics.*

[20] Based on a compilation of OCC data for monthly volume of equity-based options and monthly volume of equity-based ETF options, *see id.,* the Exchange's market share in equity-based options increased from 9.07% for the month of June 2021 to 12.23% for the month of June 2022.

[21] *See* note 16, *supra.*

[22] 15 U.S.C. 78s(b)(3)(A).

[23] 17 CFR 240.19b–4(f)(2).

[24] 15 U.S.C. 78s(b)(2)(B).

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEARCA–2022–50 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEARCA–2022–50. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEARCA–2022–50, and should be submitted on or before September 7,2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[25]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–17671 Filed 8–16–22; 8:45 am]

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[25] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95474; File No. SR–NYSEAMER–2022–34]

Self-Regulatory Organizations; NYSE American LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Extending the Expiration Date of the Temporary Amendments to Rules 9261 and 9830

August 11, 2022.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that on July 29, 2022, NYSE American LLC (''NYSE American'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes extending the expiration date of the temporary amendments to Rules 9261 and 9830 as set forth in SR–NYSEAMER–2020–69 from July 31, 2022 to October 31, 2022, in conformity with recent changes by the Financial Industry Regulatory Authority, Inc. (''FINRA''). The proposed rule change would not make any changes to the text of NYSE American Rules 9261 and 9830. 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 extending the expiration date of the temporary amendments as set forth in SR–NYSEAMER–2020–69 [4] to Rules 9261 (Evidence and Procedure in Hearing) and 9830 (Hearing) from July 31, 2022 to October 31, 2022, to harmonize with recent changes by FINRA to extend the expiration date of the temporary amendments to its Rules 9261 and 9830. SR–NYSEAMER–2020–69 temporarily granted to the Chief or Deputy Chief Hearing Officer the authority to order that hearings be conducted by video conference if warranted by public health risks posed by in-person hearings during the ongoing COVID–19 pandemic. The proposed rule change would not make any changes to the text of Exchange Rules 9261 and 9830.[5]

Background

In 2016, NYSE American (then known as NYSE MKT LLC) adopted disciplinary rules that are, with certain exceptions, substantially the same as the Rule 8000 Series and Rule 9000 Series of FINRA and its affiliate the New York Stock Exchange LLC (''NYSE''), and which set forth rules for conducting investigations and enforcement actions.[6] The NYSE American disciplinary rules were implemented on April 15, 2016.[7]

In adopting disciplinary rules modeled on FINRA's rules, NYSE American adopted the hearing and evidentiary processes set forth in Rule 9261 and in Rule 9830 for hearings in matters involving temporary and permanent cease and desist orders under the Rule 9800 Series. As adopted, the text of Rule 9261 and Rule 9830 are substantially the same as the FINRA rules with certain modifications.[8]

In response to the COVID–19 global health crisis and the corresponding need to restrict in-person activities, on

[4] *See* Securities Exchange Act Release No. 90085 (October 2, 2020), 85 FR 63603 (October 8, 2020) (SR–NYSEAMER–2020–69) (''SR–NYSEAMER–2020–69'').

[5] The Exchange may submit a separate rule filing to extend the expiration date of the proposed extension beyond October 31, 2022 if the Exchange requires additional temporary relief from the rule requirements identified in SR–NYSEAMER–2020–69. The amended NYSE American rules will revert back to their original state at the conclusion of the temporary relief period and any extension thereof.

[6] *See* Securities Exchange Act Release Nos. 77241 (February 26, 2016), 81 FR 11311 (March 3, 2016) (SR–NYSEMKT–2016–30) (''2016 Notice'').

[7] *See* NYSE MKT Information Memorandum 16–02 (March 14, 2016).

[8] *See* 2016 Notice, 81 FR at 11327 & 11332.

August 31, 2020, FINRA filed with the Commission a proposed rule change for immediate effectiveness, SR–FINRA–2020–027, which allowed FINRA's Office of Hearing Officers (''OHO'') to conduct hearings, on a temporary basis, by video conference, if warranted by the current COVID–19-related public health risks posed by an in-person hearing. Among the rules FINRA amended were Rules 9261 and 9830.[9]

Given that FINRA and OHO administers disciplinary hearings on the Exchange's behalf, and that the public health concerns addressed by FINRA's amendments apply equally to Exchange disciplinary hearings, on September 15, 2020, the Exchange filed to temporarily amend Rule 9261 and Rule 9830 to permit FINRA to conduct virtual hearings on its behalf.[10] In December 2020, FINRA filed a proposed rule change, SR–FINRA–2020–042, to extend the expiration date of the temporary amendments in SR–FINRA–2020–027 from December 31, 2020, to April 30, 2021.[11] On December 22, 2020, the Exchange similarly filed to extend the temporary amendments to Rule 9261 and Rule 9830 to April 30, 2021.[12] On April 1, 2021, FINRA filed a proposed rule change, SR–FINRA–2021–006, to extend the expiration date of the temporary rule amendments to, among other rules, FINRA Rule 9261 and 9830 from April 30, 2021, to August 31, 2021.[13] On April 20, 2021, the Exchange filed to extend the temporary amendments to Rule 9261 and Rule 9830 to August 31, 2021.[14] On August 13, 2021, FINRA filed a proposed rule change, SR–FINRA–2021–019, to extend the expiration date of the temporary amendments to, among other rules, FINRA Rule 9261 and 9830 from August 31, 2021, to December 31, 2021.[15] On August 27, 2021, the Exchange filed to extend the temporary amendments to Rule 9261 and Rule 9830 to December 31, 2021.[16] On December 7, 2021, FINRA filed a proposed rule change, SR–FINRA–2021–031, to extend the expiration date of the temporary amendments in both SR–FINRA–2020–015 and SR–FINRA–2020–027 from December 31, 2021, to March 31, 2022.[17] On December 27, 2021, the Exchange filed to extend the temporary amendments to Rule 9261 and Rule 9830 to March 31, 2022, after which the temporary amendments will expire absent another proposed rule change filing by the Exchange.[18] On March 7, 2022, FINRA filed to extend the expiration date of the temporary rule amendments to, among other rules, FINRA Rule 9261 and 9830 from March 31, 2022, to July 31, 2022.[19] On March 30, 2022, the Exchange filed to extend the temporary amendments to Rule 9261 and Rule 9830 to July 31, 2022, after which the temporary amendments will expire absent another proposed rule change filing by the Exchange.[20]

Even though it has been more than two years since the World Health Organization declared COVID–19 a pandemic, FINRA has determined that uncertainty still remains around this disease. The continued presence of COVID–19 variants including the quickly emerging Omicron BA.4 and BA.5 subvariants, dissimilar vaccination rates throughout the United States, and the current medium to high COVID–19 community levels in many states indicate that COVID–19 remains an active and real public health concern.[21] Due to the uncertainty and the lack of a clear timeframe for a sustained and widespread abatement of COVID–19-related health concerns and corresponding restrictions,[22] FINRA believes that there is a continued need for temporary relief beyond July 31, 2022.[23] On July 8, 2022, FINRA accordingly filed to extend the expiration date of the temporary rule amendments to, among other rules, FINRA Rule 9261 and 9830 from July 31, 2022, to October 31, 2022.[24]

Proposed Rule Change

Consistent with FINRA's recent proposal, the Exchange proposes to extend the expiration date of the temporary rule amendments to NYSE American Rules 9261 and 9830 as set forth in SR–NYSEAMER–2020–69 from July 31, 2022, to October 31, 2022.

As set forth in SR–FINRA–2022–018, even though it has been more than two years since the World Health Organization declared COVID–19 a pandemic, uncertainty still remains around this disease. The continued presence of COVID–19 variants including the quickly emerging Omicron BA.4 and BA.5 subvariants, dissimilar vaccination rates throughout the United States, and the current medium to high COVID–19 community levels in many states indicate that COVID–19 remains an active and real public health concern.[25] Due to the uncertainty and the lack of a clear timeframe for a sustained and widespread abatement of COVID–19-related health concerns and corresponding restrictions,[26] FINRA believes that there is a continued need for temporary relief beyond July 31, 2022.[27] FINRA accordingly proposed to extend the expiration date of the temporary rule amendments from July 31, 2022, to October 31, 2022.

The Exchange proposes to similarly extend the expiration date of the temporary rule amendments to NYSE American Rules 9261 and 9830 as set

[9] *See* Securities Exchange Act Release No. 89737 (September 2, 2020), 85 FR 55712 (September 9, 2020) (SR–FINRA–2020–027) (''SR–FINRA–2020–027'').

[10] *See* note 4, *supra.*

[11] *See* Securities Exchange Act Release No. 90619 (December 9, 2020), 85 FR 81250 (December 15, 2020) (SR–FINRA–2020–042).

[12] *See* Securities Exchange Act Release No. 90823 (December 30, 2020), 86 FR 650 (January 6, 2021) (SR–NYSEAMER–2020–88).

[13] *See* Securities Exchange Act Release No. 91495 (April 7, 2021), 86 FR 19306 (April 13, 2021) (SR–FINRA–2021–006).

[14] *See* Securities Exchange Act Release No. 91631 (April 22, 2021), 86 FR 22471 (April 28, 2021) (SR–NYSEAMER–2021–23).

[15] *See* Securities Exchange Act Release No. 92685 (August 17, 2021), 86 FR 47169 (August 23, 2021) (SR–FINRA–2021–019).

[16] *See* Securities Exchange Act Release No. 92910 (September 9, 2021), 86 FR 51418 (September 15, 2021) (SR–NYSEAMER–2021–37).

[17] *See* Securities Exchange Act Release No. 93758 (December 13, 2021), 86 FR 71695 (December 17, 2021) (SR–FINRA–2021–31).

[18] See Securities Exchange Act Release No. 93917 (January 6, 2022), 87 FR 1825 (January 12, 2022) (SR–NYSEAMER–2021–49).

[19] See Securities Exchange Act Release No. 94430 (March 16, 2022), 87 FR 16262 (March 22, 2022) (SR–FINRA–2022–004).

[20] *See* Securities Exchange Act Release No. 94665 (April 11, 2022), 87 FR 22594 (April 15, 2022) (SR–NYSEAMER–2022–16).

[21] *See* Securities Exchange Act Release No. 95281 (July 14, 2022), 87 FR 43335 (July 20, 2022) (SR–FINRA–2022–018) (''SR–FINRA–2022–018''). FINRA noted that, for example, there has been a notable upward trend in the number of daily COVID–19 cases in the United States since April 1, 2022. *See https://covid.cdc.gov/covid-data-tracker/#trends_dailycases.* In addition, on June 9, 2022, the Biden Administration announced its operational plan for COVID–19 vaccinations for children under the age of five. *See https://www.whitehouse.gov/briefing-room/statements-releases/2022/06/09/fact-sheetbiden-administration-announces-operational-plan-for-covid-19-vaccinations-for-children-under-5. See* SR–FINRA–2022–018, 87 FR at FR 43335, n. 6.

[22] For instance, FINRA noted that the Centers for Disease Control and Prevention (''CDC'') recommends that people wear a mask in public indoor settings in areas with a high COVID–19 community level regardless of vaccination status or individual risk. *See https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/about-face-coverings.html.* The CDC also recommends that people wear a mask in indoor areas of public transportation and transportation hubs to protect themselves and those around them and help keep travel and public transportation safer for everyone. *See https://www.cdc.gov/coronavirus/2019-ncov/travelers/masks-public-transportation.html.* Furthermore, numerous states currently have mask mandates in certain settings, such as healthcare and correctional facilities. *See* SR–FINRA–2022–018, 87 FR at 43335, n.7.

[23] *See* SR–FINRA–2022–018, 87 FR at 43335.

[24] *See* SR–FINRA–2022–018, 87 FR at 43335–36.

[25] *See* note 21, *supra.*

[26] *See* note 22, *supra.*

[27] *See* SR–FINRA–2022–018, 87 FR at 43337.

forth in SR–NYSEAMER–2020–69 from July 31, 2022, to October 31, 2022. The Exchange agrees with FINRA that, even though it has been more than two years since the World Health Organization declared COVID–19 a pandemic, uncertainty still remains around this disease. The Exchange also agrees that, due to the uncertainty and the lack of a clear timeframe for a sustained and widespread abatement of COVID–19-related health concerns and corresponding restrictions, for the reasons set forth in SR–FINRA–2022–018, there is a continued need for this temporary relief beyond July 31, 2022. The proposed change would permit OHO to continue to assess, based on critical COVID–19 data and criteria and the guidance of health and security consultants, whether an in-person hearing would compromise the health and safety of the hearing participants such that the hearing should proceed by video conference. As noted in SR–FINRA–2022–018, in deciding whether to schedule a hearing by video conference, OHO may consider a variety of other factors in addition to COVID–19 trends. Similarly, as noted in SR–FINRA–2022–018, in SR–FINRA–2020–027, FINRA provided a non-exhaustive list of other factors OHO may take into consideration, including a hearing participant's individual health concerns and access to the connectivity and technology necessary to participate in a video conference hearing.[28] The Exchange believes that this is a reasonable procedure to continue to follow for hearings under Rules 9261 and 9830 chaired by a FINRA employee.

As noted below, the Exchange has filed the proposed rule change for immediate effectiveness and has requested that the SEC waive the requirement that the proposed rule change not become operative for 30 days after the date of the filing, so the Exchange can implement the proposed rule change immediately.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,[29] in general, and furthers the objectives of Section 6(b)(5),[30] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to, and perfect the mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is designed to provide a fair procedure for the disciplining of members and persons associated with members, consistent with Sections 6(b)(7) and 6(d) of the Act.[31]

The Exchange believes that the proposed rule change supports the objectives of the Act by providing greater harmonization between Exchange rules and FINRA rules of similar purpose, resulting in less burdensome and more efficient regulatory compliance. As such, the proposed rule change will foster cooperation and coordination with persons engaged in facilitating transactions in securities and will remove impediments to and perfect the mechanism of a free and open market and a national market system.

The proposed rule change, which extends the expiration date of the temporary amendments to Exchange rules consistent with FINRA's extension to its Rules 9261 and 9830 as set forth in SR–FINRA–2022–018, will permit the Exchange to continue to effectively conduct hearings during the COVID–19 pandemic. Given the current and frequently changing COVID–19 conditions and the uncertainty around when those conditions will see meaningful, widespread and sustained improvement, without this relief allowing OHO to proceed by video conference, some or all hearings may have to be postponed. The ability to conduct hearings by video conference will permit the adjudicatory functions of the Exchange's disciplinary rules to continue unabated, thereby avoiding protracted delays. The Exchange believes that this is especially important in matters where temporary and permanent cease and desist orders are sought because the proposed rule change would enable those hearings to continue to proceed without delay, thereby enabling the Exchange to continue to take immediate action to stop significant, ongoing customer harm, to the benefit of the investing public.

As set forth in detail in the SR–NYSEAMER–2020–69, the temporary relief to permit hearings to be conducted via video conference maintains fair process and will continue to provide fair process consistent with Sections 6(b)(7) and 6(d) of the Act[32] while striking an appropriate balance between providing fair process and enabling the Exchange to fulfill its statutory obligations to protect investors and maintain fair and orderly markets while avoiding the COVID–19-related public health risks for hearing participants. The Exchange notes that this proposal, like SR–NYSEAMER–2020–69, provides only temporary relief. As proposed, the changes would be in place through October 31, 2022. As noted in SR–NYSEAMER–2020–69 and above, the amended rules will revert back to their original state at the conclusion of the temporary relief period and, if applicable, any extension thereof.

Accordingly, the proposed rule change extending this temporary relief is in the public interest and consistent with the Act's purpose.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed temporary rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not intended to address competitive issues but is rather intended solely to extend temporary relief necessitated by the continued impacts of the COVID–19 pandemic and the related health and safety risks of conducting in-person activities. The Exchange believes that the proposed rule change will prevent unnecessary impediments to critical adjudicatory processes and its ability to fulfill its statutory obligations to protect investors and maintain fair and orderly markets that would otherwise result if the temporary amendments were to expire on July 31, 2022.

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 Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[33] and Rule 19b–4(f)(6) thereunder.[34] Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative

[28] *See* SR–FINRA–2022–018, 87 FR at 43336, n. 16.

[29] 15 U.S.C. 78f(b).

[30] 15 U.S.C. 78f(b)(5).

[31] 15 U.S.C. 78f(b)(7) & 78f(d).

[32] 15 U.S.C. 78f(b)(7) & 78f(d).

[33] 15 U.S.C. 78s(b)(3)(A)(iii).

[34] 17 CFR 240.19b–4(f)(6).

prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.

A proposed rule change filed under Rule 19b–4(f)(6) [35] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b4(f)(6)(iii),[36] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange has indicated that there is a continued need to extend the temporary relief because the Exchange agrees with FINRA that the COVID–19 related health concerns necessitating this relief will not meaningfully subside by July 31, 2022.[37] The Exchange also states that extending the temporary relief provided in SR–NYSEAMER–2020–69 immediately upon filing and without a 30-day operative delay will allow the Exchange to continue critical adjudicatory and review processes so that the Exchange may continue to operate effectively and meet its critical investor protection goals, while also protecting the health and safety of hearing participants.[38] The Commission also notes that this proposal extends without change the temporary relief previously provided by SR–NYSEAMER–2020–69.[39] As proposed, the temporary changes would be in place through October 31, 2022 and the amended rules will revert back to their original state at the conclusion of the temporary relief period and, if applicable, any extension thereof.[40] For these reasons, the Commission believes that waiver of the 30-day operative delay for this proposal is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposal operative upon filing.[41]

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) [42] 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–NYSEAMER–2022–34 on the subject line.

Paper Comments

- Send paper comments in triplicate to: Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEAMER–2022–34. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEAMER–2022–34 and should be submitted on or before September 7, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[43]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–17664 Filed 8–16–22; 8:45 am]

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[35] 17 CFR 240.19b–4(f)(6).

[36] 17 CFR 240.19b–4(f)(6)(iii).

[37] *See supra* Item II; *see also* SR–FINRA–2022–018, 87 FR 43335, at 43336.

[38] *See* 87 FR 43335, at 43337–38 (noting the same in granting FINRA's request to waive the 30-day operative delay so that SR–FINRA–2022–018 would become operative immediately upon filing).

[39] *See supra* note 4.

[40] *See supra* note 5. As noted above, the Exchange states that if it requires temporary relief from the rule requirements identified in this proposal beyond October 31, 2022, it may submit a separate rule filing to extend the effectiveness of the temporary relief under these rules.

[41] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule change's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[42] 15 U.S.C. 78s(b)(2)(B).

[43] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95476; File No. SR–NYSENAT–2022–14]

Self-Regulatory Organizations; NYSE National, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Extending the Expiration Date of the Temporary Amendments to Rules 10.9261 and 10.9830

August 11, 2022.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that on July 29, 2022, NYSE National Inc. (''NYSE National'' 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 extending the expiration date of the temporary amendments to Rules 10.9261 and 10.9830 as set forth in SR–NYSENAT–

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

2020–31 from July 31, 2022, to October 31, 2022, in conformity with recent changes by the Financial Industry Regulatory Authority, Inc. (''FINRA''). The proposed rule change would not make any changes to the text of NYSE National Rules 10.9261 and 10.9830. 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.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes extending the expiration date of the temporary amendments as set forth in SR–NYSENAT–2020–31 [4] to Rules 10.9261 (Evidence and Procedure in Hearing) and 10.9830 (Hearing) from July 31, 2022, to October 31, 2022 to harmonize with recent changes by FINRA to extend the expiration date of the temporary amendments to its Rules 9261 and 9830. SR–NYSENAT–2020–31 temporarily granted to the Chief or Deputy Chief Hearing Officer the authority to order that hearings be conducted by video conference if warranted by public health risks posed by in-person hearings during the ongoing COVID–19 pandemic. The proposed rule change would not make any changes to the text of Exchange Rules 10.9261 and 10.9830.[5]

Background

In 2018, NYSE National adopted disciplinary rules that are, with certain exceptions, substantially the same as the disciplinary rules of its affiliate NYSE American LLC, which are in turn substantially similar to the FINRA Rule 8000 Series and Rule 9000 Series, and which set forth rules for conducting investigations and enforcement actions.[6]

In adopting disciplinary rules modeled on FINRA's rules, NYSE National adopted the hearing and evidentiary processes set forth in Rule 10.9261 and in Rule 10.9830 for hearings in matters involving temporary and permanent cease and desist orders under the Rule 10.9800 Series. As adopted, the text of Rule 10.9261 and Rule 10.9830 are substantially the same as the FINRA rules with certain modifications.[7]

In response to the COVID–19 global health crisis and the corresponding need to restrict in-person activities, on August 31, 2020, FINRA filed with the Commission a proposed rule change for immediate effectiveness, SR–FINRA–2020–027, which allowed FINRA's Office of Hearing Officers (''OHO'') to conduct hearings, on a temporary basis, by video conference, if warranted by the current COVID–19-related public health risks posed by an in-person hearing. Among the rules FINRA amended were Rules 9261 and 9830.[8]

Given that that FINRA and OHO administers disciplinary hearings on the Exchange's behalf, and that the public health concerns addressed by FINRA's amendments apply equally to Exchange disciplinary hearings, on September 29, 2020, the Exchange filed to temporarily amend Rule 10.9261 and Rule 10.9830 to permit FINRA to conduct virtual hearings on its behalf.[9] In December 2020, FINRA filed a proposed rule change, SR–FINRA–2020–042, to extend the expiration date of the temporary amendments in SR–FINRA–2020–027 from December 31, 2020, to April 30, 2021.[10] On December 22, 2020, the Exchange similarly filed to extend the temporary amendments to Rule 10.9261 and Rule 10.9830 to April 30, 2021.[11]

On April 1, 2021, FINRA filed a proposed rule change, SR–FINRA–2021–006, to extend the expiration date of the temporary rule amendments to, among other rules, FINRA Rule 9261 and 9830 from April 30, 2021, to August 31, 2021.[12] On April 20, 2021, the Exchange filed to extend the temporary amendments to Rule 10.9261 and Rule 10.9830 to August 31, 2021.[13] On August 13, 2021, FINRA filed a proposed rule change, SR–FINRA–2021–019, to extend the expiration date of the temporary amendments to, among other rules, FINRA Rule 9261 and 9830 from August 31, 2021, to December 31, 2021.[14] On August 27, 2021, the Exchange filed to extend the temporary amendments to Rule 10.9261 and Rule 10.9830 to December 31, 2021.[15] On December 7, 2021, FINRA filed a proposed rule change, SR–FINRA–2021–031, to extend the expiration date of the temporary amendments in both SR–FINRA–2020–015 and SR–FINRA–2020–027 from December 31, 2021, to March 31, 2022.[16] On December 27, 2021, the Exchange filed to extend the temporary amendments to Rule 10.9261 and Rule 10.9830 to March 31, 2022, after which the temporary amendments will expire absent another proposed rule change filing by the Exchange.[17] On March 7, 2022, FINRA filed to extend the expiration date of the temporary rule amendments to, among other rules, FINRA Rule 9261 and 9830 from March 31, 2022, to July 31, 2022.[18] On March 29, 2022, the Exchange filed to extend the temporary amendments to Rule 9261 and Rule 9830 to July 31, 2022, after which the temporary amendments will expire absent another proposed rule change filing by the Exchange.[19]

Even though it has been more than two years since the World Health Organization declared COVID–19 a pandemic, FINRA has determined that

[4] *See* Securities Exchange Act Release No. 90137 (October 8, 2020), 85 FR 65087 (October 14, 2020) (SR–NYSENAT–2020–31) (''SR–NYSENAT–2020–31'').

[5] The Exchange may submit a separate rule filing to extend the expiration date of the proposed extension beyond October 31, 2022 if the Exchange requires additional temporary relief from the rule requirements identified in SR–NYSENAT–2020–31. The amended NYSE National rules will revert back to their original state at the conclusion of the temporary relief period and any extension thereof.

[6] *See* Securities Exchange Act Release No. 83289 (May 17, 2018), 83 FR 23968, 23976 (May 23, 2018) (SR–NYSENAT–2018–02) (''2018 Approval Order'').

[7] *See id.*

[8] *See* Securities Exchange Act Release No. 89737 (September 2, 2020), 85 FR 55712 (September 9, 2020) (SR–FINRA–2020–027) (''SR–FINRA–2020–027'').

[9] *See* note 3, *supra.*

[10] *See* Securities Exchange Act Release No. 90619 (December 9, 2020), 85 FR 81250 (December 15, 2020) (SR–FINRA–2020–042).

[11] *See* Securities Exchange Act Release No. 90822 (December 30, 2020), 86 FR 627 (January 6, 2021) (SR–NYSENAT–2020–39).

[12] *See* Securities Exchange Act Release No. 91495 (April 7, 2021), 86 FR 19306 (April 13, 2021) (SR–FINRA–2021–006).

[13] *See* Securities Exchange Act Release No. 91634 (April 22, 2021), 86 FR 22477 (April 28, 2021) (SR–NYSENAT–2021–11).

[14] *See* Securities Exchange Act Release No. 92685 (August 17, 2021), 86 FR 47169 (August 23, 2021) (SR–FINRA–2021–019).

[15] *See* Securities Exchange Act Release No. 92908 (September 9, 2021), 86 FR 51424 (September 15, 2021) (SR–NYSENAT–2021–16).

[16] *See* Securities Exchange Act Release No. 93758 (December 13, 2021), 86 FR 71695 (December 17, 2021) (SR–FINRA–2021–31).

[17] *See* Securities Exchange Act Release No. 93919 (January 6, 2022), 87 FR 1804 (January 12, 2022) (SR–NYSENAT–2021–25).

[18] *See* Securities Exchange Act Release No. 94430 (March 16, 2022), 87 FR 16262 (March 22, 2022) (SR–FINRA–2022–004).

[19] *See* Securities Exchange Act Release No. 94662 (April 11, 2022), 87 FR 22601 (April 15, 2022) (SR–NYSENAT–2022–03).

uncertainty still remains around this disease. The continued presence of COVID–19 variants including the quickly emerging Omicron BA.4 and BA.5 subvariants, dissimilar vaccination rates throughout the United States, and the current medium to high COVID–19 community levels in many states indicate that COVID–19 remains an active and real public health concern.[20] Due to the uncertainty and the lack of a clear timeframe for a sustained and widespread abatement of COVID–19-related health concerns and corresponding restrictions,[21] FINRA believes that there is a continued need for temporary relief beyond July 31, 2022.[22] On July 8, 2022, FINRA accordingly filed to extend the expiration date of the temporary rule amendments to, among other rules, FINRA Rule 9261 and 9830 from July 31, 2022, to October 31, 2022.[23]

Proposed Rule Change

Consistent with FINRA's recent proposal, the Exchange proposes to extend the expiration date of the temporary rule amendments to NYSE National Rules 10.9261 and 10.9830 as set forth in SR–NYSENAT–2020–31 from July 31, 2022, to October 31, 2022.

As set forth in SR–FINRA 2022–018, even though it has been more than two years since the World Health Organization declared COVID–19 a pandemic, uncertainty still remains around this disease. The continued presence of COVID–19 variants including the quickly emerging Omicron BA.4 and BA.5 subvariants, dissimilar vaccination rates throughout the United States, and the current medium to high COVID–19 community levels in many states indicate that COVID–19 remains an active and real public health concern.[24] Due to the uncertainty and the lack of a clear timeframe for a sustained and widespread abatement of COVID–19-related health concerns and corresponding restrictions,[25] FINRA believes that there is a continued need for temporary relief beyond July 31, 2022.[26] FINRA accordingly proposed to extend the expiration date of the temporary rule amendments from July 31, 2022, to October 31, 2022.

The Exchange proposes to similarly extend the expiration date of the temporary rule amendments to NYSE National Rules 10.9261 and 10.9830 as set forth in SR–NYSENAT–2020–31 from July 31, 2022, to October 31, 2022. The Exchange agrees with FINRA that, even though it has been more than two years since the World Health Organization declared COVID–19 a pandemic, uncertainty still remains around this disease. The Exchange also agrees that, due to the uncertainty and the lack of a clear timeframe for a sustained and widespread abatement of COVID–19-related health concerns and corresponding restrictions, for the reasons set forth in SR–FINRA–2022–018, there is a continued need for this temporary relief beyond July 31, 2022. The proposed change would permit OHO to continue to assess, based on critical COVID–19 data and criteria and the guidance of health and security consultants, whether an in-person hearing would compromise the health and safety of the hearing participants such that the hearing should proceed by video conference. As noted in SR–FINRA–2022–018, in deciding whether to schedule a hearing by video conference, OHO may consider a variety of other factors in addition to COVID–19 trends. Similarly, as noted in SR–FINRA–2022–018, in SR–FINRA–2020–027, FINRA provided a non-exhaustive list of other factors OHO may take into consideration, including a hearing participant's individual health concerns and access to the connectivity and technology necessary to participate in a video conference hearing.[27] The Exchange believes that this is a reasonable procedure to continue to follow for hearings under Rules 10.9261 and 10.9830 chaired by a FINRA employee.

As noted below, the Exchange has filed the proposed rule change for immediate effectiveness and has requested that the SEC waive the requirement that the proposed rule change not become operative for 30 days after the date of the filing, so the Exchange can implement the proposed rule change immediately.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,[28] in general, and furthers the objectives of Section 6(b)(5),[29] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to, and perfect the mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is designed to provide a fair procedure for the disciplining of members and persons associated with members, consistent with Sections 6(b)(7) and 6(d) of the Act.[30]

The Exchange believes that the proposed rule change supports the objectives of the Act by providing greater harmonization between Exchange rules and FINRA rules of similar purpose, resulting in less burdensome and more efficient regulatory compliance. As such, the proposed rule change will foster cooperation and coordination with persons engaged in facilitating transactions in securities and will remove impediments to and perfect the mechanism of a free and open market and a national market system.

The proposed rule change, which extends the expiration date of the temporary amendments to Exchange rules consistent with FINRA's extension to its Rules 9261 and 9830 as set forth in SR–FINRA–2022–018, will permit the Exchange to continue to effectively conduct hearings during the COVID–19 pandemic. Given the current and frequently changing COVID–19 conditions and the uncertainty around when those conditions will see meaningful, widespread and sustained improvement, without this relief

[20] *See* Securities Exchange Act Release No. 95281 (July 14, 2022), 87 FR 43335 (July 20, 2022) (SR–FINRA–2022–018) (''SR–FINRA–2022–018''). FINRA noted that, for example, there has been a notable upward trend in the number of daily COVID–19 cases in the United States since April 1, 2022. *See https://covid.cdc.gov/covid-data-tracker/#trends_dailycases.* In addition, on June 9, 2022, the Biden Administration announced its operational plan for COVID–19 vaccinations for children under the age of five. *See https://www.whitehouse.gov/briefing-room/statements-releases/2022/06/09/fact-sheetbiden-administration-announces-operational-plan-for-covid-19-vaccinations-for-children-under-5/. See* SR–FINRA–2022–018, 87 FR at 43335, n. 6.

[21] For instance, FINRA noted that the Centers for Disease Control and Prevention (''CDC'') recommends that people wear a mask in public indoor settings in areas with a high COVID–19 community level regardless of vaccination status or individual risk. *See https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/about-face-coverings.html.* The CDC also recommends that people wear a mask in indoor areas of public transportation and transportation hubs to protect themselves and those around them and help keep travel and public transportation safer for everyone. *See https://www.cdc.gov/coronavirus/2019-ncov/travelers/masks-public-transportation.html.* Furthermore, numerous states currently have mask mandates in certain settings, such as healthcare and correctional facilities. *See* SR–FINRA–2022–018, 87 FR at 43335, n.7.

[22] *See* SR–FINRA–2022–018, 87 FR 43336.

[23] *See* SR–FINRA–2022–018, 87 FR 43335–36.

[24] *See* note 20, *supra.*

[25] *See* note 21, *supra.*

[26] *See* SR–FINRA–2022–018, 87 FR at 43337.

[27] *See* SR–FINRA–2022–018, 87 FR at 43337, n. 16.

[28] 15 U.S.C. 78f(b).

[29] 15 U.S.C. 78f(b)(5).

[30] 15 U.S.C. 78f(b)(7) & 78f(d).

allowing OHO to proceed by video conference, some or all hearings may have to be postponed. The ability to conduct hearings by video conference will permit the adjudicatory functions of the Exchange's disciplinary rules to continue unabated, thereby avoiding protracted delays. The Exchange believes that this is especially important in matters where temporary and permanent cease and desist orders are sought because the proposed rule change would enable those hearings to continue to proceed without delay, thereby enabling the Exchange to continue to take immediate action to stop significant, ongoing customer harm, to the benefit of the investing public.

As set forth in detail in SR–NYSENAT–2020–31, the temporary relief to permit hearings to be conducted via video conference maintains fair process and will continue to provide fair process consistent with Sections 6(b)(7) and 6(d) of the Act [31] while striking an appropriate balance between providing fair process and enabling the Exchange to fulfill its statutory obligations to protect investors and maintain fair and orderly markets while avoiding the COVID–19-related public health risks for hearing participants. The Exchange notes that this proposal, like SR–NYSENAT–2020–31, provides only temporary relief. As proposed, the changes would be in place through October 31, 2022. As noted in SR–NYSENAT–2020–31 and above, the amended rules will revert back to their original state at the conclusion of the temporary relief period and, if applicable, any extension thereof.

Accordingly, the proposed rule change extending this temporary relief is in the public interest and consistent with the Act's purpose.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed temporary rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not intended to address competitive issues but is rather intended solely to extend temporary relief necessitated by the continued impacts of the COVID–19 pandemic and the related health and safety risks of conducting in-person activities. The Exchange believes that the proposed rule change will prevent unnecessary impediments to critical adjudicatory processes and its ability to fulfill its statutory obligations to protect investors and maintain fair and orderly markets that would otherwise result if the temporary amendments were to expire on July 31, 2022.

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 Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [32] and Rule 19b–4(f)(6) thereunder.[33] Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.

A proposed rule change filed under Rule 19b–4(f)(6) [34] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b4(f)(6)(iii),[35] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange has indicated that there is a continued need to extend the temporary relief because the Exchange agrees with FINRA that the COVID–19 related health concerns necessitating this relief will not meaningfully subside by July 31, 2022.[36] The Exchange also states that extending the temporary relief provided in SR–NYSENAT–2020–31 immediately upon filing and without a 30-day operative delay will allow the Exchange to continue critical adjudicatory and review processes so that the Exchange may continue to operate effectively and meet its critical investor protection goals, while also protecting the health and safety of hearing participants.[37] The Commission also notes that this proposal extends without change the temporary relief previously provided by SR–NYSENAT–2020–31.[38] As proposed, the temporary changes would be in place through October 31, 2022 and the amended rules will revert back to their original state at the conclusion of the temporary relief period and, if applicable, any extension thereof.[39] For these reasons, the Commission believes that waiver of the 30-day operative delay for this proposal is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposal operative upon filing.[40]

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) [41] 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–NYSENAT–2022–14 on the subject line.

[31] 15 U.S.C. 78f(b)(7) & 78f(d).

[32] 15 U.S.C. 78s(b)(3)(A)(iii).

[33] 17 CFR 240.19b–4(f)(6).

[34] 17 CFR 240.19b–4(f)(6).

[35] 17 CFR 240.19b–4(f)(6)(iii).

[36] *See supra* Item II; *see also* SR–FINRA–2022–018, 87 FR 43335, at 43336.

[37] *See* 87 FR 43335, at 43337–38 (noting the same in granting FINRA's request to waive the 30-day operative delay so that SR–FINRA–2022–018 would become operative immediately upon filing).

[38] *See supra* note 4.

[39] *See supra* note 5. As noted above, the Exchange states that if it requires temporary relief from the rule requirements identified in this proposal beyond October 31, 2022, it may submit a separate rule filing to extend the effectiveness of the temporary relief under these rules.

[40] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule change's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[41] 15 U.S.C. 78s(b)(2)(B).

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–NYSENAT–2022–14. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSENAT–2022–14 and should be submitted on or before September 7, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[42]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–17666 Filed 8–16–22; 8:45 am]

BILLING CODE 8011–01–P

[42] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95472; File No. SR–ICC–2022–007]

Self-Regulatory Organizations; ICE Clear Credit LLC; Order Approving Proposed Rule Change Relating to the Clearance of Additional Credit Default Swap Contracts

August 11, 2022.

I. Introduction

On June 16, 2022, ICE Clear Credit LLC (''ICC'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] a proposed rule change to revise the ICC Rulebook (the ''Rules'') [3] to provide for the clearance of additional Standard Emerging Market Sovereign [4] CDS contracts (collectively, the ''EM Contracts''). The proposed rule change was published for comment in the **Federal Register** on June 22, 2022.[5] The Commission did not receive comments regarding the proposed rule change. For the reasons discussed below, the Commission is approving the proposed rule change.

II. Description of the Proposed Rule Change

The proposed rule change would amend Subchapter 26D of the Rules to provide for the clearance of the following EM Contracts: the Arab Republic of Egypt, Kingdom of Bahrain, and Sultanate of Oman.[6] The proposed rule change would do so by amending the term ''Eligible SES Reference Entities'' in Rule 26D–102 (Definitions) to include the Arab Republic of Egypt, Kingdom of Bahrain, and Sultanate of Oman in the list of specific Eligible SES Reference Entities to be cleared by ICC. ICC represents that these additional EM Contracts have terms consistent with the other EM Contracts approved for clearing at ICC and governed by Subchapter 26D of the Rules, and that clearance of these additional EM contracts would not require any changes to ICC's Risk Management Framework.[7]

III. Discussion and Commission Findings

Section 19(b)(2)(C) of the Act directs the Commission to approve a proposed rule change of a self-regulatory organization if it finds that such proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to such organization.[8] Section 17A(b)(3)(F) of the Act requires, among other things, that the rules of ICC be designed to promote the prompt and accurate clearance and settlement of securities transactions and, to the extent applicable, derivative agreements, contracts, and transactions, as well as to assure the safeguarding of securities and funds which are in the custody or control of ICC or for which it is responsible.[9]

The Commission finds that the proposed rule change is consistent with Section 17A(b)(3)(F) of the Act.[10] The Commission has reviewed the terms and conditions of the additional EM Contracts proposed for clearing and has determined that those terms and conditions are substantially similar to the terms and conditions of the other contracts listed in Subchapter 26D of the ICC Rules, all of which ICC currently clears, with the key difference being that the underlying reference obligations will be issuances by the Arab Republic of Egypt, Kingdom of Bahrain, and Sultanate of Oman. Moreover, after reviewing the Notice and ICC's Rules, policies and procedures, the Commission finds that ICC would clear the additional EM Contracts pursuant to its existing clearing arrangements and related financial safeguards, protections and risk management procedures.

In addition, based on its own experience and expertise, including a review of data on volume, open interest, and the number of ICC Clearing Participants (''CPs'') that currently trade in the additional EM Contracts as well as certain model parameters for the additional EM Contracts, the Commission finds that ICC's rules, policies, and procedures are reasonably designed to price and measure the potential risk presented by the additional EM Contracts, collect financial resources in proportion to such risk, and liquidate this product in the event of a CP default. This should

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Capitalized terms used but not defined herein have the meanings specified in the Rules.

[4] The term ''Standard Emerging Market Sovereign'' is abbreviated in the Rules as ''SES,'' as used below.

[5] Self-Regulatory Organizations; ICE Clear Credit LLC; Notice of Filing of Proposed Rule Change Relating to the Clearance of Additional Credit Default Swap Contracts; Exchange Act Release No. 95139 (June 22, 2022); 87 FR 38435 (June 28, 2022) (File No. SR–ICC–2022–007) (''Notice'').

[6] The description that follows is excerpted from the Notice, 87 FR at 38435.

[7] *See* Notice, 87 FR at 38435.

[8] 15 U.S.C. 78s(b)(2)(C).

[9] 15 U.S.C. 78q–1(b)(3)(F).

[10] 15 U.S.C. 78q–1(b)(3)(F).

help ensure ICC's ability to maintain the financial resources it needs to provide its critical services and function as a central counterparty, thereby promoting the prompt and accurate settlement of the additional EM Contracts and other credit default swap transactions. For the same reasons, the Commission believes that the proposed rule change should help assure the safeguarding of securities or funds in the custody or control of ICC.

Therefore, the Commission finds that clearance of the additional EM Contracts would promote the prompt and accurate clearance and settlement of securities transactions and would help assure safeguarding of securities and funds in the custody or control of ICC, consistent with Section 17A(b)(3)(F) of the Act.[11]

IV. Conclusion

On the basis of the foregoing, the Commission finds that the proposed rule change is consistent with the requirements of the Act, and in particular, with the requirements of Section 17A(b)(3)(F) of the Act.[12]

It is therefore ordered pursuant to Section 19(b)(2) of the Act[13] that the proposed rule change (SR–ICC–2022–007), be, and hereby is, approved.[14]

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–17662 Filed 8–16–22; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 34672; File No. 812–15349]

Varagon Capital Corporation, et al.

August 11, 2022.

AGENCY: Securities and Exchange Commission (''Commission'' or ''SEC'').

ACTION: Notice.

Notice of application for an order (''Order'') under sections 17(d) and 57(i) of the Investment Company Act of 1940 (the ''Act'') and rule 17d–1 under the Act to permit certain joint transactions otherwise prohibited by sections 17(d) and 57(a)(4) of the Act and rule 17d–1 under the Act.

SUMMARY OF APPLICATION: Applicants request an order to amend a previous order granted by the Commission that permits certain business development companies (''BDCs'') and closed-end management investment companies to co-invest in portfolio companies with each other and with certain affiliated investment entities.

APPLICANTS: Varagon Capital Corporation, VCC Advisors, LLC, Varagon Capital Partners, L.P., Varagon Structured Notes Issuer, LLC, VCAP Cayman (L), L.P., VCAP Cayman (L) SPV–1, L.P., VCAP Cayman (U), L.P., VCP Holding I, L.P., VCP Holding II, L.P., VIVA Fund I, L.P., VCC Equity Holdings, LLC, and VCC Funding, LLC.

FILING DATES: The application was filed on June 15, 2022, and amended on August 8, 2022.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing on any application by emailing the SEC's Secretary at *Secretarys-Office@sec.gov* and serving the Applicants with a copy of the request by email, if an email address is listed for the relevant Applicant below, or personally or by mail, if a physical address is listed for the relevant Applicant below. Hearing requests should be received by the Commission by 5:30 p.m. on, September 6, 2022, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by emailing the Commission's Secretary at *Secretarys-Office@sec.gov.*

ADDRESSES: The Commission: *Secretarys-Office@sec.gov.* Applicants: Afsar Farman-Farmaian, Esq., Varagon Capital Corporation, at *afarman-farmaian@varagon.com,* and Steven B. Boehm, Esq., Payam Siadatpour, Esq., and Anne G. Oberndorf, Esq., Eversheds Sutherland (US) LLP, at *anneoberndorf@eversheds-sutherland.us.*

FOR FURTHER INFORMATION CONTACT: Kaitlin C. Bottock, Branch Chief, at (202) 551–6825 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: For Applicants' representations, legal analysis, and conditions, please refer to Applicants' first amended and restated application, dated August 8, 2022, which may be obtained via the Commission's website by searching for the file number at the top of this document, or for an Applicant using the Company name search field, on the SEC's EDGAR system. The SEC's EDGAR system may be searched at, *http://www.sec.gov/edgar/searchedgar/legacy/companysearch.html.* You may also call the SEC's Public Reference Room at (202) 551–8090.

For the Commission, by the Division of Investment Management, under delegated authority.

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–17659 Filed 8–16–22; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95475; File No. SR–NYSEARCA–2022–44]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Extending the Expiration Date of the Temporary Amendments to Rules 10.9261 and 10.9830

August 11, 2022.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that on July 29, 2022, NYSE Arca, Inc. (''NYSE Arca'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I 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 extending the expiration date of the temporary amendments to Rules 10.9261 and 10.9830 as set forth in SR–NYSEArca–2020–85 from July 31, 2022, to October 31, 2022, in conformity with recent changes by the Financial Industry Regulatory Authority, Inc. (''FINRA''). The proposed rule change would not make any changes to the text of NYSE Arca Rules 10.9261 and 10.9830. The proposed rule change is available on the

[11] 15 U.S.C. 78q–1(b)(3)(F).

[12] 15 U.S.C. 78q–1(b)(3)(F).

[13] 15 U.S.C. 78s(b)(2).

[14] In approving the proposed rule change, the Commission considered the proposal's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[15] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

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.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes extending the expiration date of the temporary amendments as set forth in SR–NYSEArca–2020–85 [4] to Rules 10.9261 (Evidence and Procedure in Hearing) and 10.9830 (Hearing) from July 31, 2022, to October 31, 2022, to harmonize with recent changes by FINRA to extend the expiration date of the temporary amendments to its Rules 9261 and 9830. SR–NYSEArca–2020–85 temporarily granted to the Chief or Deputy Chief Hearing Officer the authority to order that hearings be conducted by video conference if warranted by public health risks posed by in-person hearings during the ongoing COVID–19 pandemic. The proposed rule change would not make any changes to the text of Exchange Rules 10.9261 and 10.9830.[5]

Background

In 2019, NYSE Arca adopted disciplinary rules based on the text of the Rule 8000 and Rule 9000 Series of its affiliate NYSE American LLC (''NYSE American''), with certain changes. The NYSE American disciplinary rules are, in turn, substantially the same as the Rule 8000 Series and Rule 9000 Series of FINRA and the New York Stock Exchange LLC.[6] The NYSE Arca disciplinary rules were implemented on May 27, 2019.[7]

In adopting disciplinary rules modeled on FINRA's rules, NYSE Arca adopted the hearing and evidentiary processes set forth in Rule 10.9261 and in Rule 10.9830 for hearings in matters involving temporary and permanent cease and desist orders under the Rule 10.9800 Series. As adopted, the text of Rule 10.9261 and Rule 10.9830 are substantially the same as the FINRA rules with certain modifications.[8]

In response to the COVID–19 global health crisis and the corresponding need to restrict in-person activities, on August 31, 2020, FINRA filed with the Commission a proposed rule change for immediate effectiveness, SR–FINRA–2020–027, which allowed FINRA's Office of Hearing Officers (''OHO'') to conduct hearings, on a temporary basis, by video conference, if warranted by the current COVID–19-related public health risks posed by an in-person hearing. Among the rules FINRA amended were Rules 9261 and 9830.[9]

Given that that FINRA and OHO administers disciplinary hearings on the Exchange's behalf, and that the public health concerns addressed by FINRA's amendments apply equally to Exchange disciplinary hearings, on September 23, 2020, the Exchange filed to temporarily amend Rule 10.9261 and Rule 10.9830 to permit FINRA to conduct virtual hearings on its behalf.[10] In December 2020, FINRA filed a proposed rule change, SR–FINRA–2020–042, to extend the expiration date of the temporary amendments in SR–FINRA–2020–027 from December 31, 2020, to April 30, 2021.[11] On December 22, 2020, the Exchange similarly filed to extend the temporary amendments to Rule 10.9261 and Rule 10.9830 to April 30, 2021.[12] On April 1, 2021, FINRA filed a proposed rule change, SR–FINRA–2021–006, to extend the expiration date of the temporary rule amendments to, among other rules, FINRA Rule 9261 and 9830 from April 30, 2021, to August 31, 2021.[13] On April 20, 2021, the Exchange filed to extend the temporary amendments to Rule 10.9261 and Rule 10.9830 to August 31, 2021.[14] On August 13, 2021, FINRA filed a proposed rule change, SR–FINRA–2021–019, to extend the expiration date of the temporary amendments to, among other rules, FINRA Rule 9261 and 9830 from August 31, 2021, to December 31, 2021.[15] On August 27, 2021, the Exchange filed to extend the temporary amendments to Rule 10.9261 and Rule 10.9830 to December 31, 2021.[16] On December 7, 2021, FINRA filed a proposed rule change, SR–FINRA–2021–031, to extend the expiration date of the temporary amendments to, among other rules, FINRA Rule 9261 and 9830 from December 31, 2021, to March 31, 2022.[17] On December 27, 2021, the Exchange filed to extend the temporary amendments to Rule 10.9261 and Rule 10.9830 to March 31, 2022, after which the temporary amendments will expire absent another proposed rule change filing by the Exchange.[18] On March 7, 2022, FINRA filed to extend the expiration date of the temporary rule amendments to, among other rules, FINRA Rule 9261 and 9830 from March 31, 2022, to July 31, 2022.[19] On March 29, 2022, the Exchange filed to extend the temporary amendments to Rule 9261 and Rule 9830 to July 31, 2022, after which the temporary amendments will expire absent another proposed rule change filing by the Exchange.[20]

Even though it has been more than two years since the World Health Organization declared COVID–19 a pandemic, FINRA has determined that uncertainty still remains around this disease. The continued presence of COVID–19 variants including the quickly emerging Omicron BA.4 and BA.5 subvariants, dissimilar vaccination

[4] *See* Securities Exchange Act Release No. 90088 (October 5, 2020), 85 FR 64186 (October 9, 2020) (SR–NYSEArca–2020–85) (''SR–NYSEArca–2020–85'').

[5] The Exchange may submit a separate rule filing to extend the expiration date of the proposed extension beyond October 31, 2022 if the Exchange requires additional temporary relief from the rule requirements identified in SR–NYSEArca–2020–85. The amended NYSE Arca rules will revert back to their original state at the conclusion of the temporary relief period and any extension thereof.

[6] *See* Securities Exchange Act Release No. 85639 (April 12, 2019), 84 FR 16346 (April 18, 2019) (SR–NYSEArca–2019–15) (''2019 Notice'').

[7] *See* NYSE Arca Equities RB–19–060 & NYSE Arca Options RB–19–02 (April 26, 2019).

[8] *See* 2019 Notice, 84 FR at 16365 & 16373–4.

[9] *See* Securities Exchange Act Release No. 89737 (September 2, 2020), 85 FR 55712 (September 9, 2020) (SR–FINRA–2020–027) (''SR–FINRA–2020–027'').

[10] *See* note 4, *supra.*

[11] *See* Securities Exchange Act Release No. 90619 (December 9, 2020), 85 FR 81250 (December 15, 2020) (SR–FINRA–2020–042).

[12] *See* Securities Exchange Act Release No. 90820 (December 30, 2020), 86 FR 647 (January 6, 2021) (SR–NYSEArca–2020–116).

[13] *See* Securities Exchange Act Release No. 91495 (April 7, 2021), 86 FR 19306 (April 13, 2021) (SR–FINRA–2021–006).

[14] *See* Securities Exchange Act Release No. 91633 (April 22, 2021), 86 FR 22474 (April 28, 2021) (SR–NYSEArca–2021–27).

[15] *See* Securities Exchange Act Release No. 92685 (August 17, 2021), 86 FR 47169 (August 23, 2021) (SR–FINRA–2021–019).

[16] *See* Securities Exchange Act Release No. 92909 (September 9, 2021), 86 FR 51415 (September 15, 2021) (SR–NYSEArca–2021–76).

[17] *See* Securities Exchange Act Release No. 93758 (December 13, 2021), 86 FR 71695 (December 17, 2021) (SR–FINRA–2021–31).

[18] *See* Securities Exchange Act Release No. 93918 (January 6, 2022), 87 FR 1810 (January 12, 2022) (SR–NYSEArca–2021–107).

[19] *See* Securities Exchange Act Release No. 94430 (March 16, 2022), 87 FR 16262 (March 22, 2022) (SR–FINRA–2022–004).

[20] *See* Securities Exchange Act Release No. 94663 (April 11, 2022), 87 FR 22587 (April 15, 2022) (SR–NYSEARCA–2022–18).

rates throughout the United States, and the current medium to high COVID–19 community levels in many states indicate that COVID–19 remains an active and real public health concern.[21] Due to the uncertainty and the lack of a clear timeframe for a sustained and widespread abatement of COVID–19-related health concerns and corresponding restrictions,[22] FINRA believes that there is a continued need for temporary relief beyond July 31, 2022.[23] On July 8, 2022, FINRA accordingly filed to extend the expiration date of the temporary rule amendments to, among other rules, FINRA Rule 9261 and 9830 from July 31, 2022, to October 31, 2022.[24]

Proposed Rule Change

Consistent with FINRA's recent proposal, the Exchange proposes to extend the expiration date of the temporary rule amendments to NYSE Arca Rules 10.9261 and 10.9830 as set forth in SR–NYSEArca–2020–85 from July 31, 2022, to October 31, 2022.

As set forth in SR–FINRA–2022–018, even though it has been more than two years since the World Health Organization declared COVID–19 a pandemic, uncertainty still remains around this disease. The continued presence of COVID–19 variants including the quickly emerging Omicron BA.4 and BA.5 subvariants, dissimilar vaccination rates throughout the United States, and the current medium to high COVID–19 community levels in many states indicate that COVID–19 remains an active and real public health concern.[25] Due to the uncertainty and the lack of a clear timeframe for a sustained and widespread abatement of COVID–19-related health concerns and corresponding restrictions,[26] FINRA believes that there is a continued need for temporary relief beyond July 31, 2022.[27] FINRA accordingly proposed to extend the expiration date of the temporary rule amendments from July 31, 2022, to October 31, 2022.

The Exchange proposes to similarly extend the expiration date of the temporary rule amendments to NYSE Arca Rules 10.9261 and 10.9830 as set forth in SR–NYSEArca–2020–85 from July 31, 2022, to October 31, 2022. The Exchange agrees with FINRA that, even though it has been more than two years since the World Health Organization declared COVID–19 a pandemic, uncertainty still remains around this disease. The Exchange also agrees that, due to the uncertainty and the lack of a clear timeframe for a sustained and widespread abatement of COVID–19-related health concerns and corresponding restrictions, for the reasons set forth in SR–FINRA–2022–018, there is a continued need for this temporary relief beyond July 31, 2022. The proposed change would permit OHO to continue to assess, based on critical COVID–19 data and criteria and the guidance of health and security consultants, whether an in-person hearing would compromise the health and safety of the hearing participants such that the hearing should proceed by video conference. As noted in SR–FINRA–2022–018, in deciding whether to schedule a hearing by video conference, OHO may consider a variety of other factors in addition to COVID–19 trends. Similarly, as noted in SR–FINRA–2022–018, in SR–FINRA–2020–027, FINRA provided a non-exhaustive list of other factors OHO may take into consideration, including a hearing participant's individual health concerns and access to the connectivity and technology necessary to participate in a video conference hearing.[28] The Exchange believes that this is a reasonable procedure to continue to follow for hearings under Rules 10.9261 and 10.9830 chaired by a FINRA employee.

As noted below, the Exchange has filed the proposed rule change for immediate effectiveness and has requested that the SEC waive the requirement that the proposed rule change not become operative for 30 days after the date of the filing, so the Exchange can implement the proposed rule change immediately.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,[29] in general, and furthers the objectives of Section 6(b)(5),[30] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to, and perfect the mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is designed to provide a fair procedure for the disciplining of members and persons associated with members, consistent with Sections 6(b)(7) and 6(d) of the Act.[31]

The Exchange believes that the proposed rule change supports the objectives of the Act by providing greater harmonization between Exchange rules and FINRA rules of similar purpose, resulting in less burdensome and more efficient regulatory compliance. As such, the proposed rule change will foster cooperation and coordination with persons engaged in facilitating transactions in securities and will remove impediments to and perfect the mechanism of a free and open market and a national market system.

The proposed rule change, which extends the expiration date of the temporary amendments to Exchange rules consistent with FINRA's extension to its Rules 9261 and 9830 as set forth in SR–FINRA–2022–018, will permit the Exchange to continue to effectively conduct hearings during the COVID–19 pandemic. Given the current and frequently changing COVID–19 conditions and the uncertainty around when those conditions will see meaningful, widespread and sustained improvement, without this relief allowing OHO to proceed by video conference, some or all hearings may have to be postponed. The ability to

[21] *See* Securities Exchange Act Release No. 95281 (July 14, 2022), 87 FR 43335 (July 20, 2022) (SR–FINRA–2022–018) (''SR–FINRA–2022–018''). FINRA noted that, for example, there has been a notable upward trend in the number of daily COVID–19 cases in the United States since April 1, 2022. *See https://covid.cdc.gov/covid-data-tracker/#trends_dailycases.* In addition, on June 9, 2022, the Biden Administration announced its operational plan for COVID–19 vaccinations for children under the age of five. *See https://www.whitehouse.gov/briefing-room/statements-releases/2022/06/09/fact-sheetbiden-administration-announces-operational-plan-for-covid-19-vaccinations-for-children-under-5/. See* SR–FINRA–2022–018, 87 FR at 43335, n. 6.

[22] For instance, FINRA noted that the Centers for Disease Control and Prevention (''CDC'') recommends that people wear a mask in public indoor settings in areas with a high COVID–19 community level regardless of vaccination status or individual risk. *See https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/about-face-coverings.html.* The CDC also recommends that people wear a mask in indoor areas of public transportation and transportation hubs to protect themselves and those around them and help keep travel and public transportation safer for everyone. See *https://www.cdc.gov/coronavirus/2019-ncov/travelers/masks-public-transportation.html.* Furthermore, numerous states currently have mask mandates in certain settings, such as healthcare and correctional facilities. *See* SR–FINRA–2022–018, 87 FR at 43335, n. 7.

[23] *See* SR–FINRA–2022–018, 87 FR 43335.

[24] *See* SR–FINRA–2022–018, 87 FR at 87 FR 43335–36.

[25] *See* note 21, *supra.*

[26] *See* note 22, *supra.*

[27] *See* SR–FINRA–2022–018, 87 FR at 43337.

[28] *See* SR–FINRA–2022–018, 87 FR at 87 FR 43336, n. 16.

[29] 15 U.S.C. 78f(b).

[30] 15 U.S.C. 78f(b)(5).

[31] 15 U.S.C. 78f(b)(7) & 78f(d).

conduct hearings by video conference will permit the adjudicatory functions of the Exchange's disciplinary rules to continue unabated, thereby avoiding protracted delays. The Exchange believes that this is especially important in matters where temporary and permanent cease and desist orders are sought because the proposed rule change would enable those hearings to continue to proceed without delay, thereby enabling the Exchange to continue to take immediate action to stop significant, ongoing customer harm, to the benefit of the investing public.

As set forth in detail in the SR–NYSEArca–2020–85, the temporary relief to permit hearings to be conducted via video conference maintains fair process and will continue to provide fair process consistent with Sections 6(b)(7) and 6(d) of the Act[32] while striking an appropriate balance between providing fair process and enabling the Exchange to fulfill its statutory obligations to protect investors and maintain fair and orderly markets while avoiding the COVID–19-related public health risks for hearing participants. The Exchange notes that this proposal, like SR–NYSEArca–2020–85, provides only temporary relief. As proposed, the changes would be in place through October 31, 2022. As noted in SR–NYSEArca–2020–85 and above, the amended rules will revert back to their original state at the conclusion of the temporary relief period and, if applicable, any extension thereof.

Accordingly, the proposed rule change extending this temporary relief is in the public interest and consistent with the Act's purpose.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed temporary rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not intended to address competitive issues but is rather intended solely to extend temporary relief necessitated by the continued impacts of the COVID–19 pandemic and the related health and safety risks of conducting in-person activities. The Exchange believes that the proposed rule change will prevent unnecessary impediments to critical adjudicatory processes and its ability to fulfill its statutory obligations to protect investors and maintain fair and orderly markets that would otherwise result if the temporary amendments were to expire on July 31, 2022.

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 Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[33] and Rule 19b–4(f)(6) thereunder.[34] Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.

A proposed rule change filed under Rule 19b–4(f)(6)[35] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b4(f)(6)(iii),[36] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange has indicated that there is a continued need to extend the temporary relief because the Exchange agrees with FINRA that the COVID–19 related health concerns necessitating this relief will not meaningfully subside by July 31, 2022.[37] The Exchange also states that extending the temporary relief provided in SR–NYSEArca–2020–85 immediately upon filing and without a 30-day operative delay will allow the Exchange to continue critical adjudicatory and review processes so that the Exchange may continue to operate effectively and meet its critical investor protection goals, while also protecting the health and safety of hearing participants.[38] The Commission also notes that this proposal extends without change the temporary relief previously provided by SR–NYSEArca–2020–85.[39] As proposed, the temporary changes would be in place through October 31, 2022 and the amended rules will revert back to their original state at the conclusion of the temporary relief period and, if applicable, any extension thereof.[40] For these reasons, the Commission believes that waiver of the 30-day operative delay for this proposal is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposal operative upon filing.[41]

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)[42] 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–NYSEArca–2022–44 on the subject line.

[32] 15 U.S.C. 78f(b)(7) & 78f(d).

[33] 15 U.S.C. 78s(b)(3)(A)(iii).

[34] 17 CFR 240.19b–4(f)(6).

[35] 17 CFR 240.19b–4(f)(6).

[36] 17 CFR 240.19b–4(f)(6)(iii).

[37] *See supra* Item II; *see also* SR–FINRA–2022–018, 87 FR 43335, at 43336.

[38] *See* 87 FR 43335, at 43337–38 (noting the same in granting FINRA's request to waive the 30-day operative delay so that SR–FINRA–2022–018 would become operative immediately upon filing).

[39] *See supra* note 4.

[40] *See supra* note 5. As noted above, the Exchange states that if it requires temporary relief from the rule requirements identified in this proposal beyond October 31, 2022, it may submit a separate rule filing to extend the effectiveness of the temporary relief under these rules.

[41] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule change's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[42] 15 U.S.C. 78s(b)(2)(B).

Paper Comments

• Send paper comments in triplicate to: Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEArca–2022–44. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEArca–2022–44 and should be submitted on or before September 7, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[43]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–17665 Filed 8–16–22; 8:45 am]

BILLING CODE 8011–01–P

[43] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95481; File No. SR–NYSEARCA–2022–49]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change to the NYSE Arca Equities Proprietary Market Data Fees To Adopt an Enterprise Fee for Broker-Dealer Subscribers of NYSE ArcaBook

August 11, 2022.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on August 1, 2022, NYSE Arca, Inc. (''NYSE Arca'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes changes to the NYSE Arca Equities Proprietary Market Data Fees (''Fee Schedule'') to adopt an Enterprise Fee for Broker-Dealer subscribers of NYSE ArcaBook. 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 changes to the Fee Schedule to adopt an Enterprise Fee for Broker-Dealer subscribers of NYSE ArcaBook. The Exchange proposes to make the fee change operative on August 1, 2022.

The Exchange currently offers a Professional User Fee Cap for broker-dealers that are subscribers of NYSE ArcaBook at $75,000 per month.[4] To illustrate the application of the Professional User Fee Cap, a broker-dealer with 2,500 internal professional users who receives NYSE ArcaBook would pay $110,000 per month in professional user fees (500 users at $60 per month plus 2,000 users at $40 per month).[5] This broker-dealer's fees, however, are currently capped at $75,000 per month.

The Exchange also currently offers a Non-Professional User Fee Cap for broker-dealers that are subscribers of NYSE ArcaBook at $40,000 per month.[6] To illustrate the application of the Non-Professional User Fee Cap, a broker-dealer with 10,000 non-professional users who receives NYSE ArcaBook would pay $45,000 per month in non-professional user fees (1,500 users at $10 per month plus 1,500 users at $6 per month plus 7,000 users at $3 per month).[7] This broker-dealer's fees, however, are also currently capped at $40,000 per month.

Subscribers whose fees are capped are required to count and report to the Exchange the total number of professional users and non-professional users that are permissioned to receive the data feed.

[4] *See* Securities Exchange Act Release No. 82100 (November 16, 2017), 82 FR 55660 (November 22, 2017) (SR–NYSEARCA–2017–130) (Notice of Filing and Immediate Effectiveness of Proposed Rule Changes to the NYSE Arca Equities Proprietary Market Data Fees). The Professional User Fee Cap applies to internal users of a broker-dealer subscriber.

[5] The Professional User Fees for broker-dealer subscribers of NYSE ArcaBook is $60 per month for 1–500 users and $40 per month for 501 or more users. *See* Fee Schedule, available here: *https://www.nyse.com/publicdocs/nyse/data/NYSE_Arca_Equities_Proprietary_Data_Fee_Schedule.pdf.*

[6] *See* Securities Exchange Act Release No. 72560 (July 8, 2014), 79 FR 40801 (July 14, 2014) (SR–NYSEARCA–2014–72) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending the Fees for NYSE ArcaBook).

[7] The Non-Professional User Fees for broker-dealer subscribers of NYSE ArcaBook is $10 per month for 1–1,500 users, $6 per month for 1,501–3,000 users and $3 per month for 3,001 or more users. *See* Fee Schedule, available here: *https://www.nyse.com/publicdocs/nyse/data/NYSE_Arca_Equities_Proprietary_Data_Fee_Schedule.pdf.*

As part of the Exchange's efforts to ease administrative burdens on its customers and expand enterprise coverage to external professional users to whom customers may redistribute NYSE ArcaBook data, the Exchange proposes to adopt an Enterprise Fee for broker-dealers that are subscribers of NYSE ArcaBook of $115,000 per month. The proposed fee is the sum of the Professional User Fee Cap of $75,000 per month and the Non-Professional User Fee Cap of $40,000 per month. To illustrate the application of the proposed Enterprise Fee, a broker-dealer with 2,500 internal professional users and 10,000 non-professional users, would currently be capped at $115,000 per month ($75,000 per month under the Professional User Fee Cap plus $40,000 per month under the Non-Professional User Fee Cap).

Applicability of Proposed Rule Change

The purpose of the proposal is to offer customers an additional subscription method without imposing any new or higher fees, and to lower the administrative burden on broker-dealer subscribers by not requiring the broker-dealer to count and report to the Exchange the number of professional users and non-professional users separately and expand enterprise coverage to external professional users to which a broker-dealer subscriber redistributes NYSE ArcaBook data feed under the broker-dealer's subscription. The Exchange believes eliminating the distinction between professional users and non-professional users in a brokerage relationship will lessen current distinctions among broker-dealers. As proposed, all broker-dealers that choose to utilize the enterprise license will be treated the same in that each broker-dealer that chooses an enterprise license would pay the same amount of the fee without having to count and report the number of professional users and non-professional users separately. With the proposed fee change, the broker-dealer in the above example could choose an enterprise license and would continue to pay the same amount as it does today and would be able to provide NYSE ArcaBook to internal and external professional and non-professional users at no additional cost. The proposed change will not increase any fee or charge to current subscribers.

As noted above, no current subscriber will be subject to higher fees by the proposed fee change. To the extent a current subscriber pays the capped fees of $75,000 per month for professional users and $40,000 per month for non-professional users, the subscriber can simply choose to amend its subscription to an enterprise license and continue to pay $115,000 per month, the same amount the subscriber pays currently, with the added benefit of not counting the number of professional users and non-professional users.

The proposed Enterprise Fee for NYSE ArcaBook will result in a fee reduction for broker-dealer subscribers with sufficiently large numbers of professional and non-professional users, as described in the example above. Broker-dealers that purchase NYSE ArcaBook typically have thousands of users. If a broker-dealer subscriber has a smaller number of professional and/or non-professional users of NYSE ArcaBook, then it may continue to use the per user fee structure and the fees it pays will not change. By providing an enterprise license for broker-dealers with a large number of professional and non-professional users, the Exchange believes that more broker-dealers may choose to offer NYSE ArcaBook, thereby expanding the distribution of this market data for the benefit of investors. The Exchange also believes that offering an enterprise license expands the range of options for offering NYSE ArcaBook and would allow broker-dealers greater choice in selecting the most appropriate level of data and fees for the professional and non-professional users they are servicing. The Exchange also notes that the concept of adopting an enterprise license fee is not novel.[8] In addition, the Exchange currently has an enterprise license applicable to subscribers to NYSE Arca BBO and NYSE Arca Trades market data feeds.[9]

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[10] in general, and Sections 6(b)(4) and 6(b)(5) of the Act,[11] in particular, in that it provides an equitable allocation of reasonable fees among users and recipients of the data and is not designed to permit unfair discrimination among customers, issuers, and brokers.

In adopting Regulation NMS, the Commission granted self-regulatory organizations (''SROs'') and broker-dealers increased authority and flexibility to offer new and unique market data to the public. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, 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]

With respect to market data, the decision of the United States Court of Appeals for the District of Columbia Circuit in *NetCoalition* v. *SEC* upheld the Commission's reliance on the existence of competitive market mechanisms to evaluate the reasonableness and fairness of fees for proprietary market data:

> In fact, the legislative history indicates that the Congress intended that the market system ''evolve through the interplay of competitive forces as unnecessary regulatory restrictions are removed'' and that the SEC wield its regulatory power ''in those situations where competition may not be sufficient,'' such as in the creation of a ''consolidated transactional reporting system.'' [13]

The court agreed with the Commission's conclusion that ''Congress intended that 'competitive forces should dictate the services and practices that constitute the U.S. national market system for trading equity securities.' '' [14]

More recently, the Commission confirmed that it applies a ''market-based'' test in its assessment of market data fees, and that under that test:

> the Commission considers whether the exchange was subject to significant competitive forces in setting the terms of its proposal for [market data], including the level of any fees. If an exchange meets this burden, the Commission will find that its fee rule is consistent with the Act unless there is a substantial countervailing basis to find that the terms of the rule violate the Act or the rules thereunder.[15]

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[8] *See e.g.,* Section 123(c) Enterprise License Fees for Nasdaq Depth-of-Book Data at *https://listingcenter.nasdaq.com/rulebook/nasdaq/rules/Nasdaq%20Equity%207*.

[9] *See* NYSE Arca Equities Proprietary Market Data Fees at *https://www.nyse.com/publicdocs/nyse/data/NYSE_Arca_Equities_Proprietary_Data_Fee_Schedule.pdf*.

[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).

[13] *NetCoalition* v. *SEC*, 615 F.3d 525, 535 (D.C. Cir. 2010) (quoting H.R. Rep. No. 94–229 at 92 (1975), *as reprinted in* 1975 U.S.C.C.A.N. 323).

[14] *Id.* at 535.

[15] *See* Securities Exchange Act Release No. 34–90217 (October 16, 2020), 85 FR 67392 (October 22, 2020) (SR–NYSENAT–2020–05) (Order Approving a Proposed Rule Change to Establish Fees for the NYSE National Integrated Feed) (internal quotation marks omitted), quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74781 (December 9, 2008) (NYSE ArcaBook Approval Order).

More specifically, the proposed rule change will expand competition by providing customers an additional subscription method (without imposing any new or higher fees) that would reduce the administrative burden of counting and reporting to the Exchange the number of professional and non-professional users. With this proposed rule change, customers will have the ability to choose which subscription options suits its needs best. For the broker-dealers who have a large user base of professional and non-Professional users, the ability to subscribe to an enterprise license would eliminate their administrative burden of counting and reporting users, as well as eliminate the burden to validate the non-professional user status to ensure accurate non-professional user count, and would cap their Arcabook device fees at the enterprise rate. If a current broker-dealer subscriber has a smaller number of professional and/or non-professional users of NYSE ArcaBook, then it may continue to use the per user fee structure and the fees it pays will not change or increase. As proposed, all broker-dealers that choose to utilize the proposed enterprise license would pay the same amount of the fee without having to count and report to the number of professional users and non-professional users separately and will not need to validate non-professional user status.

The Exchange notes that NYSE ArcaBook is entirely optional. The Exchange is not required to make NYSE ArcaBook available or to offer any specific pricing alternatives to any customers, nor is any firm required to purchase NYSE ArcaBook. Unlike some other data products (*e.g.,* the consolidated quotation and last-sale information feeds) that firms are required to purchase in order to fulfil regulatory obligations,[16] a customer's decision whether to purchase any of the Exchange's proprietary market data feeds is entirely discretionary. Most firms that choose to subscribe to proprietary market data products from the Exchange and its affiliates do so for the primary goals of using them to increase their revenues, reduce their expenses, and in some instances compete directly with the Exchange (including for order flow); those firms are able to determine for themselves whether NYSE ArcaBook or any other similar products are attractively priced or not.

Firms that do not wish to purchase NYSE ArcaBook have a variety of alternative market data products from which to choose. For example, the Nasdaq Stock Market (''Nasdaq'') provides an enterprise license for the dissemination of Nasdaq TotalView, which competes with NYSE ArcaBook. More specifically, Nasdaq provides broker-dealer subscribers an enterprise license that permits internal and external distribution to both professional and non-professional users for a monthly fee of $500,000.[17] Alternatively, if NYSE ArcaBook does not provide sufficient value to firms as offered based on the uses those firms have or planned to make of it, such firms may simply choose to conduct their business operations in ways that do not use NYSE ArcaBook or use them at different levels or in different configurations.

In setting the proposed fees, the Exchange considered the competitiveness of the market for proprietary data and all of the implications of that competition. The Exchange believes that it has considered all relevant factors and has not considered irrelevant factors in order to establish reasonable fees. The existence of numerous alternatives to the Exchange's offering, including proprietary data from other sources, ensures that the Exchange cannot set unreasonable fees when subscribers can elect these alternatives or choose not to purchase a specific proprietary data product if the attendant fees are not justified by the returns that any particular data recipient would achieve through the purchase.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. As noted above, the proposed rule change will expand competition by providing customers with an additional subscription method that would reduce the administrative burden and cap the fees. Customers that choose to purchase the proposed enterprise license will benefit from the ability to grow their use base without paying additional incremental fees, reduced administrative burden by eliminating the need to validate non-professional user status, and eliminating the need to count and report the number of professional and/or non-professional users. Customers that choose not to purchase the proposed enterprise license can continue to use the current fee structure and the fees it pays will not change.

Intramarket Competition. The Exchange believes that the proposed rule change does not put any market participant at a relative disadvantage compared to other market participants. As noted above, the proposed fee schedule would apply to all subscribers of NYSE ArcaBook, and customers may not only choose whether to subscribe to the feed at all but may tailor their subscription to include only the products and uses that they deem suitable for their business needs. The Exchange also believes that the proposed rule change neither favors nor penalizes one or more categories of market participants in a manner that would impose an undue market on competition.

Intermarket Competition. The Exchange believes that the proposed rule change does not impose a burden on competition on other exchanges that is not necessary or appropriate; indeed, the Exchange believes the proposed rule change would have the effect of increasing competition. In setting fees at issue here, the Exchange is constrained by the fact that, if its pricing is unattractive to customers, customers will have its pick of an increasing number of alternative venues to use instead of the Exchange. Given this competition, no one exchange's market data fees can impose an unnecessary burden on competition, and the Exchange's proposed fees do not do so here.

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) [18] of the Act and

[16] The Exchange notes that broker-dealers are not required to purchase proprietary market data to comply with their best execution obligations. *See In the Matter of the Application of Securities Industry and Financial Markets Association for Review of Actions Taken by Self-Regulatory Organizations,* Release Nos. 34- 72182; AP–3–15350; AP–3–15351 (May 16, 2014). Similarly, there is no requirement in Regulation NMS or any other rule that proprietary data be utilized for order routing decisions, and some broker-dealers and ATSs have chosen not to do so.

[17] *See* Nasdaq TotalView, Enterprise License Option, available at *http://www.nasdaqtrader.com/Trader.aspx?id=DPUSData.*

[18] 15 U.S.C. 78s(b)(3)(A).

subparagraph (f)(2) of Rule 19b–4 [19] 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) [20] 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–NYSEARCA–2022–49 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEARCA–2022–49. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEARCA–2022–49 and should be submitted on or before September 7, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[21]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–17670 Filed 8–16–22; 8:45 am]

BILLING CODE 8011–01–P

[19] 17 CFR 240.19b–4(f)(2).

[20] 15 U.S.C. 78s(b)(2)(B).

[21] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–95477; File No. SR–NYSECHX–2022–19]

Self-Regulatory Organizations; NYSE Chicago, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Harmonize Rules 10.9261 and 10.9830 With Recent Changes by the Financial Industry Regulatory Authority, Inc.

August 11, 2022.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that on July 29, 2022, the NYSE Chicago, Inc. (''NYSE Chicago'' 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 harmonize Rules 10.9261 and 10.9830 with recent changes by the Financial Industry Regulatory Authority, Inc. (''FINRA'') that temporarily grants the Chief or Deputy Chief Hearing Officer the authority to order that hearings be conducted by video conference if warranted by public health risks posed by in-person hearings during the ongoing novel coronavirus (''COVID–19'') pandemic. As proposed, these temporary amendments would be in effect through October 31, 2022. 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.

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 harmonize Rules 10.9261 (Evidence and Procedure in Hearing) and 10.9830 (Hearing) with recent changes by FINRA to its Rules 9261 and 9830 that temporarily grants to the Chief or Deputy Chief Hearing Officer the authority to order that hearings be conducted by video conference if warranted by public health risks posed by in-person hearings during the ongoing COVID–19 pandemic. As proposed, these temporary amendments would be in effect through October 31, 2022.[4]

Background

In 2022, NYSE Chicago adopted disciplinary rules that are, with certain exceptions, substantially the same as the disciplinary rules of its affiliate NYSE Arca, Inc., which are in turn substantially similar to the FINRA Rule

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] The Exchange may submit a separate rule filing to extend the expiration date of the proposed temporary amendments if the Exchange requires temporary relief from the rule requirements identified in this proposal beyond October 31, 2022. The amended NYSE Chicago rules will revert back to their original [current] [sic] state at the conclusion of the temporary relief period and any extension thereof.

8000 Series and Rule 9000 Series, and which set forth rules for conducting investigations and enforcement actions.[5]

In adopting disciplinary rules modeled on FINRA's rules, NYSE Chicago adopted the hearing and evidentiary processes set forth in Rule 10.9261 and in Rule 10.9830 for hearings in matters involving temporary and permanent cease and desist orders under the Rule 9800 Series. As adopted, the text of Rule 10.9261 and Rule 10.9830 are substantially the same as the FINRA rules with certain modifications.[6]

In 2020, in view of the ongoing spread of COVID–19 and its effect on FINRA's adjudicatory functions nationwide, FINRA filed a temporary rule change to grant FINRA's Office of Hearing Officers (''OHO'') and the National Adjudicatory Council (''NAC'') the authority to conduct certain hearings by video conference, if warranted by the current COVID–19-related public health risks posed by in-person hearings. Among the rules FINRA amended were Rules 9261 and 9830.[7]

FINRA represented in its filing that its protocol for conducting hearings by video conference would ensure that such hearings maintain fair process for the parties by, among other things, FINRA's use of a high quality, secure and user-friendly video conferencing service and provide thorough instructions, training and technical support to all hearing participants.[8] According to FINRA, the proposed changes were a reasonable interim solution to allow FINRA's critical adjudicatory processes to continue to function while protecting the health and safety of hearing participants as FINRA works towards resuming in-person hearings in a manner that is compliant with the current guidance of public health authorities.[9]

Since the Initial FINRA Filing (in 2020), FINRA periodically extended the temporary relief as the COVID–19 pandemic and concerns surrounding its spread persisted.[10] According to FINRA, even though it has been more than two years since the World Health Organization declared COVID–19 a pandemic, uncertainty still remains around this disease. The continued presence of COVID–19 variants including the quickly emerging Omicron BA.4 and BA.5 subvariants, dissimilar vaccination rates throughout the United States, and the current medium to high COVID–19 community levels in many states indicate that COVID–19 remains an active and real public health concern.[11]

Due to the uncertainty and the lack of a clear timeframe for a sustained and widespread abatement of COVID–19-related health concerns and corresponding restrictions,[12] FINRA believes that there is a continued need for temporary relief beyond its most recent extension until July 31, 2022.[13] On July 8, 2022, FINRA accordingly filed to extend the expiration date of the temporary rule amendments to, among other rules, FINRA Rule 9261 and 9830 from July 31, 2022, to October 31, 2022.[14]

Pursuant to a regulatory services agreement (''RSA''), FINRA's Office of Hearing Officers will administer all aspects of adjudications, including assigning hearing officers to serve as NYSE Chicago hearing officers. A hearing officer from OHO will, among other things, preside over the disciplinary hearing, select and chair the hearing panel, and prepare and issue written decisions. The Chief or Deputy Hearing Officer for all Exchange disciplinary hearings are currently drawn from OHO and are all FINRA employees. The Exchange believes that OHO will utilize the same video conference protocol and processes for Exchange matters under the RSA as it proposes for FINRA matters.

Given that FINRA and its Office of Hearing Officers administers disciplinary hearings on the Exchange's behalf, and given that the public health concerns addressed by FINRA's amendments apply equally to the Exchange's disciplinary hearings, the Exchange proposes to temporarily amend its disciplinary rules to allow FINRA to conduct virtual hearings on its behalf.

Proposed Rule Change

Rule 10.9261(b) states that if a disciplinary hearing is held, a party shall be entitled to be heard in-person, by counsel, or by the party's representative. Absent an agreement by all parties to proceed in another manner, an Exchange disciplinary hearings are in-person. As noted, the Chief and Deputy Hearing Officers for all Exchange and cross-market matters are supplied by OHO and are FINRA employees. Accordingly, absent an agreement by all parties to proceed in another manner, under Rule 10.9261(b) the Chief or Deputy Hearing Officer conducts disciplinary hearings in-person.

Similarly, Rule 10.9830 outlines the requirements for hearings for temporary and permanent cease and desist orders. Rule 10.9830(a), however, does not specify that a party shall be entitled to be heard in-person, by counsel, or by the party's representative.

Consistent with FINRA's temporary amendment to FINRA Rules 9261 and 9830, the Exchange proposes to temporarily grant the Chief or Deputy Chief Hearing Officer temporary authority to order, upon consideration

[5] *See* Securities Exchange Act Release No. 95020 (June 1, 2022), 87 FR 35034, (June 8, 2022) (SR–NYSECHX–2022–10) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change to Adopt Investigation, Disciplinary, Sanction, and Other Procedural Rules Modeled on the Rules of the Exchange's Affiliates) (''2022 Notice of Disciplinary Rules'').

[6] *See id.*

[7] *See* Securities Exchange Act Release Nos. 83289 (September 2, 2020), 85 FR 55712 (September 9, 2020) (SR–FINRA–2020–027) (''Initial FINRA Filing''). FINRA also proposed to temporarily amend FINRA Rules 1015 and 9524. FINRA Rule 1015 governs the process by which an applicant for new or continuing membership can appeal a decision rendered by FINRA's Department of Member Supervision under FINRA Rule 1014 or 1017 and request a hearing which would be conducted by a subcommittee of the NAC. *See id.* at 55714. The Exchange has not adopted FINRA Rule 1015. FINRA Rule 9524 governs the process by which a statutorily disqualified member firm or associated person can appeal the Department's recommendation to deny a firm or sponsoring firm's application to the NAC. *See id.* Under the Exchange's version of Rule 10.9524, if the CRO rejects the application, the ETP Holder or applicant may request a review by the Exchange Board of Directors. This differs from FINRA's process, which provides for a hearing before the NAC and further consideration by the FINRA Board of Directors.

[8] *See* Initial FINRA Filing, 85 FR at 55713.

[9] *See id.*

[10] *See, e.g.,* Securities Exchange Act Release No. 94430 (March 16, 2022), 87 FR 16262 (March 22, 2022) (SR–FINRA–2022–004) (most recent extension of temporary relief until July 31, 2022).

[11] *See* Securities Exchange Act Release No. 95281 (July 14, 2022), 87 FR 43335 (July 20, 2022) (SR–FINRA–2022–018) (''SR–FINRA–2022–018''). FINRA noted that, for example, there has been a notable upward trend in the number of daily COVID–19 cases in the United States since April 1, 2022. *See https://covid.cdc.gov/covid-data-tracker/#trends_dailycases.* In addition, on June 9, 2022, the Biden Administration announced its operational plan for COVID–19 vaccinations for children under the age of five. *See https://www.whitehouse.gov/briefing-room/statements-releases/2022/06/09/fact-sheetbiden-administration-announces-operational-plan-for-covid-19-vaccinations-for-children-under-5/. See* SR–FINRA–2022–018, 87 FR at 43335, n. 6.

[12] For instance, FINRA noted that the Centers for Disease Control and Prevention (''CDC'') recommends that people wear a mask in public indoor settings in areas with a high COVID–19 community level regardless of vaccination status or individual risk. *See https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/about-face-coverings.html.* The CDC also recommends that people wear a mask in indoor areas of public transportation and transportation hubs to protect themselves and those around them and help keep travel and public transportation safer for everyone. *See https://www.cdc.gov/coronavirus/2019-ncov/travelers/masks-public-transportation.html.* Furthermore, numerous states currently have mask mandates in certain settings, such as healthcare and correctional facilities. *See* SR–FINRA–2022–018, 87 FR at 43335, n. 7.

[13] *See* SR–FINRA–2022–018, 87 FR at 43335.

[14] *See* SR–FINRA–2022–018, 87 FR at 43335–36.

of the current COVID–19-related public health risks presented by an in-person hearing, that a hearing under those rules be conducted by video conference. The proposed change will permit OHO to make an assessment, based on critical COVID–19 data and criteria and the guidance of health and security consultants, whether an in-person hearing would compromise the health and safety of the hearing participants such that the hearing should proceed by video conference. As noted, FINRA has adopted a detailed and thorough protocol to ensure that hearings conducted by video conference will maintain fair process for the parties.[15] The Exchange believes that this is a reasonable procedure to follow in hearings under Rules 10.9261 and 10.9830 chaired by a FINRA employee.[16]

To effectuate these changes, the Exchange proposes to add the following sentence to Rule 10.9261(b):

> Upon consideration of the current public health risks presented by an in-person hearing, the Chief Hearing Officer or Deputy Chief Hearing Officer may, on a temporary basis, determine that the hearing shall be conducted, in whole or in part, by video conference.

The proposed text is identical to the language adopted by FINRA.[17]

Similarly, the Exchange proposes to add the following text to Rule 10.9830(a):

> Upon consideration of the current public health risks presented by an in-person hearing, the Chief Hearing Officer or Deputy Chief Hearing Officer may, on a temporary basis, determine that the hearing shall be conducted, in whole or in part, by video conference.

Once again, the proposed language is identical to the language adopted by FINRA.[18]

Consistent with FINRA's most recent filing, the Exchange proposes that these temporary amendments would be in effect through October 31, 2022.[19]

As noted below, the Exchange has filed the proposed rule change for immediate effectiveness and has requested that the SEC waive the requirement that the proposed rule change not become operative for 30 days after the date of the filing, so the Exchange can implement the proposed rule change immediately.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,[20] in general, and furthers the objectives of Section 6(b)(5),[21] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to, and perfect the mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is designed to provide a fair procedure for the disciplining of members and persons associated with members, consistent with Sections 6(b)(7) and 6(d) of the Act.[22]

The Exchange believes that the proposed rule change support the objectives of the Act by providing greater harmonization between Exchange rules and FINRA rules of similar purpose, resulting in less burdensome and more efficient regulatory compliance. As previously noted, the text of Rule 10.9261 and Rule 10.9830 is substantially the same as FINRA's rule. As such, the proposed rule change will foster cooperation and coordination with persons engaged in facilitating transactions in securities and will remove impediments to and perfect the mechanism of a free and open market and a national market system.

The Exchange believes that the proposed temporary rule change will permit the Exchange to effectively conduct hearings during the COVID–19 pandemic in situations where in-person hearings present likely public health risks. Given the current and frequently changing COVID–19 conditions and the uncertainty around when those conditions will see meaningful, widespread and sustained improvement, without this relief allowing OHO to proceed by video conference, some or all hearings may have to be postponed.

The ability to conduct hearings by video conference will thereby permit the adjudicatory functions of the Exchange's disciplinary rules to continue unabated, thereby avoiding protracted delays. The Exchange believes that this is especially important in matters where temporary and permanent cease and desist orders are sought because the proposed rule change would enable those hearings to proceed without delay, thereby enabling the Exchange to take immediate action to stop significant, ongoing customer harm, to the benefit of the investing public.

Conducting hearings via video conference will give the parties and adjudicators simultaneous visual and oral communication without the risks inherent in physical proximity during a pandemic. Temporarily permitting hearings for disciplinary matters to proceed by video conference maintains fair process by providing respondents a timely opportunity to address and potentially resolve any allegations of misconduct.

As noted, FINRA will use a high quality, secure video conferencing technology with features that will allow the parties to reasonably approximate those tasks that are typically performed at an in-person hearing, such as sharing documents, marking documents, and utilizing breakout rooms. FINRA will also provide training for participants on how to use the video conferencing platform and detailed guidance on the procedures that will govern such hearings. Moreover, the Chief or Deputy Chief Hearing Officer may take into consideration, among other things, a hearing participant's access to connectivity and technology in scheduling a video conference hearing and can also, at their discretion, allow a party or witness to participate by telephone, if necessary, to address such access issues.[23]

The Exchange believes that the temporary relief to permit hearings to be conducted via video conference maintains fair process and will continue to provide fair process consistent with Sections 6(b)(7) and 6(d) of the Act[24] while striking an appropriate balance between providing fair process and enabling the Exchange to fulfill its statutory obligations to protect investors and maintain fair and orderly markets while avoiding the COVID–19-related public health risks for hearing participants. The Exchange notes that this proposal provides only temporary relief, which would be in place through October 31, 2022. As noted in herein (*see supra* note 4), the amended rules will revert back to their original state at the conclusion of the temporary relief

[15] *See* Initial FINRA Filing, 85 FR at 55713.

[16] The Exchange notes, as did FINRA, that SEC's Rules of Practice pertaining to temporary cease-and-desist orders provide that parties and witnesses may participate by telephone or, in the Commission's discretion, through the use of alternative technologies that allow remote access, such as a video link. *See* SEC Rule of Practice 511(d)(3); Comment (d); *see* Initial FINRA Filing, 85 FR at 55714, n. 21.

[17] *See* Initial FINRA Filing, 85 FR at 55712.

[18] *Id.*

[19] *See* SR–FINRA–2022–018, 87 FR at 43337. *See supra* note 4.

[20] 15 U.S.C. 78f(b).

[21] 15 U.S.C. 78f(b)(5).

[22] 15 U.S.C. 78f(b)(7) and 78f(d).

[23] *See* text accompanying note 8, *supra.*

[24] 15 U.S.C. 78f(b)(7) & 78f(d).

period and, if applicable, any extension thereof.

Accordingly, the proposed rule change extending this temporary relief is in the public interest and consistent with the Act's purpose.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed temporary rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not intended to address competitive issues but is rather intended solely to provide temporary relief given the impacts of the COVID–19 pandemic and the related health and safety risks of conducting in-person activities. In the Initial FINRA Filing, FINRA provides an abbreviated economic impact assessment maintaining that the changes are necessary to temporarily rebalance the attendant benefits and costs of the obligations under FINRA Rules 1015, 9261, 9524 and 9830 in response to the impacts of the COVID–19 pandemic that is equally applicable to the changes the Exchange proposes.[25] The Exchange accordingly incorporates FINRA's abbreviated economic impact assessment by reference. The Exchange believes that the proposed rule change will prevent unnecessary impediments to critical adjudicatory processes and its ability to fulfill its statutory obligations to protect investors and maintain fair and orderly markets that would otherwise result if the temporary amendments were not in place.

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 Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[26] and Rule 19b–4(f)(6) thereunder.[27] Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.

A proposed rule change filed under Rule 19b–4(f)(6)[28] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b4(f)(6)(iii),[29] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange has indicated that the proposal would provide greater harmonization between Exchange rules and FINRA rules of similar purpose, resulting in less burdensome and more efficient regulatory compliance at a time when the health risks of in-person hearings are significant. The Exchange also states that the temporary relief provided in this proposal immediately upon filing and without a 30-day operative delay will allow the Exchange to continue critical adjudicatory and review processes so that the Exchange may continue to operate effectively and meet its critical investor protection goals, while also protecting the health and safety of hearing participants.[30] As proposed, the temporary changes would be in place through October 31, 2022 and the amended rules will revert back to their original state at the conclusion of the temporary relief period and, if applicable, any extension thereof.[31] For these reasons, the Commission believes that waiver of the 30-day operative delay for this proposal is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposal operative upon filing.[32]

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)[33] 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–NYSECHX–2022–19 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–NYSECHX–2022–19. 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

[25] *See* Initial FINRA Filing, 85 FR at 55716.

[26] 15 U.S.C. 78s(b)(3)(A)(iii).

[27] 17 CFR 240.19b–4(f)(6).

[28] 17 CFR 240.19b–4(f)(6).

[29] 17 CFR 240.19b–4(f)(6)(iii).

[30] *See* 87 FR 43335, at 43337–38 (noting the same in granting FINRA's request to waive the 30-day operative delay so that SR–FINRA–2022–018 would become operative immediately upon filing).

[31] *See supra* note 4. As noted above, the Exchange states that if it requires temporary relief from the rule requirements identified in this proposal beyond October 31, 2022, it may submit a separate rule filing to extend the effectiveness of the temporary relief under these rules.

[32] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule change's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[33] 15 U.S.C. 78s(b)(2)(B).

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–NYSECHX–2022–19 and should be submitted on or before September 7, 2022.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[34]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2022–17667 Filed 8–16–22; 8:45 am]

BILLING CODE 8011–01–P

SOCIAL SECURITY ADMINISTRATION

[Docket No: SSA–2022–0044]

Agency Information Collection Activities: Comment Request

The Social Security Administration (SSA) publishes a list of information collection packages requiring clearance by the Office of Management and Budget (OMB) in compliance with Public Law 104–13, the Paperwork Reduction Act of 1995, effective October 1, 1995. This notice includes one new collection.

SSA is soliciting comments on the accuracy of the agency's burden estimate; the need for the information; its practical utility; ways to enhance its quality, utility, and clarity; and ways to minimize burden on respondents, including the use of automated collection techniques or other forms of information technology. Mail, email, or fax your comments and recommendations on the information collection(s) to the OMB Desk Officer and SSA Reports Clearance Officer at the following addresses or fax numbers.

(OMB), Office of Management and Budget, Attn: Desk Officer for SSA, Comments: *https://www.reginfo.gov/public/do/PRAMain.* Submit your comments online referencing Docket ID Number [SSA–2022–0044].

(SSA), Social Security Administration, OLCA, Attn: Reports Clearance Director, 3100 West High Rise, 6401 Security Blvd., Baltimore, MD 21235, Fax: 410–966–2830, Email address: *OR.Reports.Clearance@ssa.gov.*

Or you may submit your comments online through *https://www.reginfo.gov/public/do/PRAMain,* referencing Docket ID Number [SSA–2022–0044].

SSA submitted the information collection below to OMB for clearance. Your comments regarding this information collection would be most useful if OMB and SSA receive them 30 days from the date of this publication. To be sure we consider your comments, we must receive them no later than September 16, 2022. Individuals can obtain copies of the OMB clearance package by writing to *OR.Reports.Clearance@ssa.gov.*

1. The National Beneficiary Survey (NBS)—0960–NEW

Background

SSA's Social Security Disability Insurance (SSDI) and SSI programs provide a crucial and necessary income for people with disabilities. By improving employment outcomes for SSDI beneficiaries and SSI recipients, SSA supports the effort to reduce the reliance of people with disabilities on these programs. SSA previously conducted seven rounds of the National Beneficiary Survey (NBS) in 2004, 2005, 2006, 2010, 2015, 2017, and 2019. Conducting the prior rounds of the NBS provided SSA with an important understanding of the work interests and experiences of SSI recipients and SSDI beneficiaries, and helped SSA gain information about their impairments; health; living arrangements; family structure; pre-disability occupation; and use of non-SSA programs (e.g., the Supplemental Nutrition Assistance Program). The prior rounds of NBS data are available to researchers and the public. SSA contracted with Mathematica to conduct the NBS data collection.

NBS Project Description

The primary purpose of the new NBS is to: (1) assess beneficiary well-being and interest in work; (2) learn about beneficiary work experiences (successful and unsuccessful); and (3) identify factors that promote or restrict long-term work success. As with the previous NBS rounds, the current NBS will collect information on factors such as health; living arrangements; family structure; current occupation; use of non-SSA programs; knowledge of SSDI and SSI work incentive programs; obstacles to work; and beneficiary interest and motivation to return to work.

SSA is requesting approval to administer Round 8 of the NBS in 2023. The information we will collect is not something we could obtain from SSA administrative data or other sources. In the Round 8 NBS, the sample design is similar to the ones we used for the prior NBS. The sample includes the nationally representative beneficiary samples (RBS) of adult SSDI and SSI disability program participants, as well as the successful worker sample (SWS) which includes beneficiaries who worked above the substantial gainful activity for at least three consecutive months during the six months preceding their NBS interview. SSA plans to complete 8,000 interviews: 5,000 from a cross-sectional sample of active beneficiaries (SSI and SSDI) and 3,000 from a successful worker sample, and will conduct the survey interviews primarily by telephone. We will send a letter in advance informing the beneficiary that an interviewer will contact them to conduct, or schedule a date and time for the survey. The beneficiary can also contact the 800 number we provide in the sample letter to schedule the interview or take the survey with an interviewer. We will send follow-up letters and postcards reminding the beneficiary to contact us, if they have not already done so, and we will also send postcard messages about establishing the best time for the beneficiary to take the survey.

In addition to the Round 8 NBS, we propose to conduct an experimental web and a paper-based data collection effort to test if these modes are feasible methods to collect data from nonrespondents. SSA will conduct this experiment during the administration of the Round 8 NBS, and we will include a shorter version of the instrument for web and paper administration designed to collect critical data from nonrespondents to the telephone interview modality. We will mail the abbreviated experimental paper version survey to the beneficiaries to complete and send back to Mathematica.

We will pull the sample for the experimental web and paper administration of the NBS from Round 8 SWS nonrespondents. Respondent participation in the NBS is voluntary and the decision to participate has no impact on current or future receipt of payments or benefits. Respondents are current SSDI beneficiaries and SSI recipients.

Type of Request: Request for a new information collection.

[34] 17 CFR 200.30–3(a)(12).

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Average wait time for mathematica teleservice centers (minutes) **	Total annual opportunity cost (dollars) ***
Representative Beneficiary Sample	5,000	1	60	5,000	*$11.70	**5	***$63,379
Successful Worker Sample	3,000	1	70	3,500	*11.70	**5	***43,875
Successful Worker Sample web-based experiment	125	1	25	52	*11.70		***608
Successful Worker Sample, paper-based experiment respondent	100	1	25	42	*11.70		***491
Totals	8,225			8,594			***108,353

*We based this figure on the average DI payments based on SSA's current FY 2022 data (*https://www.ssa.gov/legislation/2022factsheet.pdf*).
**We based this figure on Mathematica's FY 2022 average wait times for their teleservice centers, based on Mathematica's current management information data.
***This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

Dated: August 11, 2022.

Naomi Sipple,

Reports Clearance Officer, Social Security Administration.

[FR Doc. 2022–17627 Filed 8–16–22; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF STATE

[Public Notice: 11824]

Notification of the Fifteenth Meeting of the CAFTA–DR Environmental Affairs Council

ACTION: Notice of the fifteenth meeting of the Dominican Republic-Central America-United States Free Trade Agreement (CAFTA–DR) Environmental Affairs Council and request for comments; invitation to public session.

SUMMARY: The Department of State and the Office of the United States Trade Representative (USTR) are providing notice that the parties to CAFTA–DR intend to hold the fifteenth meeting of the Environmental Affairs Council (the Council) established under Chapter 17 (Environment Chapter) of that agreement on October 6–7, 2022, in Washington, DC. The Department of State and USTR also invite written comments or questions regarding implementation of Chapter 17 and any topics that should be discussed at the Council meeting consistent with its purpose. When preparing comments, we encourage submitters to refer to Chapter 17 of the CAFTA–DR and to the CAFTA–DR Environmental Cooperation Agreement (ECA) (*documents available at https://www.state.gov/key-topics-office-of-environmental-quality-and-transboundary-issues/current-trade-agreements-with-environmental-chapters/#cafta-dr* and *https://ustr.gov/issue-areas/environment/bilateral-and-regional-trade-agreements*). Instructions on how to submit comments are under the heading **ADDRESSES**.

DATES: The public session of the Council will be held on October 7, 2022, from 9 a.m. to 12 p.m. EDT in Washington, DC. Please contact Bradley Blecker and Sigrid Simpson for the location of this meeting in Washington, DC or to request a link to join virtually. Addresses and confirmations of attendance and comments and suggestions are requested in writing no later than October 2, 2022.

ADDRESSES: Written comments or suggestions should be submitted to both:

(1) Bradley Blecker, U.S. Department of State, Bureau of Oceans and International Environmental and Scientific Affairs, Office of Environmental Quality, by email to *BleckerBT@state.gov* with the subject line ''CAFTA–DR EAC Meeting''; and

(2) Sigrid Simpson, Director for Environment and Natural Resources, Office of the United States Trade Representative, by email to *Sigrid.A.Simpson@ustr.eop.gov* with the subject line ''CAFTA–DR EAC Meeting''.

If you have access to the internet, you can view and comment on this notice by going to: *http://www.regulations.gov/#!home* and searching for docket number DOS–2022–0024.

FOR FURTHER INFORMATION CONTACT: Bradley Blecker, (202) 394–3316, or Sigrid Simpson, (202) 881–6592.

SUPPLEMENTARY INFORMATION: Article 17.5 of the CAFTA–DR establishes an Environmental Affairs Council (the Council) and provides that, unless the CAFTA–DR parties otherwise agree, the Council will meet annually to oversee the implementation of, and review progress under, Chapter 17, and to consider the status of cooperation activities developed under the ECA. Article 17.5 further requires that, unless the parties otherwise agree, each meeting of the Council include a session in which members of the Council have an opportunity to meet with the public to discuss matters relating to the implementation of Chapter 17.

On October 6, the Council will meet in a closed government-to-government session to (1) review implementation of the Environment Chapter, including by highlighting increased levels of environmental protection, environmental enforcement, and related achievements in the past year, with a focus on wildlife trafficking, illegal logging and deforestation, and climate change and clean technologies; (2) discuss efforts to tackle the climate crisis, combat illegal, unreported, and unregulated (IUU) fishing, and end plastic pollution; (3) receive a report from the CAFTA–DR Secretariat for Environmental Matters on the status of public submissions; and (4) review activities under the CAFTA–DR Environmental Cooperation Program and possible cooperation for the future.

The Council invites all interested persons to attend a public session on Chapter 17 implementation, beginning at 9:00 a.m. EDT on October 7. At the session, the Council will welcome questions, input, and information about challenges and achievements in implementation of the Environment Chapter obligations and the related ECA. If you would like to attend in Washington, DC or connect virtually to the public session, please notify Bradley Blecker and Sigrid Simpson at the email addresses listed under the heading **ADDRESSES**. Please include your full name and identify any organization or group you represent.

Visit the State website at *www.state.gov* and the USTR website at *www.ustr.gov* for more information.

Sherry Zalika Sykes,

Director, Office of Environmental Quality, U.S. Department of State.

[FR Doc. 2022–17653 Filed 8–16–22; 8:45 am]

BILLING CODE 4710–09–P

DEPARTMENT OF STATE

[Public Notice: 11823]

Notification of Meetings of the United States-Peru Environmental Affairs Council, Environmental Cooperation Commission, and Sub-Committee on Forest Sector Governance

ACTION: Notice of meetings and request for comments; invitation to public session.

SUMMARY: The U.S. Department of State and the Office of the United States Trade Representative (USTR) are providing notice that on September 12–13, 2022, the United States and Peru will hold the eighth meeting of the Environmental Affairs Council (the ''Council''), the tenth meeting of the Sub-Committee on Forest Sector Governance (the ''Sub-Committee''), and the sixth meeting of the Environmental Cooperation Commission (the ''Commission''). The purpose of the three meetings, respectively, is to review implementation of Chapter 18 (Environment) of the United States-Peru Trade Promotion Agreement (PTPA); the PTPA Annex on Forest Sector Governance (Annex 18.3.4); and the United States-Peru Environmental Cooperation Agreement (ECA). All interested persons are invited to attend the public session and to submit written comments or to ask questions regarding implementation of Chapter 18, Annex 18.3.4, and the ECA, and to raise any issues that should be discussed at the meetings consistent with their respective purposes. In preparing comments, submitters are encouraged to refer to Chapter 18 of the PTPA, including Annex 18.3.4, and the ECA (available at *https://www.state.gov/key-topics-office-of-environmental-quality-and-transboundary-issues/current-trade-agreements-with-environmental-chapters/#peru*). Instructions on how to submit comments are under the heading **ADDRESSES.**

DATES: The public sessions of the Council, Commission, and Sub-Committee meetings will be held on September 13, 2022 at 9:30 a.m. (EDT). Please contact Elizabeth Linske and Sigrid Simpson for the location of this meeting and information for virtual participation. Confirmations of attendance and comments or suggestions are requested in writing no later than September 7, 2022.

ADDRESSES: Written comments or suggestions should be submitted to both:

(1) Elizabeth Linske, U.S. Department of State, Bureau of Oceans and International Environmental and Scientific Affairs, Office of Environmental Quality, by email at *LinskeE@state.gov* with the subject line ''UNITED STATES-PERU EAC/ECC MEETING'' and

(2) Sigrid Simpson, Office of the United States Trade Representative, Office of Environment and Natural Resources, by email at *Sigrid.A.Simpson@ustr.eop.gov* with the subject line ''UNITED STATES-PERU EAC/ECC MEETING.''

In your email, please include your full name and affiliation.

If you have access to the internet, you can view and comment on this notice by going to: *http://www.regulations.gov/#!home* and searching for docket number DOS–2022–0023.

FOR FURTHER INFORMATION CONTACT: Elizabeth Linske, (202) 344–9852 or Sigrid Simpson, (202) 881–6592.

SUPPLEMENTARY INFORMATION: The PTPA entered into force on February 1, 2009. Article 18.6 of the PTPA establishes an Environmental Affairs Council, which is required to meet once a year unless otherwise agreed by the Parties to discuss the implementation of Chapter 18. Annex 18.3.4 to the PTPA establishes a Sub-Committee on Forest Sector Governance. The Sub-Committee is a specific forum for the Parties to share views and information on any matter arising under the PTPA Annex on Forest Sector Governance. The ECA entered into force on August 23, 2009. Article III of the ECA establishes an Environmental Cooperation Commission and makes the Commission responsible for developing a Work Program. Article 18.6 of the PTPA and Article VI of the ECA provide that meetings of the Council and Commission respectively include a public session, unless the Parties otherwise agree. At its first meeting, the Sub-Committee on Forest Sector Governance committed to hold a public session after each Sub-Committee meeting.

Sherry Zalika Sykes,

Director, Office of Environmental Quality, Department of State.

[FR Doc. 2022–17652 Filed 8–16–22; 8:45 am]

BILLING CODE 4710–09–P

SUSQUEHANNA RIVER BASIN COMMISSION

Commission Meeting

AGENCY: Susquehanna River Basin Commission.

ACTION: Notice.

SUMMARY: The Susquehanna River Basin Commission will conduct its regular business meeting on September 15, 2022 in Baltimore, Maryland. Details concerning the matters to be addressed at the business meeting are contained in the **SUPPLEMENTARY INFORMATION** section of this notice. Also the Commission published a document in the **Federal Register** on July 12, 2022, concerning its public hearing on August 11, 2022, in Harrisburg, Pennsylvania.

DATES: The meeting will be held on Thursday, September 15, 2022, at 9 a.m.

ADDRESSES: This public meeting will be conducted in person and digitally from the Caracas Room, Kimpton Hotel Monaco Baltimore at 2 North Charles Street, Baltimore, Maryland 21201.

FOR FURTHER INFORMATION CONTACT: Jason E. Oyler, General Counsel and Secretary to the Commission, telephone: 717–238–0423; fax: 717–238–2436.

SUPPLEMENTARY INFORMATION: The business meeting will include actions or presentations on the following items: (1) adoption of a revised Civil Penalty Matrix and a revised Policy and Guidance Statement for the Settlement of Civil Penalties/Enforcement Actions; (2) adoption of the Commission's Fiscal Year 2024 Budget; (3) adoption of member jurisdictions allocation for FY2024; (4) approval of contracts, grants and agreements; (5) and actions on 20 regulatory program projects.

This agenda is complete at the time of issuance, but other items may be added, and some stricken without further notice. The listing of an item on the agenda does not necessarily mean that the Commission will take final action on it at this meeting. When the Commission does take final action, notice of these actions will be published in the **Federal Register** after the meeting. Any actions specific to projects will also be provided in writing directly to project sponsors.

The meeting will be conducted both in person at the U.S. Army Corps of Engineers, Baltimore District headquarters and digitally. The public is invited to attend the Commission's business meeting. You can access the Business Meeting through a computer (Audio and Video) by following the link: *https://srbc.webex.com/srbc/j.php?MTID=m296635b23fd682a18bc26d79257993b5* then enter meeting number 177 385 1780 and password CommBusMtg0915. You may also participant telephonically by dialing 1–877–668–4493 and entering the meeting number 177 385 1780 followed by the # sign.

Written comments pertaining to items on the agenda at the business meeting

may be mailed to the Susquehanna River Basin Commission, 4423 North Front Street, Harrisburg, Pennsylvania 17110–1788, or submitted electronically through *www.srbc.net/about/meetings-events/business-meeting.html.* Such comments are due to the Commission on or before August 22, 2022. Comments will not be accepted at the business meeting noticed herein.

Authority: Pub. L. 91–575, 84 Stat. 1509 *et seq.,* 18 CFR parts 806, 807, and 808.

Dated: August 12, 2022.

Jason E. Oyler,

General Counsel and Secretary to the Commission.

[FR Doc. 2022–17700 Filed 8–16–22; 8:45 am]

BILLING CODE 7040–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

NextGen Advisory Committee: Solicitation of Nominations for Appointment

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

ACTION: Solicitation of nominations for appointment to the NextGen Advisory Committee (NAC).

SUMMARY: This notice announces a solicitation for nominations for membership on the NextGen Advisory Committee (NAC).

DATES: Nominations must be received no later than 6:00 p.m. Eastern Time on September 19, 2022. Nominations received after the due date may be retained for evaluation for future NAC vacancies after all other nominations received by the due date have been evaluated and considered.

ADDRESSES: Nominations can be submitted electronically (by email) to *9-FAA-NexGen-Advisory-Committee@faa.gov.* The subject line should state ''NAC Nomination.'' The body of the email must contain content or attachments that address all requirements as specified in the below ''Materials to Submit'' section. Incomplete/partial submittals, as well as those that exceed the specified document length, may not be considered for evaluation. An email confirmation from the FAA will be sent upon receipt of all complete nominations that meet the criteria in the ''Materials to Submit'' section. Anyone wishing to submit an application by paper may do so by contacting Kimberly Noonan at *Kimberly.Noonan@faa.gov* or calling 202–267–3760. The FAA will notify those appointed by the Secretary of Transportation to serve on the NAC in writing.

FOR FURTHER INFORMATION CONTACT: Kimberly Noonan, NAC Coordinator, U.S. Department of Transportation, at *Kimberly.Noonan@faa.gov* or 202–267–3760. Additional information on the NAC, including the current roster, charter, tasks, and previous meeting minutes, may be found at: *https://www.faa.gov/about/office_org/headquarters_offices/ang/nac.*

SUPPLEMENTAL INFORMATION:

I. Background

The Secretary of Transportation established the NAC under agency authority in accordance with the provisions of the Federal Advisory Committee Act (FACA), as amended, Public Law 92–463, 5 U.S.C. app. 2, to provide independent advice and recommendations to the FAA, and to respond to specific tasks received directly from the FAA. The advice, recommendations, and tasks related to concepts, requirements, operational capabilities, the associated use of technology, and related considerations to operations that affect the future of the Air Traffic Management System and the integration of new technologies. In addition, the NAC recommends consensus-driven advice for the FAA's consideration relating to Air Traffic Management System modernization, which the FAA may adopt.

This notice seeks to fill current and future vacancies on the NAC and does not affect the status of NAC members whose terms have not expired.

II. Description of Duties

The objective of the NAC is to advise the FAA, using consensus-based meeting methodologies, on (1) investment priorities, (2) NextGen priorities and performance analyses report, (3) trajectory-based operations deployment and planning consistent with the FAA's NextGen Vision, and (4) ad hoc tasks received directly from the FAA. The NAC will act solely in an advisory capacity and will not exercise program management responsibilities. Decisions directly affecting the implementation of transportation policy will remain with the FAA Administrator and the Secretary of Transportation.

III. Membership

The NAC is comprised of members appointed by the Secretary of Transportation upon recommendation by the FAA Administrator. The membership must be equitably balanced in terms of points of view represented and functions performed. The stakeholder groups represented on the NAC include the following:

a. Air Traffic Management (Automation and Infrastructure)
b. Aircraft Manufacturers
c. Airports
d. Avionics Manufacturers
e. Department of Defense
f. Environmental Interests
g. International Entities
h. Labor
i. NASA
j. Operators (General Aviation, Air Carriers, Business Aviation)

All NAC members serve at the request of the Secretary. To the extent practicable and in accordance with the Executive Order on Advancing Racial Equity and Support for Underserved Communities through the Federal Government and the Executive Order on Diversity, Equity, Inclusion, and Accessibility, the membership of the NAC shall include persons of diverse backgrounds in race, ethnicity, religion, sexual orientation, and gender. The NAC will have no more than 30 members. Other membership terms include:

a. An appointment of up to two years.
b. Service without charge and without government compensation.
c. Ability to attend all NAC meetings (estimated three meetings per year).

Qualifications: Candidates must currently serve as a senior executive and corporate officer in an aviation organization with equities in air traffic management and aircraft equipment modernization to provide advice on the integration and operationalization of NextGen programs and associate technologies. Candidates must have the ability to make corporate decisions in the committee and commit resources on behalf of their organizations. Candidates must have appropriate expertise to include, but are not limited to, flight operations; air traffic management automation and infrastructure; aircraft and avionics manufacturing; airport infrastructure/operations; government; and aviation labor safety. Candidates should have the flexibility and network to reach out to their respective aviation community sector counterparts as needed to respond to FAA requests for advice. Candidates must be in good public standing and are expected to be present at all meetings to ensure the NAC deliberations include a balance of points of view.

Materials to Submit: Candidates are required to submit, in full, the following materials to be considered for NAC membership. Failure to submit the required information may disqualify a candidate from the review process:

a. A biography of the nominee, including professional and academic credentials.

b. A resume or curriculum vitae, which must include relevant job experience, qualifications, former service on a(n) Federal Advisory Committee(s) and/or Aviation Rulemaking Committee(s), and contact information (email, telephone, and mailing address).

c. A one-page statement describing how the candidate will add value to the NAC, taking into consideration current membership requirements and the candidate's unique background, experience, and perspective that will advance the conversation.

Current NAC members who wish to be reappointed to the committee must also respond to this solicitation notice.

Issued in Washington, DC.

Kimberly Noonan,

Manager, Stakeholder and Collaboration Division (A), NextGen Office of Collaboration and Messaging, ANG–M, Office of the Assistant Administrator for NextGen, Federal Aviation Administration.

[FR Doc. 2022–17680 Filed 8–16–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2012–0332; FMCSA–2013–0122; FMCSA–2013–0123; FMCSA–2013–0124; FMCSA–2015–0326; FMCSA–2015–0328; FMCSA–2015–0329; FMCSA–2016–0004; FMCSA–2017–0058; FMCSA–2017–0059; FMCSA–2017–0060; FMCSA–2017–0061; FMCSA–2018–0135; FMCSA–2018–0138]

Qualification of Drivers; Exemption Applications; Hearing

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice of renewal of exemptions; request for comments.

SUMMARY: FMCSA announces its decision to renew exemptions for 24 individuals from the hearing requirement in the Federal Motor Carrier Safety Regulations (FMCSRs) for interstate commercial motor vehicle (CMV) drivers. The exemptions enable these hard of hearing and deaf individuals to continue to operate CMVs in interstate commerce.

DATES: The exemptions are applicable on August 22, 2022. The exemptions expire on August 22, 2024. Comments must be received on or before September 16, 2022.

ADDRESSES: You may submit comments identified by the Federal Docket Management System Docket No. FMCSA–2012–0332, Docket No. FMCSA–2013–0122, Docket No. FMCSA–2013–0123, Docket No. FMCSA–2013–0124, Docket No. FMCSA–2015–0326, Docket No. FMCSA–2015–0328, Docket No. FMCSA–2015–0329, Docket No. FMCSA–2016–0004, Docket No. FMCSA–2017–0058, Docket No. FMCSA–2017–0059, Docket No. FMCSA–2017–0060, Docket No. FMCSA–2017–0061, Docket No. FMCSA–2018–0135, or Docket No. FMCSA–2018–0138 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *www.regulations.gov/,* insert the docket number, FMCSA–2012–0332, FMCSA–2013–0122, FMCSA–2013–0123, FMCSA–2013–0124, FMCSA–2015–0326, FMCSA–2015–0328, FMCSA–2015–0329, FMCSA–2016–0004, FMCSA–2017–0058, FMCSA–2017–0059, FMCSA–2017–0060, FMCSA–2017–0061, FMCSA–2018–0135, or FMCSA–2018–0138 in the keyword box, and click ''Search.'' Next, sort the results by ''Posted (Newer-Older),'' choose the first notice listed, and click on the ''Comment'' button. Follow the online instructions for submitting comments.
- *Mail:* Dockets Operations; U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal Holidays.
- *Fax:* (202) 493–2251.

To avoid duplication, please use only one of these four methods. See the ''Public Participation'' portion of the **SUPPLEMENTARY INFORMATION** section for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, DOT, 1200 New Jersey Avenue SE, Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m., ET, Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Dockets Operations, (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

A. Submitting Comments

If you submit a comment, please include the docket number for this notice (Docket No. FMCSA–2012–0332, Docket No. FMCSA–2013–0122, Docket No. FMCSA–2013–0123, Docket No. FMCSA–2013–0124, Docket No. FMCSA–2015–0326, Docket No. FMCSA–2015–0328, Docket No. FMCSA–2015–0329, Docket No. FMCSA–2016–0004, Docket No. FMCSA–2017–0058, Docket No. FMCSA–2017–0059, Docket No. FMCSA–2017–0060, Docket No. FMCSA–2017–0061, Docket No. FMCSA–2018–0135, or Docket No. FMCSA–2018–0138), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so that FMCSA can contact you if there are questions regarding your submission.

To submit your comment online, go to *www.regulations.gov/,* insert the docket number, FMCSA–2012–0332, FMCSA–2013–0122, FMCSA–2013–0123, FMCSA–2013–0124, FMCSA–2015–0326, FMCSA–2015–0328, FMCSA–2015–0329, FMCSA–2016–0004, FMCSA–2017–0058, FMCSA–2017–0059, FMCSA–2017–0060, FMCSA–2017–0061, FMCSA–2018–0135, or FMCSA–2018–0138 in the keyword box, and click ''Search.'' Next, sort the results by ''Posted (Newer-Older),'' choose the first notice listed, click the ''Comment'' button, and type your comment into the text box on the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

FMCSA will consider all comments and material received during the comment period.

B. Viewing Comments

To view comments go to *www.regulations.gov.* Insert the docket number, FMCSA–2012–0332, FMCSA–

2013–0122, FMCSA–2013–0123, FMCSA–2013–0124, FMCSA–2015–0326, FMCSA–2015–0328, FMCSA–2015–0329, FMCSA–2016–0004, FMCSA–2017–0058, FMCSA–2017–0059, FMCSA–2017–0060, FMCSA–2017–0061, FMCSA–2018–0135, or FMCSA–2018–0138 in the keyword box, and click ''Search.'' Next, sort the results by ''Posted (Newer-Older),'' choose the first notice listed, and click ''Browse Comments.'' If you do not have access to the internet, you may view the docket online by visiting Dockets Operations in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

C. Privacy Act

In accordance with 49 U.S.C. 31315(b)(6), DOT solicits comments from the public on the exemption request. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov.* As described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy,* the comments are searchable by the name of the submitter.

II. Background

Under 49 U.S.C. 31136(e) and 31315(b), FMCSA may grant an exemption from the FMCSRs for no longer than a 5-year period if it finds such exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption. The statute also allows the Agency to renew exemptions at the end of the 5-year period. FMCSA grants medical exemptions from the FMCSRs for a 2-year period to align with the maximum duration of a driver's medical certification.

The physical qualification standard for drivers regarding hearing found in 49 CFR 391.41(b)(11) states that a person is physically qualified to drive a CMV if that person first perceives a forced whispered voice in the better ear at not less than 5 feet with or without the use of a hearing aid or, if tested by use of an audiometric device, does not have an average hearing loss in the better ear greater than 40 decibels at 500 Hz, 1,000 Hz, and 2,000 Hz with or without a hearing aid when the audiometric device is calibrated to American National Standard (formerly ASA Standard) Z24.5—1951.

This standard was adopted in 1970 and was revised in 1971 to allow drivers to be qualified under this standard while wearing a hearing aid, 35 FR 6458, 6463 (Apr. 22, 1970) and 36 FR 12857 (July 3, 1971).

The 24 individuals listed in this notice have requested renewal of their exemptions from the hearing standard in § 391.41(b)(11), in accordance with FMCSA procedures. Accordingly, FMCSA has evaluated these applications for renewal on their merits and decided to extend each exemption for a renewable 2-year period.

III. Request for Comments

Interested parties or organizations possessing information that would otherwise show that any, or all, of these drivers are not currently achieving the statutory level of safety should immediately notify FMCSA. The Agency will evaluate any adverse evidence submitted and, if safety is being compromised or if continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315(b), FMCSA will take immediate steps to revoke the exemption of a driver.

IV. Basis for Renewing Exemptions

In accordance with 49 U.S.C. 31136(e) and 31315(b), each of the 24 applicants has satisfied the renewal conditions for obtaining an exemption from the hearing requirement. The 24 drivers in this notice remain in good standing with the Agency. In addition, for commercial driver's license (CDL) holders, the Commercial Driver's License Information System and the Motor Carrier Management Information System are searched for crash and violation data. For non-CDL holders, the Agency reviews the driving records from the State Driver's Licensing Agency. These factors provide an adequate basis for predicting each driver's ability to continue to safely operate a CMV in interstate commerce. Therefore, FMCSA concludes that extending the exemption for each of these drivers for a period of 2 years is likely to achieve a level of safety equal to that existing without the exemption.

As of August 22, 2022, and in accordance with 49 U.S.C. 31136(e) and 31315(b), the following 24 individuals have satisfied the renewal conditions for obtaining an exemption from the hearing requirement in the FMCSRs for interstate CMV drivers:

Mataio Brown (MS)
Robert Burnett (AZ)
Barry Carpenter (SD)
Lyle Eash (VA)
Buddy Gann (IN)
Jeremy Lampard (SC)
Michael McCarthy (MN)
Quinton Murphy (WI)
Michael Murrah (GA)
Karl Ortiz (MO)
Christopher Poole (OH)
Ricardo Porras-Payan (TX)
Kelly Pulvermacher (WI)
James Queen (FL)
James Redmond (IL)
Willine Smith (GA)
Brandon Soto (MO)
Darren Talley (NC)
Michael Tayman (ME)
Carlos Torres (FL)
Joshua Weaver (GA)
James Weir (AZ)
Joseph Woodle (KY)
Paul Wentworth (WA)

The drivers were included in docket number FMCSA–2012–0332, FMCSA–2013–0122, FMCSA–2013–0123, FMCSA–2013–0124, FMCSA–2015–0326, FMCSA–2015–0328, FMCSA–2015–0329, FMCSA–2016–0004, FMCSA–2017–0058, FMCSA–2017–0059, FMCSA–2017–0060, FMCSA–2017–0061, FMCSA–2018–0135, or FMCSA–2018–0138. Their exemptions are applicable as of August 22, 2022 and will expire on August 22, 2024.

V. Conditions and Requirements

The exemptions are extended subject to the following conditions: (1) each driver must report any crashes or accidents as defined in § 390.5; and (2) report all citations and convictions for disqualifying offenses under 49 CFR 383 and 49 CFR 391 to FMCSA; and (3) each driver prohibited from operating a motorcoach or bus with passengers in interstate commerce. The driver must also have a copy of the exemption when driving, for presentation to a duly authorized Federal, State, or local enforcement official. In addition, the exemption does not exempt the individual from meeting the applicable CDL testing requirements. Each exemption will be valid for 2 years unless rescinded earlier by FMCSA. The exemption will be rescinded if: (1) the person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315(b).

VI. Preemption

During the period the exemption is in effect, no State shall enforce any law or regulation that conflicts with this exemption with respect to a person operating under the exemption.

VII. Conclusion

Based upon its evaluation of the 24 exemption applications, FMCSA renews the exemptions of the aforementioned drivers from the hearing requirement in § 391.41(b)(11). In accordance with 49 U.S.C. 31136(e) and 31315(b), each exemption will be valid for two years unless revoked earlier by FMCSA.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2022–17678 Filed 8–16–22; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2022–0035]

Qualification of Drivers; Exemption Applications; Hearing

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice of applications for exemption; request for comments.

SUMMARY: FMCSA announces receipt of applications from 18 individuals for an exemption from the hearing requirement in the Federal Motor Carrier Safety Regulations (FMCSRs) to operate a commercial motor vehicle (CMV) in interstate commerce. If granted, the exemptions would enable these hard of hearing and deaf individuals to operate CMVs in interstate commerce.

DATES: Comments must be received on or before September 16, 2022.

ADDRESSES: You may submit comments identified by the Federal Docket Management System Docket No. FMCSA–2022–0035 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *www.regulations.gov/,* insert the docket number, FMCSA–2022–0035, in the keyword box, and click ''Search.'' Next, sort the results by ''Posted (Newer-Older),'' choose the first notice listed, and click on the ''Comment'' button. Follow the online instructions for submitting comments.
- *Mail:* Dockets Operations; U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal Holidays.
- *Fax:* (202) 493–2251.

To avoid duplication, please use only one of these four methods. See the ''Public Participation'' portion of the **SUPPLEMENTARY INFORMATION** section for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, DOT, 1200 New Jersey Avenue SE, Room W64–224, Washington, DC 20590–0001. Office hours are 8:30 a.m. to 5 p.m., ET, Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Dockets Operations, (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

A. Submitting Comments

If you submit a comment, please include the docket number for this notice (Docket No. FMCSA–2022–0035), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so that FMCSA can contact you if there are questions regarding your submission.

To submit your comment online, go to *www.regulations.gov/docket?D=FMCSA-2022-0035*. Next, sort the results by ''Posted (Newer-Older),'' choose the first notice listed, click the ''Comment'' button, and type your comment into the text box on the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

FMCSA will consider all comments and material received during the comment period.

B. Viewing Comments

To view comments go to *www.regulations.gov*. Insert the docket number, FMCSA–2022–0035, in the keyword box, and click ''Search.'' Next, sort the results by ''Posted (Newer-Older),'' choose the first notice listed, and click ''Browse Comments.'' If you do not have access to the internet, you may view the docket online by visiting Dockets Operations in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

C. Privacy Act

In accordance with 49 U.S.C. 31315(b)(6), DOT solicits comments from the public on the exemption request. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov*. As described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy,* the comments are searchable by the name of the submitter.

II. Background

Under 49 U.S.C. 31136(e) and 31315(b), FMCSA may grant an exemption from the FMCSRs for no longer than a 5-year period if it finds such exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption. The statute also allows the Agency to renew exemptions at the end of the 5-year period. FMCSA grants medical exemptions from the FMCSRs for a 2-year period to align with the maximum duration of a driver's medical certification.

The 18 individuals listed in this notice have requested an exemption from the hearing requirement in 49 CFR 391.41(b)(11). Accordingly, the Agency will evaluate the qualifications of each applicant to determine whether granting the exemption will achieve the required level of safety mandated by statute.

The physical qualification standard for drivers regarding hearing found in § 391.41(b)(11) states that a person is physically qualified to drive a CMV if that person first perceives a forced whispered voice in the better ear at not less than 5 feet with or without the use of a hearing aid or, if tested by use of an audiometric device, does not have an average hearing loss in the better ear greater than 40 decibels at 500 Hz, 1,000 Hz, and 2,000 Hz with or without a hearing aid when the audiometric device is calibrated to American National Standard (formerly ASA Standard) Z24.5—1951.

This standard was adopted in 1970 and was revised in 1971 to allow drivers to be qualified under this standard

while wearing a hearing aid, 35 FR 6458, 6463 (Apr. 22, 1970) and 36 FR 12857 (July 3, 1971).

On February 1, 2013, FMCSA announced in a Notice of Final Disposition titled, ''Qualification of Drivers; Application for Exemptions; National Association of the Deaf,'' (78 FR 7479), its decision to grant requests from 40 individuals for exemptions from the Agency's physical qualification standard concerning hearing for interstate CMV drivers. Since that time the Agency has published additional notices granting requests from hard of hearing and deaf individuals for exemptions from the Agency's physical qualification standard concerning hearing for interstate CMV drivers.

III. Qualifications of Applicants

Stephen Arellano

Mr. Arellano, 44, holds a class R driver's license in Colorado.

Hagop Balian

Mr. Baliam, 22, holds a class D driver's license in Illinois.

Michael Clark

Mr. Clark, 56, holds a commercial driver's license in Maryland.

Jeremy Earl

Mr. Earl, 39, holds a class DM driver's license in Illinois.

James Hall

Mr. Hall, 45, holds a class D commercial driver's license in Mississippi.

Arnold Heyen

Mr. Heyen, 56, holds a class A commercial driver's license in Nebraska.

Omar Ibrahim

Mr. Ibrahim, 41, holds a class D driver's license in Minnesota.

Majuong Kojiza

Mr. Kojiza, 40, holds a class R driver's license in Colorado.

Peter Mannella

Mr. Mannella, 57, holds a class A commercial driver's license in Washington.

Jay Manns

Mr. Manns, 41, holds a class C driver's license in Pennsylvania.

Matthew Moyer

Mr. Moyer, 38, holds a class CM driver's license in Pennsylvania.

Ismail Muse

Mr. Muse, 25, holds a class D driver's license in Utah.

Dax Nutt

Mr. Nutt, 45, holds a class CM driver's license in Texas.

Michael Piirainen

Mr. Piirainen, 45, holds a class A driver's license in Maine.

Jeremy Stockman

Mr. Stockman, 33, holds a class C driver's license in Kansas.

Zander Symansky

Mr. Symansky, 21, holds a class C driver's license in Kansas.

Dalton Taylor

Mr. Taylor, 31, holds a class D driver's license in Oklahoma.

Jorge Toledo

Mr. Toledo, 57, holds a class A commercial driver's license in Florida.

IV. Request for Comments

In accordance with 49 U.S.C. 31136(e) and 31315(b), FMCSA requests public comment from all interested persons on the exemption petitions described in this notice. We will consider all comments received before the close of business on the closing date indicated under the **DATES** section of the notice.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2022–17677 Filed 8–16–22; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

[Docket No. PHMSA–2019–0202]

Pipeline Safety: Request for Special Permit; Columbia Gas Transmission, LLC

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA); DOT.

ACTION: Notice.

SUMMARY: PHMSA is publishing this notice to solicit public comments on a request for special permit received from Columbia Gas Transmission, LLC (TCO). The special permit request is seeking relief from compliance with certain requirements of the Federal pipeline safety regulations. At the conclusion of the 30-day comment period, PHMSA will review the comments received from this notice as part of its evaluation to grant or deny the special permit request.

DATES: Submit any comments regarding this special permit request by September 16, 2022.

ADDRESSES: Comments should reference the docket number for this special permit request and may be submitted in the following ways:

- *E-Gov Website: http://www.Regulations.gov.* This site allows the public to enter comments on any **Federal Register** notice issued by any agency.
- *Fax:* 1–202–493–2251.
- *Mail:* Docket Management System: 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:* Docket Management System: U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays.

Instructions: You should identify the docket number for the special permit request you are commenting on at the beginning of your comments. If you submit your comments by mail, please submit two (2) copies. To receive confirmation that PHMSA has received your comments, please include a self-addressed stamped postcard. Internet users may submit comments at *http://www.Regulations.gov.*

Note: There is a privacy statement published on *http://www.Regulations.gov.* Comments, including any personal information provided, are posted without changes or edits to *http://www.Regulations.gov.*

Confidential Business Information: 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 notice 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 notice, it is important that you clearly designate the submitted comments as CBI. Pursuant to 49 Code of Federal Regulations (CFR) 190.343, you may ask PHMSA to give confidential treatment to information you give to the agency by taking the following steps: (1) mark each page of the original document submission containing CBI as ''Confidential''; (2) send PHMSA, along with the original document, a second copy of the original document with the CBI deleted; and (3) explain why the information you are submitting is CBI.

Unless you are notified otherwise, PHMSA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this notice. Submissions containing CBI should be sent to Kay McIver, DOT, PHMSA–PHP–80, 1200 New Jersey Avenue SE, Washington, DC 20590–0001. Any commentary PHMSA receives that is not specifically designated as CBI will be placed in the public docket for this matter.

FOR FURTHER INFORMATION CONTACT:

General: Ms. Kay McIver by telephone at 202–366–0113, or by email at *kay.mciver@dot.gov*.

Technical: Mr. Steve Nanney by telephone at 713–272–2855, or by email at *steve.nanney@dot.gov*.

SUPPLEMENTARY INFORMATION: PHMSA received a special permit request on June 22, 2022, from TCO, a subsidiary of TC Energy, Inc., seeking a waiver for two (2) pipeline segments from the requirements of 49 CFR 192.611(a) and (d): Change in class location: Confirmation or revision of maximum allowable operating pressure, and 49 CFR 192.619(a): Maximum allowable operating pressure: Steel or plastic pipelines. The requested pipeline segments are proposed to be added to special permit Docket Number PHMSA–2019–0202, due to the pipeline segments being located within the inspection area of this existing special permit.

This special permit is being requested in lieu of pipe replacement, pressure reduction, or new pressure tests for a Class 1 to 3 location change on two (2) gas transmission pipeline segments totaling 1,651.00 feet (approximately 0.313 miles). These pipeline segments, which have changed from a Class 1 to a Class 3 location, are as follows:

New special permit segment	County, state	Outside diameter (inches)	Line name	Length (feet)	Year installed	Maximum allowable operating pressure (pounds per square inch gauge)
1	Loudoun, VA	30	VC	481.00	1962	898
2	Montgomery, MD	30	MC	1,170.00	1962	898

The special permit request, proposed special permit with conditions, and draft environmental assessment (DEA) for the above listed TCO pipeline segments are available for review and public comments in Docket No. PHMSA–2019–0202. PHMSA invites interested persons to review and submit comments on the special permit request and DEA in the docket. Please include any comments on potential safety and environmental impacts that may result if the special permit is granted. Comments may include relevant data.

Before issuing a decision on the special permit request, PHMSA will evaluate all comments received on or before the comments closing date. Comments received after the closing date will be evaluated, if it is possible to do so without incurring additional expense or delay. PHMSA will consider each relevant comment it receives in making its decision to grant or deny this special permit request.

Issued in Washington, DC, on August 11, 2022, under authority delegated in 49 CFR 1.97.

Alan K. Mayberry,

Associate Administrator for Pipeline Safety.

[FR Doc. 2022–17688 Filed 8–16–22; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

[Docket No. PHMSA–2019–0201]

Pipeline Safety: Request for Special Permit; Columbia Gulf Transmission, LLC

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA); DOT.

ACTION: Notice.

SUMMARY: PHMSA is publishing this notice to solicit public comments on a request for special permit received from Columbia Gulf Transmission, LLC (CGT). The special permit request is seeking relief from compliance with certain requirements of the Federal pipeline safety regulations. At the conclusion of the 30-day comment period, PHMSA will review the comments received from this notice as part of its evaluation to grant or deny the special permit request.

DATES: Submit any comments regarding this special permit request by September 16, 2022.

ADDRESSES: Comments should reference the docket number for this special permit request and may be submitted in the following ways:

- *E-Gov Website: http://www.Regulations.gov.* This site allows the public to enter comments on any **Federal Register** notice issued by any agency.
- *Fax:* 1–202–493–2251.
- *Mail:* Docket Management System: 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: Docket Management System:* U.S. Department of Transportation, Docket Operations, M–30, West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays.

Instructions: You should identify the docket number for the special permit request you are commenting on at the beginning of your comments. If you submit your comments by mail, please submit two (2) copies. To receive confirmation that PHMSA has received your comments, please include a self-addressed stamped postcard. Internet users may submit comments at *http://www.Regulations.gov*.

Note: There is a privacy statement published on *http://www.Regulations.gov*. Comments, including any personal information provided, are posted without changes or edits to *http://www.Regulations.gov*.

Confidential Business Information: 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 notice 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 notice, it is important that you clearly designate the submitted comments as CBI. Pursuant to 49 Code of Federal Regulations (CFR) 190.343, you may ask PHMSA to give confidential treatment to information you give to the agency by taking the following steps: (1) mark each page of the original document submission containing CBI as ''Confidential''; (2) send PHMSA, along with the original document, a second copy of the original document with the CBI deleted; and (3) explain why the information you are submitting is CBI. Unless you are notified otherwise, PHMSA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this notice.

Submissions containing CBI should be sent to Kay McIver, DOT, PHMSA–PHP–80, 1200 New Jersey Avenue SE, Washington, DC 20590–0001. Any commentary PHMSA receives that is not specifically designated as CBI will be placed in the public docket for this matter.

FOR FURTHER INFORMATION CONTACT:

General: Ms. Kay McIver by telephone at 202–366–0113, or by email at *kay.mciver@dot.gov*.

Technical: Mr. Steve Nanney by telephone at 713–272–2855, or by email at *steve.nanney@dot.gov*.

SUPPLEMENTARY INFORMATION: PHMSA received a special permit request on June 22, 2022, from CGT, a subsidiary of TC Energy, Inc., seeking a waiver for two (2) pipeline segments from the requirements of 49 CFR 192.611(a) and (d): Change in class location: Confirmation or revision of maximum allowable operating pressure, and 49 CFR 192.619(a): Maximum allowable operating pressure: Steel or plastic pipelines. The requested pipeline segments are proposed to be added to special permit Docket Number PHMSA–2019–0201, due to the pipeline segments being located within the inspection areas of this existing special permit.

This special permit is being requested in lieu of pipe replacement, pressure reduction, or new pressure tests for a Class 1 to 3 location change on two (2) gas transmission pipeline segments totaling 3,806.00 feet (approximately 0.721 miles). These pipeline segments, which have changed from a Class 1 to a Class 3 location, are as follows:

New special permit segment	County/parish, state	Outside diameter (inches)	Line name	Length (feet)	Year installed	Maximum allowable operating pressure (pounds per square inch gauge)
1	Vermillion, LA	24	EL 200	953.00	1954	973
2	Rowan, KY	30	ML 100	2,853.00	1954	935

The special permit request, proposed special permit with conditions, and draft environmental assessment (DEA) for the above listed CGT pipeline segments are available for review and public comments in Docket No. PHMSA–2019–0201. PHMSA invites interested persons to review and submit comments on the special permit request and DEA in the docket. Please include any comments on potential safety and environmental impacts that may result if the special permit is granted. Comments may include relevant data.

Before issuing a decision on the special permit request, PHMSA will evaluate all comments received on or before the comments closing date. Comments received after the closing date will be evaluated, if it is possible to do so without incurring additional expense or delay. PHMSA will consider each relevant comment it receives in making its decision to grant or deny this special permit request.

Issued in Washington, DC on August 11, 2022, under authority delegated in 49 CFR 1.97.

Alan K. Mayberry,

Associate Administrator for Pipeline Safety.

[FR Doc. 2022–17690 Filed 8–16–22; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

[Docket No. PHMSA–2022–0084]

Pipeline Safety: Request for Special Permit; Columbia Gulf Transmission, LLC

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA); DOT.

ACTION: Notice.

SUMMARY: PHMSA is publishing this notice to solicit public comments on a request for special permit received from Columbia Gulf Transmission, LLC (CGT). The special permit request is seeking relief from compliance with certain requirements of the Federal pipeline safety regulations. At the conclusion of the 30-day comment period, PHMSA will review the comments received from this notice as part of its evaluation to grant or deny the special permit request.

DATES: Submit any comments regarding this special permit request by September 16, 2022.

ADDRESSES: Comments should reference the docket number for this special permit request and may be submitted in the following ways:

- *E-Gov Website: http://www.Regulations.gov*. This site allows the public to enter comments on any **Federal Register** notice issued by any agency.
- *Fax:* 1–202–493–2251.
- *Mail:* Docket Management System: 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:* Docket Management System: U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays.

Instructions: You should identify the docket number for the special permit request you are commenting on at the beginning of your comments. If you submit your comments by mail, please submit two (2) copies. To receive confirmation that PHMSA has received your comments, please include a self-addressed stamped postcard. Internet users may submit comments at *http://www.Regulations.gov*.

Note: There is a privacy statement published on *http://www.Regulations.gov*. Comments, including any personal information provided, are posted without

changes or edits to *http://www.Regulations.gov*.

Confidential Business Information: 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 notice 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 notice, it is important that you clearly designate the submitted comments as CBI. Pursuant to 49 Code of Federal Regulations (CFR) 190.343, you may ask PHMSA to give confidential treatment to information you give to the agency by taking the following steps: (1) mark each page of the original document submission containing CBI as ''Confidential''; (2) send PHMSA, along with the original document, a second copy of the original document with the CBI deleted; and (3) explain why the information you are submitting is CBI. Unless you are notified otherwise, PHMSA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this notice. Submissions containing CBI should be sent to Kay McIver, DOT, PHMSA–PHP–80, 1200 New Jersey Avenue SE, Washington, DC 20590–0001. Any commentary PHMSA receives that is not specifically designated as CBI will be placed in the public docket for this matter.

FOR FURTHER INFORMATION CONTACT:

General: Ms. Kay McIver by telephone at 202–366–0113, or by email at *kay.mciver@dot.gov*.

Technical: Mr. Steve Nanney by telephone at 713–272–2855, or by email at *steve.nanney@dot.gov*.

SUPPLEMENTARY INFORMATION: PHMSA received a special permit request on June 22, 2022, from CGT, a subsidiary of TC Energy, Inc., seeking a waiver from the requirements of 49 CFR 192.611(a) and (d): Change in class location: Confirmation or revision of maximum allowable operating pressure, and 49 CFR 192.619(a): Maximum allowable operating pressure: Steel or plastic pipelines.

This special permit is being requested in lieu of pipe replacement, pressure reduction, or new pressure tests for a Class 1 to 3 location change on seven (7) gas transmission pipeline segments totaling 41,265.00 feet (approximately 7.815 miles). These pipeline segments, which have changed from a Class 1 to a Class 3 location, are as follows:

Special permit segment No.	County, state	Outside diameter (inches)	Line name	Length (feet)	Year installed	Maximum allowable operating pressure (pounds per square inch gauge)
1	Madison, KY	30	ML 100	6,600.00	1954	935
2	Madison, KY	30	ML 200	6,500.00	1963/1964	1,007
3	Madison, KY	36	ML 300	7,450.00	1970	1,007
4	Madison, KY	36	ML 300	165.00	1970	1,007
5	Madison, KY	30	ML 100	6,800.00	1954	935
6	Madison, KY	30	ML 200	6,850.00	1963/1964	1,007
7	Madison, KY	36	ML 300	6,900.00	1970	1,007

The special permit request, proposed special permit with conditions, and draft environmental assessment (DEA) for the above listed CGT pipeline segments are available for review and public comments in Docket No. PHMSA–2022–0084. PHMSA invites interested persons to review and submit comments on the special permit request and DEA in the docket. Please include any comments on potential safety and environmental impacts that may result if the special permit is granted. Comments may include relevant data.

Before issuing a decision on the special permit request, PHMSA will evaluate all comments received on or before the comments closing date. Comments received after the closing date will be evaluated, if it is possible to do so without incurring additional expense or delay. PHMSA will consider each relevant comment it receives in making its decision to grant or deny this special permit request.

Issued in Washington, DC, on August 11, 2022, under authority delegated in 49 CFR 1.97.

Alan K. Mayberry,

Associate Administrator for Pipeline Safety.

[FR Doc. 2022–17689 Filed 8–16–22; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF THE TREASURY

Bureau of the Fiscal Service

Proposed Collection of Information: FHA New Account Request, Transition Request, and Transfer Request

AGENCY: Bureau of the Fiscal Service, Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. Currently the Bureau of the Fiscal Service within the Department of the Treasury is soliciting comments concerning the collections of information required to comply with the terms and conditions of FHA New Account Request, Transition Request, and Transfer Request.

DATES: Written comments should be received on or before October 17, 2022 to be assured of consideration.

ADDRESSES: Direct all written comments and requests for additional information to Bureau of the Fiscal Service, Bruce A. Sharp, Room #4006–A, P.O. Box 1328, Parkersburg, WV 26106–1328, or *bruce.sharp@fiscal.treasury.gov*.

SUPPLEMENTARY INFORMATION:

Title: FHA New Account Request, Transition Request, and Transfer Request.

OMB Number: 1530–0054.

Form Numbers and Titles: FS Form 5354—FHA Transaction Request, FS Form 5366—FHA New Account Request, FS Form 5367—FHA Debenture Transfer Request.

Abstract: The information is used to (1) establish a book-entry account; (2) change information on a book-entry

account; and (3) transfer ownership of a book-entry account on the HUD system, maintained by the Federal Reserve Bank of Philadelphia.

Current Actions: Extension of a currently approved collection.

Type of Review: Regular.

Affected Public: Individuals or Households.

Estimated Number of Respondents: 300.

Estimated Time per Respondent: 10 minutes.

Estimated Total Annual Burden Hours: 50.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: 1. Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; 2. the accuracy of the agency's estimate of the burden of the collection of information; 3. ways to enhance the quality, utility, and clarity of the information to be collected; 4. ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and 5. estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: August 12, 2022.

Bruce A. Sharp,

Bureau PRA Clearance Officer.

[FR Doc. 2022–17682 Filed 8–16–22; 8:45 am]

BILLING CODE 4810–AS–P

DEPARTMENT OF THE TREASURY

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Departmental Offices Information Collection Requests

AGENCY: Departmental Offices, 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 should be received on or before September 16, 2022 to be assured of consideration.

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 Melody Braswell by emailing *PRA@treasury.gov,* calling (202) 622–1035, or viewing the entire information collection request at *www.reginfo.gov.*

SUPPLEMENTARY INFORMATION:

Title: Application, Reports, Post-Award Actions, and Recordkeeping for the Direct Component and the Centers of Excellence Research Grants Program under the RESTORE Act.

OMB Control Number: 1505–0250.

Type of Review: Revision of a currently approved collection.

Description: The Department of the Treasury administers the Direct Component and the Centers of Excellence Research Grants Program authorized under the RESTORE Act. Treasury awards grants for these two programs from proceeds in connection with administrative and civil penalties paid after July 6, 2012, under the Federal Water Pollution Control Act relating to the *Deepwater Horizon* Oil Spill and deposited into the Gulf Coast Restoration Trust Fund. Direct Component grants are awarded to the States of Alabama, Louisiana, Mississippi, and Texas, and 23 Florida counties and 20 Louisiana parishes and Centers of Excellence grants are awarded to the States of Alabama, Florida, Louisiana, Mississippi, and Texas. The information collection for both programs identify the eligible recipients; describes proposed activities; determines an appropriate amount of funding; ensures compliance with the RESTORE Act, Treasury's regulations, and Federal laws and policies on grants; tracks grantee progress; provides for approvals of post-award actions; and reports on the effectiveness of the programs. Treasury's transition in Fiscal Year 23 of both RESTORE Act programs to a new online grants management system will provide the benefit of conversion to more interactive forms, like web-based forms or editable PDFs. The collection has been updated to provide for this transition.

Affected Public: State, Local, or Tribal Governments.

Estimated Number of Respondents: 48.

Estimated Annual Responses: 498.

Frequency of Response: On Occasion.

Estimated Total Annual Burden Hours: 5,979.

Estimated Total Cost: $298,950.

Authority: 44 U.S.C. 3501 *et seq.*

Melody Braswell,

Treasury PRA Clearance Officer.

[FR Doc. 2022–17648 Filed 8–16–22; 8:45 am]

BILLING CODE 4810–AK–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–NEW]

Agency Information Collection Activity: GI Bill Comparison Tool Ratings Survey

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the Veterans Benefits Administration (VBA), Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden and it includes the actual data collection instrument.

DATES: 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. Refer to ''OMB Control No. 2900–NEW.

FOR FURTHER INFORMATION CONTACT: Maribel Aponte, Office of Enterprise and Integration, Data Governance Analytics (008), 810 Vermont Ave. NW, Washington, DC 20006, (202) 266–4688 or email *maribel.aponte@va.gov.* Please refer to ''OMB Control No. 2900–NEW'' in any correspondence.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct

or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Authority: Executive Order 12862; Paperwork Reduction Act of 1995 Section 3507.

Title: GI Bill Comparison Tool Ratings Survey, No Form.

OMB Control Number: 2900–NEW.

Type of Review: New Information Collection.

Abstract: The Comparison Tool Survey submitted for OMB's approval through regular ICR 3-year collection for the Collection of Qualitative Feedback on Agency Service Delivery'' is being submitted to Veterans and eligible beneficiaries who recently graduated from college. The sampled customers will be contacted through an invitation email. A link will be enclosed so the survey may be completed using an online interface, with customized customer information. The survey itself consists of a handful of questions revolving around a human-centered design, focusing on such elements as trust, emotion, effective, and ease with the services and educational care they received. The information provided will be used by VA to measure how recent graduates who used the GI Bill feel about the institution they attended, and the education they received. This includes quality of classes, in person versus online learning, GI Bill support (or supportiveness of school certifying officials), degree of support for the Veteran community at the institution, and overall experience. This ICR survey collection will be sent via, email. Without this type of feedback from the Survey, VA will not have timely information to adjust its services to meet customer needs.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at 87 FR 113 on June 13, 2022, page 35851.

Affected Public: Individuals and households.

Estimated Annual Burden: 118 hours.

Estimated Average Burden per Respondent: 5 minutes.

Frequency of Response: Twice Annually.

Estimated Number of Respondents: 1416.

By direction of the Secretary.

Maribel Aponte,

VA PRA Clearance Officer, Office of Enterprise and Integration/Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2022–17674 Filed 8–16–22; 8:45 am]

BILLING CODE 8320–01–P

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Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 800, 801, *et al.*

Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 800, 801, 808, and 874

[Docket No. FDA–2021–N–0555]

RIN 0910–AI21

Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, we, or the Agency) is establishing a regulatory category for over-the-counter (OTC) hearing aids and making related amendments to update the regulatory framework for hearing aids. Specifically, we define OTC hearing aids and establish applicable requirements; amend existing rules for consistency with the new OTC category; repeal the conditions for sale applicable to hearing aids; amend the existing labeling requirements for hearing aids; and update regulations relating to decisions on applications for exemption from Federal preemption that will become obsolete as a result of changes to the hearing aid requirements. In creating a regulatory category for OTC hearing aids and amending existing rules, we intend to provide reasonable assurance of safety and effectiveness for these devices as well as foster access to, and innovation in, hearing aid technology, thereby protecting and promoting the public health.

DATES:

Effective date: This rule is effective October 17, 2022.

Compliance dates: For hearing aids that have been legally offered for sale prior to October 17, 2022, including hearing aids that already have a 510(k) clearance, compliance with the new or revised requirements must be achieved by April 14, 2023. For hearing aids that have not been offered for sale prior to October 17, 2022, or have been offered for sale but are required to submit a new 510(k) due to changes unrelated to this rule, compliance with the new or revised requirements applicable to the hearing aid, and obtaining 510(k) clearance if applicable, must be achieved before marketing the device on or after October 17, 2022.

Incorporation by reference: The incorporation by reference of certain material listed in this rule is approved by the Director of the Federal Register as of October 17, 2022.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this final rule, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT:

With regard to the final rule: Srinivas Nandkumar, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–6480, *Srinivas.Nandkumar@fda.hhs.gov.*

With regard to the information collection: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary

A. Purpose of the Final Rule

Hearing loss affects an estimated 30 million people in the United States and can have a significant impact on communication, social participation, and overall health and quality of life. Despite the high prevalence and public health impact of hearing loss, only about one-fifth of people who could benefit from a hearing aid seek intervention. Several barriers likely impede the use of hearing aids in hearing-impaired individuals such as high cost, stigma of being perceived as old or debilitated, and value (perceived hearing benefit relative to price). FDA is finalizing rules to address some of these concerns.

Moreover, the FDA Reauthorization Act of 2017 (FDARA) (Pub. L. 115–52) directs FDA to establish a category of OTC hearing aids through rulemaking, and FDARA sets forth various requirements for OTC hearing aids, including for reasonable assurance of safety and effectiveness, as well as Federal preemption provisions. In addition to protecting and promoting the public health, these rules establish the OTC category and implement the requirements of FDARA.

B. Summary of the Major Provisions of the Final Rule

FDA is establishing a regulatory category for OTC hearing aids to improve access to hearing aid technology for Americans. OTC hearing aids are intended to address perceived mild to moderate hearing loss in people aged 18 or older. Along with the OTC category, we are finalizing multiple related changes to the overall regulatory framework for hearing aids to harmonize existing rules with the new OTC category. We have determined that the requirements set forth in this rulemaking will protect the public health by providing reasonable assurance of safety and effectiveness for hearing aids, as well as promote the hearing health of Americans by lowering barriers to access and fostering innovation in hearing aid technology.

Among other things, FDARA amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by defining OTC hearing aids and providing the authorities to establish the OTC category of hearing aids among provisions that are, by definition, general controls. We are finalizing general controls for OTC hearing aids consistent with FDARA.

We are finalizing lower output limits than we proposed but have not substantially changed the other electroacoustic performance requirements for OTC hearing aids. We have simplified the phrasing throughout the required labeling and have restated the maximum insertion depth for OTC hearing aids in terms of a fixed measurement. However, we are not realigning the air-conduction hearing aid classification regulations as proposed.

This rulemaking also affects other regulations that applied to hearing aids. FDA had established device restrictions for hearing aids that included labeling requirements as well as conditions for sale. We are removing these device restrictions for hearing aids and establishing a new regulation for prescription hearing aid labeling. Further, FDA had by regulation granted or denied exemptions from Federal preemption for State requirements pertaining to hearing aids. The removal of the device restrictions on hearing aids, as well as certain provisions of FDARA, impact most of these previous exemption decisions, for example, by altering their scope. We are removing the regulations codifying these decisions and establishing other regulations clarifying some of the effects of statutory preemption under FDARA.

C. Legal Authority

The FD&C Act establishes a comprehensive system for the regulation of devices intended for human use. Hearing aids are devices intended for human use and so are subject to, among other requirements, the device provisions of the FD&C Act. FDA has authority to establish regulatory controls needed to provide reasonable assurance of safety and effectiveness for these devices. As such, FDA is establishing regulatory controls for OTC hearing aids and amending regulatory controls for prescription hearing aids. Moreover, the FD&C Act directs the establishment of an electronic radiation control program, and hearing aids and personal sound amplification products (PSAPs) are electronic products, subject to the electronic radiation control requirements.

Specific to OTC hearing aids, the FD&C Act and FDARA authorize multiple controls, including authority for FDA to establish requirements for device labeling, output limits, conditions for sale and distribution, and other requirements that provide reasonable assurance of safety and effectiveness of OTC hearing aids. FDARA specifically directs FDA to establish a category of OTC hearing aids by regulation that must include the aforementioned requirements.

More generally, the FD&C Act further provides for labeling requirements as general controls such that devices (and other medical products) will not be misbranded. The FD&C Act also authorizes FDA to issue regulations for the efficient enforcement of the FD&C Act. We are establishing the following regulations pursuant to these authorities and to fulfill the directive under FDARA.

Additionally, both the FD&C Act and FDARA include preemption provisions applicable to hearing aids.

D. Costs and Benefits

This rule to establish OTC hearing aids and align other regulations generates potential cost savings for consumers with perceived mild to moderate hearing impairment who wish to buy lower cost hearing aids not bundled with professional services and not requiring professional advice, fitting, adjustment, or maintenance but who are currently unable to buy such products online because of State regulations or because they do not shop online. This rule also generates costs for hearing aid manufacturers for changing labeling of existing hearing aids as well as for reading the rule and revising internal standard operating procedures in response to the rule. We estimate benefits of between $6 million and $147 million per year based on 5th and 95th percentile Monte Carlo results with a mean of $63 million per year. We estimate annualized costs of between $1 million and $2 million per year based on 5th and 95th percentile Monte Carlo results with a mean of $1 million per year. Combining benefits and costs, we used Monte Carlo analysis to estimate annualized net benefits of between $5 million and $145 million per year based on the 5th and 95th Monte Carlo percentile results with a mean of $62 million per year at both 3 percent and 7 percent discount rates.

II. Table of Abbreviations and Acronyms Commonly Used in This Document

Abbreviation/acronym	What it means
510(k)	A premarket notification for certain devices.
ANSI	American National Standards Institute.
APA	Administrative Procedure Act.
ASA	Acoustical Society of America.
ASHA	American Speech-Language-Hearing Association.
CDRH	Center for Devices and Radiological Health.
CFR	Code of Federal Regulations.
cm^3	Centimeter cubed (cubic centimeter).
CTA	Consumer Technology Association.
dB	Decibel.
dBA	A-weighted decibel.
EA	Environmental assessment.
ENT	Ear-Nose-Throat.
FDA	Food and Drug Administration.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
FDARA	FDA Reauthorization Act of 2017.
FONSI	Finding of no significant impact.
FR	Federal Register.
FRIA	Final Regulatory Impact Analysis.
IQA	Information Quality Act.
ISO	International Organization for Standardization.
ITU	International Telecommunication Union.
mm	Millimeter.
ms	Millisecond.

Abbreviation/acronym	What it means
MSW	Municipal solid waste.
NASEM	National Academies of Sciences, Engineering, and Medicine.
NIOSH	National Institute for Occupational Safety and Health.
OMB	Office of Management and Budget.
OSPL90	Output sound pressure level with 90-dB input.
OTC	Over-the-counter.
PRA	Paperwork Reduction Act of 1995.
PSAP	Personal sound amplification product.
Pub. L	Public Law.
RMS	Root mean square.
SPL	Sound pressure level.
U.S.C	United States Code.
WHO	World Health Organization.

III. Background

FDA is defining and establishing general controls for an OTC category of hearing aids. We intend these controls to provide for reasonable assurance of safety and effectiveness for these devices, thereby protecting the public health. We also intend these controls to help improve access to and foster innovation in hearing aid technology for Americans, thereby promoting the public health. We are making various other revisions, as described in this document, to align existing regulations with statutory requirements and the new OTC category.

For brevity, we will use the following terms as shorthand in this document: ''Over-the-Counter Hearing Aid Controls'' for the general controls for OTC hearing aids that we are finalizing under § 800.30 (21 CFR 800.30).

''Commercial activity involving OTC hearing aids'' to refer to any or all of the following activities: servicing, marketing, sale, dispensing, use, customer support, or distribution of OTC hearing aids through in-person transactions, by mail, or online.

''Customizable'' or ''customization,'' unless otherwise noted, to refer to the elements of the statutory definition for OTC hearing aids described in section 520(q)(1)(A)(iii) and (iv) of the FD&C Act (21 U.S.C. 360j(q)(1)(A)(iii) and (iv)). That is, for the purposes of this document, a customizable hearing aid is one that, through tools, tests, or software, allows the user to control the hearing aid and customize it to the user's hearing needs. To do so, the hearing aid may use wireless technology or include tests for self-assessment of hearing loss. (See also the response to Comment 1 explaining customization in more technical terms.)

''Involvement of a licensed person'' to refer to the supervision, prescription, or other order, involvement, or intervention of a licensed person.

''State or local requirement'' to refer to any State or local law, regulation, order, or other requirement.

A. Need for the Regulation

Hearing loss affects an estimated 30 million people in the United States and can have a significant impact on communication, social participation, and overall health and quality of life (Refs. 1 and 2). Despite the high prevalence and public health impact of hearing loss, only about one-fifth of people who could benefit from a hearing aid seek intervention (Ref. 3). The use of hearing aids has been linked to, among other health benefits, reductions in the incidence or severity of cognitive decline, depression, and other health problems in older adults (Refs. 2, 4, and 5). Additionally, benefits of hearing aid use can include improved social participation and a better quality of life.

Besides health benefits for individuals, more-widespread adoption of hearing aids could have broader effects. By increasing social participation, hearing aids could help to improve inclusion of individuals in family, economic, civic, and religious life. Thus, reducing barriers to hearing aid access might contribute to such improvements. This could be particularly true for people of color, rural Americans, low-income individuals, and others for whom barriers to hearing aid access may be especially burdensome.

Several barriers likely impede the use of hearing aids in hearing-impaired individuals such as high cost, stigma of being perceived as old or debilitated, and value (perceived hearing benefit relative to price) (Ref. 6). FDA is finalizing rules to address some of these concerns.

Moreover, section 709 of FDARA directs FDA to establish a category of OTC hearing aids through rulemaking, and sets forth various requirements for OTC hearing aids, including for reasonable assurance of safety and effectiveness, as well as Federal preemption provisions. In addition to protecting and promoting the public health, these rules establish the OTC category and implement the requirements of FDARA.

B. History of This Rulemaking and Public Participation

On October 20, 2021, in the **Federal Register**, FDA proposed multiple regulatory changes, including proposing requirements for OTC hearing aids, that would serve to provide reasonable assurance of safety and effectiveness of hearing aids, address barriers to access to hearing aids, and effectuate the requirements of section 709 of FDARA (86 FR 58150). Although the October 2021 proposal was the first step in this rulemaking, the proposal followed other steps FDA had already taken to initiate an update of the regulatory framework for hearing aids. Please refer to the aforementioned issue of the **Federal Register** for further details on the proposal and other steps taken by FDA.

We received more than 1,000 comments on the proposed rule by the close of the comment period, which was January 18, 2022. Commenters included consumers, professionals, professional associations, hearing aid manufacturers, public health organizations, public advocacy groups, members of Congress, and State agencies. We describe and respond to the comments in section V of this document. We have grouped similar comments together under the same number, and in some cases, we have separated different issues discussed in the same comment and designated them as distinct comments for purposes of our responses. The number assigned to each comment or comment topic is purely for organizational purposes and does not signify the comment's value or importance or the order in which we received comments.

C. Summary of Changes Between Proposed and Final Rules

In response to comments, we have made (and declined) a number of changes for the final rule. The following summarizes the outcomes that may be of greatest interest to readers:

Output limits. We are finalizing lower output limits than we proposed. The general limit will be 111 decibels of sound pressure level (dB SPL), with 117 dB SPL allowable for devices while input-controlled compression is activated.

Gain limit. We did not propose, and are not finalizing, a separate gain limit.

Design requirements. We have revised the allowable insertion depth. The most medial (innermost) component of an OTC hearing aid must be reasonably expected to remain at least 10 millimeters (mm) from the tympanic membrane (eardrum). We are also requiring that all OTC hearing aids have a user-adjustable volume control.

Labeling. We have improved phrasing throughout the labeling to make it more understandable for hearing aid users (non-experts).

Conditions for sale. We are not requiring age verification for the sale of OTC hearing aids. Prescription hearing aid sales will be subject to the requirements in § 801.109 (21 CFR 801.109), including that they be sold only to or on the prescription or other order of a practitioner licensed by law to use or order the use of (prescribe) the devices (which is as proposed).

Scope and definitions. Perceived mild to moderate hearing impairment remains the scope of the intended use of OTC hearing aids, and we are declining to require measurements of hearing loss to establish prospective users' qualification to purchase OTC hearing aids.

OTC category and self-fitting air-conduction hearing aid classification. We are not requiring that OTC hearing aids be self-fitting devices, and we have provided clarification on the difference between customization and fitting.

Quality System requirements. OTC hearing aids will be subject to the requirements under part 820 (21 CFR part 820), which describes a quality management system appropriate for medical devices.

We explain those decisions and others, as well as provide our thinking on other topics in the sections that follow.

D. Incorporation by Reference

FDA is incorporating by reference ANSI/CTA–2051, ''Personal Sound Amplification Performance Criteria,'' dated January 2017, which was approved by the Office of the Federal Register. You may obtain a copy from the Consumer Technology Association (CTA), 1919 S. Eads St., Arlington, VA 22202; https://www.cta.tech, 703–907–7600. Among other things, it describes how to measure frequency response and includes technical data for adaptations for different circumstances and provides a standardized way to quantify frequency response for OTC hearing aids and to meet the related electroacoustic performance requirements.

FDA is also incorporating by reference ANSI/ASA S3.22–2014 (R2020), ''Specification of Hearing Aid Characteristics,'' dated June 5, 2020, which was approved by the Office of the Federal Register. You may obtain a copy from the Acoustical Society of America (ASA), 1305 Walt Whitman Road, Suite 300, Melville, NY 11747 Telephone: 1 (631) 390–0215, Fax: 1 (631) 923–2875, Email: *asastds@acousticalsociety.org* or the American National Standards Institute (ANSI), 1889 L Street NW, 11th Floor, Washington, DC 20036; *https://www.ansi.org,* 202–293–8020. ANSI/ASA S3.22–2014 (R2020) describes tolerances and test methods used for certain measurements of hearing aid performance. The application of ANSI/ASA S3.22–2014 (R2020) provides professional hearing instrument specialists with standardized technical information to help them select the correct hearing aid and ensure optimal fit and performance for hearing aid users.

IV. Legal Authority

The FD&C Act establishes a comprehensive system for the regulation of devices, as defined in section 201(h) of the FD&C Act (21 U.S.C. 321(h)), intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) defines three classes of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three classes of devices are class I (general controls), class II (special controls), and class III (premarket approval) (see 21 U.S.C. 360c). Hearing aids are devices intended for human use and are subject to the FD&C Act. Currently, air-conduction hearing aids are generally either class I or class II devices.

The FD&C Act also directs the establishment of an electronic product radiation control program under section 532(a) to protect the public health and safety (see 21 U.S.C. 360ii(a)), and requires, among other things, that manufacturers of electronic products provide notification of certain defects (see 21 U.S.C. 360*ll*). Section 531(1)(B) of the FD&C Act defines electronic product radiation as, among other phenomena, any sonic, infrasonic, or ultrasonic wave emitted from an electronic product as the result of the operation of an electronic circuit (see 21 U.S.C. 360hh(1)(B)). In turn, any manufactured or assembled product which, when in operation, contains or acts as part of an electronic circuit and emits (or in the absence of effective shielding or other controls would emit) electronic product radiation would be an electronic product (see 21 U.S.C. 360hh(2)(A)). As such, hearing aids and PSAPs emit electronic product radiation and are electronic products, meaning they are subject to the electronic product radiation control requirements.

FDARA amended the FD&C Act to apply requirements specific to certain hearing aids and defined the term ''over-the-counter hearing aid'' (see 21 U.S.C. 360j(q)). We are issuing these requirements for OTC hearing aids pursuant to section 709(b) of FDARA, which authorizes FDA to establish requirements for labeling, output limits, conditions for sale and distribution of OTC hearing aids, and other requirements that provide for reasonable assurance of safety and effectiveness of these devices.

In addition, the FD&C Act provides that a device is misbranded unless, among other requirements, its labeling bears adequate directions for use (see section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)). Consistent with section 502 of the FD&C Act, FDA has issued regulations that exempt certain kinds of devices from the requirement for adequate directions for use. Section 502(f)(2) further requires adequate warnings against use of a device in those pathological conditions, or by children, where use of the device may be dangerous to health. The labeling must also bear adequate warnings against unsafe dosage or methods or duration of administration or application (see section 502(f)(2) of the FD&C Act). Such warnings must be in such manner and form as are necessary for the protection of the users (see section 502(f)(2) of the FD&C Act).

A device is also misbranded if its labeling is false or misleading in any particular (see section 502(a) of the FD&C Act). Section 201(n) of the FD&C Act states that in determining whether labeling or advertising is misleading, there shall be taken into account not only representations made or suggested but also the extent to which labeling or advertising fails to reveal material facts.

Other misbranding provisions under the FD&C Act would apply as well,

including section 502(c), which deems a device to be misbranded if any word, statement, or other information required by or under authority of the FD&C Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

Additionally, section 701(a) of the FD&C Act authorizes FDA to issue regulations for the efficient enforcement of the FD&C Act (21 U.S.C. 371(a)). The regulations established in this rulemaking are for the efficient enforcement of the FD&C Act because they will provide standards for the legal marketing of safe and effective hearing aids.

Violations of any final rules from this rulemaking, once in effect, would render the hearing aids adulterated and/or misbranded under sections 501 and/or 502 of the FD&C Act, and subject to enforcement action, for example, seizure (see section 304 of the FD&C Act (21 U.S.C. 334)), injunction (see section 302 of the FD&C Act (21 U.S.C. 332)), and criminal prosecution (see section 303 of the FD&C Act (21 U.S.C. 333)). Prohibited acts include, among others, introducing an adulterated or misbranded device into interstate commerce (see section 301 of the FD&C Act (21 U.S.C. 331)). Sections 538 and 539 of the FD&C Act additionally set forth prohibited acts and provisions for enforcement for electronic product radiation control (see 21 U.S.C. 360*oo* and 360pp, respectively).

Under section 521 of the FD&C Act, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement that is different from, or in addition to, any requirement applicable under the FD&C Act to the device and that relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under the FD&C Act (21 U.S.C. 360k). Section 521 of the FD&C Act also provides that FDA may grant an exemption from preemption under certain circumstances. Section 709(b) of FDARA also includes a preemption provision with respect to requirements for OTC hearing aids.

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

In the proposed rule, FDA welcomed comments on all aspects of the proposal, and we specifically requested comments on certain topics to encourage more-targeted feedback. Such topics included:

the clarity of the definitions and ways to improve them;

labeling requirements;

equitable access to hearing aids and information about them;

whether State or local requirements for returns would promote or restrict or interfere with commercial activities involving OTC hearing aids;

design requirements to limit insertion depth;

proposals for modification of, or alternatives to, the current applicable Quality System requirements for OTC hearing aids;

conditions for sale of OTC hearing aids to prevent sale to or for people younger than 18;

the removal of regulations in 21 CFR part 808 (part 808) regarding exemptions from Federal preemption for State and local requirements respecting hearing aids;

possible effects of the rule on small manufacturers;

data concerning the environmental assessment and our proposal for a finding of no significant impact (FONSI);

topics related to the Paperwork Reduction Act of 1995 (PRA) and associated estimates for recordkeeping burdens; and

potential impacts on Indian Tribes from this rulemaking.

As appropriate, we summarize such comments that we received, along with other pertinent comments, and respond to them in the corresponding subsections that follow. As we indicated in the proposal, we considered only comments submitted to the docket for this rulemaking that were timely and pertinent (see 86 FR 58150–58161).

The vast majority of comments that we received supported rulemaking to encourage wider adoption of safe and effective hearing aids for people who could benefit from them. FDA agrees that rulemaking can encourage wider adoption of such devices, and we expect this final rule to do so. Many commenters conveyed enthusiasm for affordable hearing aids and/or wider availability without the involvement of a licensed person, telling us that they expect the difference to make hearing aids accessible to them—in some cases, for the first time. Some comments observed that hearing impairment often correlates with lower income, suggesting that lower prices may be particularly helpful for people who may want to use hearing aids and that OTC hearing aids could serve an important role in achieving equitable health outcomes.

Still, many commenters voiced both support and concern for the role of licensed persons and the value of professional services for hearing health. In finalizing this rule, FDA is not suggesting that licensed persons or their professional services are unimportant or not valuable. Indeed, we recommend consulting licensed persons in several circumstances, including for the diagnosis of hearing impairment and in the fitting and continued use of OTC hearing aids when consumers choose to seek such services. Many commenters asserted that the professional services are worth the cost. In that vein, one comment suggested that, like providing alternative distribution channels, increasing the number of audiologists and other hearing health care providers would also improve accessibility. This final rule, however, focuses on subjects within FDA's purview, establishing device requirements that provide reasonable assurance of safety and effectiveness for OTC hearing aids without the involvement of a licensed person, as directed by FDARA.

As for specific provisions, the comments generally supported establishing requirements for labeling, output (volume) limits, electroacoustic performance requirements, and other design requirements for OTC hearing aids. However, individual comments varied on the extent to which they supported specific proposals or proffered alternatives. Comments that provided a rationale and/or evidence generally lent more insight for FDA's consideration.

We acknowledge that some comments did not support this rulemaking, many of them stating that hearing aids are medical devices and should not be regulated as consumer electronics. We interpret such comments to mean that OTC hearing aids should not have a relaxed standard for safety or effectiveness, nor should OTC hearing aids be subject to less stringent requirements for product quality than other medical devices. We agree that OTC hearing aids must meet the same standard as other devices for having reasonable assurance of safety and effectiveness, consistent with the FD&C Act and section 709 of FDARA, and that OTC hearing aids be subject to the quality system requirements applicable to other devices. However, we note that different device types and categories will raise different issues related to safety and effectiveness. Thus, while devices must meet the same standard of having reasonable assurance of safety and effectiveness, different device types and categories can engender different regulatory requirements to achieve the same standard. This final rule establishes requirements specific to hearing aids and although the requirements for OTC and prescription hearing aids are not the same, these requirements, along with other applicable requirements under the FD&C Act, provide for reasonable assurance of safety and effectiveness for

both categories of hearing aids (we note that in this document when we describe the requirements in § 800.30 (21 CFR 800.30) or § 801.422 (21 CFR 801.422) as providing reasonable assurance of safety and effectiveness, we mean in conjunction with other applicable requirements under the FD&C Act).

A. Device Classification and Marketing

We received several comments about the interplay among device classification regulations, the OTC Hearing Aid Controls, and premarket notification requirements. Generally, we agree that clarification on such issues will help ensure that manufacturers identify and follow the appropriate regulatory requirements for their devices.

(Comment 1) Multiple comments requested clarification on the difference between self-fitting hearing aids classified under § 874.3325 (21 CFR 874.3325) and hearing aids that, through tools, tests, or software allow users to control the hearing aids and customize them to the users' hearing needs. Many such comments pointed out that the clarification will help manufacturers determine the applicability of premarket notification requirements and special controls.

(Response) Under section 520(q)(1)(A) of the FD&C Act, an OTC hearing aid must be controllable by the user and customizable to the user's hearing needs. We interpret the requirement for customization to hearing needs to mean that the device must allow the user to cause frequency-dependent changes based on the user's preference. This is because a single profile for gain versus frequency is unlikely to accommodate the majority of hearing needs for perceived mild to moderate impairment. For example, a flat gain profile across frequency is unlikely to meet the hearing needs of users with sloping hearing loss, the kind of impairment often associated with aging, as well as a non-flat gain profile across frequency would. However, a flat gain profile across frequency may be preferable for some people with a different kind of hearing loss. In short, to have reasonable assurance of safety and effectiveness of OTC hearing aids, the devices must offer capabilities for a variety of perceived mild to moderate hearing impairments, and customization is the method or process that allows the user to match the device output to individual preference.

We interpret the requirement for user control to mean that the user can access or select the output characteristics most significant to the user's hearing perception. For an OTC hearing aid, we consider these characteristics to include the frequency-dependent output profile and the output volume. The controls must allow the user to select the output volume and profile according to preference. The user may control the output profile, for example, with a physical toggle switch, a selection through a software interface, or providing preferences for software to select the optimal profile dynamically.

FDA views customization as a more-general concept than self-fitting. Fitting is a customization process that instills in the device frequency-dependent settings for the specific user. A self-fitting process instills frequency-dependent settings through the user interacting with the device or an accessory to the device. Self-fitting hearing aids incorporate technology, including software, that integrates user input with a self-fitting strategy and enables users to independently derive and customize their hearing aid fitting and settings (see § 874.3325(a)). A self-fitting strategy is a fitting process, with the selected output profile intended to correspond to the user's audiogram more closely than a hearing aid that is not fitted. Many hearing aids that are customizable but not fitted have a limited set of standardized output profiles, often called ''presets.''

In considering whether a hearing aid is self-fitting, FDA takes into account, among other things, the device's design and labeling. For purposes of distinguishing fitting a hearing aid from selecting among standardized output profiles, we focus on the determination and configuration of device settings that would be appropriate for the specific user, especially the frequency-dependent settings. (However, this focus does not exclude other factors that would still be relevant to determining intended use.) For example, a hearing aid outputting a preset likely would not be self-fitting, but a hearing aid that allowed the user to make frequency-dependent modifications to a preset to suit the user's preferences likely would be self-fitting.

FDA recognizes that, because a preset may approach a user's ideal fitting, a device with several presets may be difficult to distinguish from a self-fitting device. However, we note that devices with a small number of presets, for example, three, are not ordinarily considered self-fitting when the user chooses the profile. However, a hearing aid with a greater number of profiles would more closely resemble a fitting process, with the selected output profile intended to correspond to the user's audiogram more closely, in which case the hearing aid likely would be considered self-fitting. Similarly, toggling between a small number of programs, for example, for noise reduction or scene selection, would generally not indicate self-fitting, but setting or adjusting compression knee points in frequency sub-bands, would tend to indicate self-fitting. Moreover, FDA would likely consider a device that includes self-fitting functionality to be self-fitting, regardless of whether the individual user takes advantage of the functionality.

In sum, customization need not entail self-fitting, though self-fitting is a kind of customization. Whether a hearing aid is self-fitting depends on its intended use, which may be shown by, among other things, the device's design and labeling (see § 801.4 (21 CFR 801.4)). Some limited feature sets would not ordinarily cause a device to be a self-fitting hearing aid, while more advanced adjustment capability, especially for frequency-dependent settings, would tend to indicate that the device is a self-fitting hearing aid. FDA has made a minor revision to the requirement to provide specific instructions for use of tools, tests, or software to clarify that such instructions need not always refer to self-fitting; such instructions must include instructions for self-fitting only when the OTC hearing aid is a self-fitting device (see final § 800.30(c)(2)(vii)(B)).

(Comment 2) Many comments urged FDA: to clarify that the definition of OTC hearing aids under section 520(q)(1)(A) of the FD&C Act is synonymous with the identification for self-fitting air-conduction hearing aids under § 874.3325(a); to declare that self-fitting hearing aids are OTC devices; to declare that OTC hearing aids must be self-fitting; and/or to require that OTC hearing aid labeling bear the description ''self-fitting'' or a similar description.

(Response) Although FDA expects that many OTC hearing aids will be self-fitting, we do not agree with these comments. As explained in the response to Comment 1, a hearing aid may be customizable in the manner required under section 520(q)(1)(A)(iii) of the FD&C Act yet not be intended to entail fitting. Thus, we are not requiring that OTC hearing aids be self-fitting devices.

By extension, we are not requiring in this final rule that OTC hearing aids bear labeling that describes the devices as ''self-fitting'' or a similar description. However, § 801.61 (21 CFR 801.61) still applies, and this provision requires, among other things, a statement of identity on the principal display panel of an OTC device. (See also the responses to Comment 21, regarding other considerations for self-fitting

capabilities of OTC hearing aids, and Comment 18, regarding identifying and selling OTC hearing aids.)

Moreover, FDA intends that any hearing aid that uses the same fundamental scientific technology as those defined under §§ 874.3300(a) (21 CFR 874.3300(a)), 874.3305 (21 CFR 874.3305), and 874.3325 (21 CFR 874.3325) qualify as an OTC hearing aid (provided it satisfies all other applicable requirements). Some future hearing aid device types may also meet the statutory definition (and satisfy all other applicable requirements) to be available over the counter. Requiring that OTC hearing aids be a currently classified air-conduction hearing aid could have the effect of limiting the OTC category to current technologies rather than allowing the category to extend to new types of hearing aids.

(Comment 3) Some comments requested clarification on what would qualify as ''tools, tests, or software'' for the purposes of controlling an OTC hearing aid and customizing it to the user's hearing needs. Similar comments requested that FDA clarify which legacy and wireless air-conduction hearing aids would satisfy the customization requirement but not be a self-fitting hearing aid.

(Response) FDA interprets the requirement for tools, tests, or software broadly. We would, for example, consider a device that allows the user to cycle through output profiles with a push-button selector switch and to set the volume with a knob to meet the requirement. Should such a hearing aid be sufficiently customizable, and should it not incorporate wireless or self-fitting technology, then it would presumably be an air-conduction (''legacy'') hearing aid classified under § 874.3300 and could be made available OTC. (See the response to Comment 1 for more about distinguishing customization and fitting.)

(Comment 4) Comments expressed concerns about the potential to bypass premarket notification requirements and special controls if non-self-fitting hearing aids could be later configured or modified, for example, if the manufacturer ''unlocks'' self-fitting software or provides the user with options for ''advanced settings'' or the like. They urged FDA to finalize rules to prevent such an outcome.

(Response) Existing requirements already address modifications to devices, including hearing aids. Under § 807.81(a)(3) (21 CFR 807.81(a)(3)), a 510(k) is required if the device is about to be significantly changed or modified, namely, a major change or modification in the intended use or other kind of change or modification that could significantly affect the safety or effectiveness of the device. For example, a change or modification that causes a device to fall within a different classification regulation would be considered significant. Additionally, as explained in the response to Comment 1, aspects of the device's design and labeling can demonstrate the device's intended use (see § 801.4). If a wireless air-conduction hearing aid later incorporates self-fitting technology (for example, by downloading software) or such technology is later made accessible to the user (for example, by ''unlocking'' after an additional purchase), such a change would almost certainly demonstrate that the modified device was a self-fitting air-conduction hearing aid classified under § 874.3325 (assuming it was not a new device type). As such, it would be subject to the premarket notification requirements and special controls that apply to self-fitting air-conduction hearing aids.

In sum, a change in intended use or other aspect can cause a change in applicable requirements, and a device must comply with applicable regulatory requirements. As such, if a manufacturer intends to unlock or similarly upgrade its hearing aid with self-fitting technology such that it would fall within the self-fitting air-conduction hearing aid classification regulation, then prior to initial introduction into interstate commerce of the device, the manufacturer must comply with applicable requirements, including 510(k) requirements and compliance with the special controls. (See also the response to Comment 6 about the information a 510(k) should include.)

(Comment 5) Several comments requested clarification on when manufacturers of OTC hearing aids would need to submit a premarket notification, also called a 510(k). Many of these comments urged FDA to require 510(k)s for all OTC hearing aids.

(Response) FDA's existing requirements and related policies for submitting 510(k)s apply to hearing aids intended for OTC availability and use. We are not imposing additional general requirements for 510(k)s.

For manufacturers that have already legally introduced self-fitting air-conduction hearing aids into interstate commerce, changes to their devices to satisfy the OTC Hearing Aid Controls may require submission of a 510(k). However, in certain situations FDA intends not to enforce the requirement for a 510(k), as discussed in section VI on effective and compliance dates.

This policy also applies to non-self-fitting devices (wireless air-conduction and legacy air-conduction hearing aids). However, manufacturers of non-self-fitting devices may wish to consider the implications of using a test for somebody besides the user to fit the device. For devices intended for fitting based off of a user-supplied audiogram, a requirement for the involvement of a licensed person to produce the audiogram may cause the device not to be an OTC hearing aid as defined in section 520(q)(1)(A) of the FD&C Act.

Further, if a manufacturer or other non-licensed person obtains hearing ability data to customize (or even fit) a hearing aid, the manufacturer should consider whether the instrument used to obtain the data is a diagnostic (or other) device. Using a hearing aid with a diagnostic device may implicate changes to a hearing aid concerning the compatibility or interoperability with other devices, including other components or accessories, that could significantly affect the hearing aid's risk profile, necessitating a 510(k).

Notwithstanding these general principles, in each case, manufacturers should evaluate any changes in light of FDA's guidance, ''Deciding When to Submit a 510(k) for a Change to an Existing Device,'' issued October 25, 2017, which describes specific changes that generally do or do not require premarket notification.[1]

To illustrate: If a manufacturer of a wireless air-conduction hearing aid updates device labeling and adds a user self-assessment test intending the test to enable the user to independently customize and derive the fitting and settings (the device is intended to entail fitting), then FDA would anticipate the manufacturer would need to submit a 510(k). FDA's guidance document lists several considerations that would likely apply. In this example, the changes included:

the directions for use, including the use and application of the self-test to the device settings (see A4 of the aforementioned guidance on deciding when to submit a 510(k), ''Could the change affect the directions for use of the device?'');

the control mechanism and/or operating principle (see B2 of the same guidance, ''Is it a control mechanism, operating principle, or energy type change?'');

the device's design, specifically changes to its performance, components

[1] The document is available online at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-change-existing-device.*

or accessories, and human factors of the interface (see B5 of the same guidance, ''Is it any other change in design (*e.g.,* dimensions, performance specifications, wireless communication, components or accessories, or the patient/user interface)?''); and

those that significantly affect its use, potentially necessitating clinical validation data (see B5.1 and B5.3 of the same guidance, ''Does the change significantly affect the use of the device?'' and ''Are clinical data necessary to evaluate safety or effectiveness for purposes of design validation?'').

Each of those changes in this example could require a 510(k), depending on the specifics of the changes. In deciding whether to submit a 510(k), manufacturers may want to review the guidance in its entirety since the considerations for the example are not exhaustive and may or may not be applicable, depending on the specific device. Manufacturers may also want to review FDA's guidance, ''Deciding When to Submit a 510(k) for a Software Change to an Existing Device,'' issued October 25, 2017.[2]

Note that, although a wireless air-conduction hearing aid classified under § 874.3305, or a legacy air-conduction hearing aid classified under § 874.3300, is exempt from requirements for premarket notification, some changes could exceed the limitations of exemption under § 874.9 (21 CFR 874.9), depending on the specifics.

(Comment 6) Commenters requested clear guidance on the specific information manufacturers would need to submit in a 510(k) to bring devices to market quickly, avoiding unnecessary delays or unnecessarily hindering innovation.

(Response) In addition to the required information specified in the 510(k) procedures under 21 CFR part 807, subpart E, the specific information that a manufacturer should submit will vary based on the new device or specific changes made to an existing device. Therefore, providing specific guidance for all manufacturers in this final rule is not feasible. However, FDA's usual policies on the content and format of 510(k)s apply to submissions for hearing aids, including for modifications made to satisfy applicable special controls and the OTC Hearing Aid Controls. Manufacturers may wish to review publicly available information regarding the De Novo classification of self-fitting air-conduction hearing aids. (See the response to Comment 5 regarding when to submit a 510(k).)

In the case of OTC hearing aids, we anticipate that many manufacturers that submit a 510(k) could avail themselves of the Abbreviated 510(k) Program, as described in FDA's guidance of that name, issued on September 13, 2019.[3] Should a manufacturer incorporate self-fitting (or other) technology into one of its existing legacy or wireless devices and need to submit a 510(k), we would expect that the manufacturer could leverage the similarity with exempt devices as a least-burdensome way to obtain marketing authorization for the device that is not exempt from premarket notification requirements. Manufacturers of existing devices may not need to re-address questions, for example, related to electromagnetic compatibility (EMC), provided the manufacturer has not made changes that would affect EMC and require a 510(k) under our usual policies. Further, summary reports describing how the hearing aid complies with applicable special controls may be especially useful in addressing clinical data that support the effectiveness of the self-fitting strategy, usability testing, and software verification, validation, and hazard analysis.

Moreover, manufacturers that have decided to submit a 510(k), whether traditional or abbreviated, may wish to review FDA's guidance, ''Format for Traditional and Abbreviated 510(k)s,'' issued on September 13, 2019.[4] The guidance provides a general framework for the format and content of a 510(k).

(Comment 7) Commenters requested that FDA exempt certain kinds of hearing aids, including self-fitting devices, from premarket notification requirements. Some posited that FDA would accrue sufficient experience with self-fitting air-conduction hearing aids to evaluate the potential for 510(k) exemption 2 years after the effective date of this final rule. Others requested that FDA explain how OTC hearing aids will become 510(k)-exempt.

(Response) FDA's usual policies for exempting devices from premarket notification requirements apply to self-fitting air-conduction hearing aids. Stakeholders may wish to review FDA's guidance, ''Procedures for Class II Device Exemptions from Premarket Notification,'' issued February 19, 1998.[5] The guidance lists several factors that FDA may consider for exemption, including:

> The history (if any) of false or misleading claims or of risks associated with inherent characteristics of the device, such as device design or materials (FDA considers the risks associated with false or misleading claims, and the frequency, persistence, cause, or seriousness of the inherent risks of the device);
>
> How characteristics of the device necessary for its safe and effectiveness performance are well established;
>
> How changes in the device that could affect safety or effectiveness will either be readily detectable or not materially increase the risk of injury, incorrect diagnosis, or ineffective treatment;
>
> How any changes to the device would not be likely to result in a change in the device's classification; and
>
> The role of the limitations of exemption.

Although the amount of time that has passed since the classification of the device in question may affect how FDA views the factors, for example, the history of false or misleading claims, the amount of time since classification is not generally directly relevant. That is, 2 years after the effective date of this final rule may or may not afford sufficient experience and information to exempt all self-fitting air-conduction hearing aids from premarket notification requirements. We did not propose to exempt self-fitting air-conduction hearing aids and are not doing so now (see 86 FR 58150 at 58171).

B. Scope (§ 800.30(a))

We received several comments on which devices should be subject to the OTC Hearing Aid Controls and, conversely, which devices should be prescription. Sometimes these comments referred to definitions rather than scope. In this section, we respond to comments on scope, including comments where the suggested changes to the definitions affect the scope. The next section of this document, specifically for definitions, responds to comments that relate more directly to the clarity of terms or the usefulness of different terms.

(Comment 8) Comments requested clarification on the applicability of the OTC Hearing Aid Controls in circumstances in which software intended for compensation for hearing loss operates or adapts the output of other hearing products such as earbuds or headphones.

[2] The document is available online at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-software-change-existing-device.*

[3] The document is available online at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/abbreviated-510k-program.*

[4] The document is available online at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/format-traditional-and-abbreviated-510ks.*

[5] The document is available online at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/procedures-class-ii-device-exemptions-premarket-notification-guidance-industry-and-cdrh-staff.*

(Response) To date, FDA has not classified a device that adapts the output of other hearing products, such as earbuds, to compensate for perceived mild to moderate hearing impairment, including a device that accomplishes this through software. Overall, FDA encourages innovation of hearing products that are safe and effective and, to that end, intends to consider developing guidance to provide clarification on the applicability of laws and regulations implemented by FDA in circumstances where software would operate or adapt the output of hearing products to compensate for perceived mild to moderate hearing impairment. However, considering that in such circumstances, the software might be distributed separately from the hearing product, FDA has added requirements in the OTC Hearing Aid Controls for software device labeling. Similar requirements for software device labeling were also added to § 801.422. (See Additional Revision 3 in section III.D.6 describing the labeling requirements for hearing aid software.[6]) The software device labeling requirements take into consideration certain aspects associated with software not distributed with the hearing product, including that such software may not be provided in a package.

(Comment 9) A comment questioned whether a software interface for professionals such as audiologists or hearing instrument specialists would cause a hearing aid to be a prescription device if the professional could adjust the output in excess of the applicable limit.

(Response) If a manufacturer markets an OTC hearing aid that meets the OTC hearing aid definition and complies with all applicable requirements of the OTC Hearing Aid Controls—but also offers an additional separate feature, a software interface for professionals that allows only licensed persons to adjust the device output—FDA likely would not consider the hearing aid to be a prescription device, but the software interface for professionals would be a prescription device and therefore must comply with §§ 801.422 and 801.109. (Note that a software interface for an air-conduction hearing aid, which is the subject of this response, would be distinct from the hypothetical hearing-aid software device, described in the response to Comment 8, that operates or adapts the output of other hearing products such as earbuds or headphones.)

However, the intended use of a device can change after initial introduction into interstate commerce (see § 801.4). If a manufacturer intends prescription uses of a device, the manufacturer should consider how to ensure the device will satisfy all applicable requirements, for example, prescription labeling requirements. Should a manufacturer provide or allow users, and not just licensed persons, ready access to an interface that allows the user to configure the device to provide output in excess of that allowed for OTC hearing aids, this would indicate the device is intended for users (not limited to licensed persons) to set an excessively high output. FDA would be more likely to determine that the intended use was not for perceived mild to moderate hearing impairment. Additionally, such a device would not meet the required output limits in the OTC Hearing Aid Controls. Therefore, such a device would be considered a prescription hearing aid and must meet applicable requirements, including those under §§ 801.422 and 801.109; otherwise, it would be in violation of the FD&C Act.

(Comment 10) Some comments suggested that FDA limit the scope of the OTC Hearing Aid Controls to devices intended only for people with perceived mild, but not moderate, hearing impairment. Some of these comments suggested that perceived moderate hearing impairment requires the involvement of a licensed person for successful treatment, and as such, hearing aids intended for perceived moderate hearing impairment should not be available over the counter.

(Response) FDA disagrees that the involvement of a licensed person is necessary for hearing aids intended for perceived moderate hearing impairment. We are retaining perceived moderate hearing impairment within the scope of the OTC Hearing Aid Controls. The question of whether the involvement of a licensed person would benefit an individual's hearing healthcare is separate from whether the individual would benefit from the use of an OTC hearing aid. In other circumstances, the availability and use of OTC medical products to treat an illness or impairment does not imply the illness or impairment is not serious. Similarly, the availability and use of OTC medical products does not negate the benefit of a licensed person's involvement. FDA considers the use of OTC hearing aids, even when intended for perceived moderate hearing impairment, to be such a set of circumstances.

Further, by statute, OTC hearing aids include devices that are intended to compensate for perceived moderate hearing impairment, and such devices are to be available to consumers over the counter without the involvement of a licensed person (see 21 U.S.C. 360j(q)(1)(A)(ii) and (v)). Section 709(b) of FDARA requires FDA to issue regulations that include, among other requirements, provisions for reasonable assurance of safety and effectiveness. This rule will provide reasonable assurance of safety and effectiveness, without the involvement of a licensed person, for OTC hearing aids, including for hearing aids intended for perceived moderate hearing impairment.

Thus, while the involvement of a licensed person may benefit people with perceived hearing impairment, whether of a mild or moderate degree, FDA does not agree that consumers must attempt to obtain such a benefit prior to purchasing hearing aids over the counter. FDA is maintaining perceived moderate hearing impairment within the scope of the OTC Hearing Aid Controls.

(Comment 11) Some comments objected to the inclusion of ''perceived'' when referring to the kind of hearing impairment for which OTC hearing aids are intended. The commenters express concern that a person's perception of hearing loss may be too subjective, and that the use of OTC hearing aids should be based on more objective measures. Some of the comments suggested that FDA require prospective users to obtain audiograms, which are graphs or test results showing the person's ability to hear different frequencies, from a licensed person prior to purchasing an OTC hearing aid.

Besides obtaining an audiogram, other comments suggested a more general testing or examination requirement by a licensed person for prospective users, prior to purchase. In this way, these commenters suggested, OTC hearing aid users would have more certainty that OTC hearing aids would appropriately compensate for their hearing impairment, and/or the prospective user does not have an underlying, medically treatable cause of hearing impairment, for example, one of the ''red flag'' conditions. (A ''red flag'' condition is a sign or symptom that should prompt a consultation with a doctor, preferably an ear-nose-throat doctor.)

(Response) FDA disagrees. We are retaining ''perceived'' in reference to a

[6] We refer to ''additional revisions'' to indicate changes that FDA has made in further consideration of comments and the issues involved in this rulemaking, but that are additional to the suggestions made explicitly in comments. We have numbered the Additional Revisions in the order that they appear in this document, which depends upon the subject of the revision—definitions, outside package labeling, etc.—not the order in which the Additional Revisions are cross-referenced in our responses to comments.

person's degree of hearing impairment and the intended use of OTC hearing aids for legal and policy reasons. The term ''perceived'' is used in section 520(q)(1)(A)(ii) of the FD&C Act to describe the intended use for OTC hearing aids. Moreover, objective measurements of hearing impairment are not necessary for reasonable assurance of safety and effectiveness of OTC hearing aids.

Relying on perceptions of hearing impairment is also appropriate because the type and degree of impairment exist on a continuum, as does a person's perception and experience of the impairment. A given degree (quantification) of hearing impairment will not necessarily reflect whether an OTC hearing aid is likely to benefit a specific individual. We have therefore focused on communication and other perceptual experiences (such as listening to music) in which an intended user is likely to suspect or notice—that is, to perceive—hearing impairment. FDA expects this approach based on perception to assist users and prospective users better than an approach that does not.

Additionally, while FDA agrees that an audiogram would provide a prospective user with an objective measure of hearing impairment, we do not agree that the scope of the OTC Hearing Aid Controls should include only hearing aids for objectively measured impairments. Such a limitation is counter to the objectives of section 709 of FDARA, including making available hearing aids OTC, without the involvement of a licensed person, to consumers through in-person transactions, by mail, or online.

We acknowledge that this places some onus on users and prospective users. However, this is the case with respect to OTC availability of many medical products, and we are establishing requirements that will provide reasonable assurance of safety and effectiveness for such availability of hearing aids. We also observe that, while an audiogram might help a user or a licensed person tailor the hearing aid, or initially select it, even a hearing health care provider would still ask the user how the device sounds to the user. The user's perception would help the hearing health care provider make further adjustments. A person's desire to seek and use hearing aids depends more directly upon that person's perception of their hearing impairment than the definitive degree of impairment, and even a licensed person fitting and adjusting the device would also account for the user's perception. (See also the response to Comment 24 about defining hearing loss numerically.)

Further, FDA has included information in the labeling requirements for OTC hearing aids intended to help users understand whether the devices are suitable based on their perceptions, realistic expectations for hearing aid use, and suggestions on when to obtain professional assistance before and after purchase. Should prospective OTC hearing aid users still feel uncertain about their perceptions of impairment, notwithstanding the availability of the aforementioned information, they may choose to obtain or undergo professional testing prior to purchase.

(Comment 12) Some commenters suggested that FDA require a prescription for OTC hearing aids.

(Response) FDA disagrees. Requiring a prescription to purchase an OTC hearing aid would be contrary to the purposes of this rulemaking, the definition of OTC hearing aids in the FD&C Act, and FDARA which includes the mandate to establish requirements for hearing aids to be available over the counter (see section 520(q)(1)(A)(v) of the FD&C Act and section 709(b)(1) and (b)(2)(D) of FDARA). It also would negate the probable health benefits created by wider availability of hearing aids, as we described in the proposal (see 86 FR 58150 at 58152).

(Comment 13) Multiple comments suggested FDA remove dispensing from the list of commercial activities that FDA included in the definition of ''licensed person.'' The definition listed commercial activities involving OTC hearing aids for which a State or locality could not require the involvement of a licensed person. For example, a State could not require a person representing as a dispenser of OTC hearing aids to undertake special licensing or equivalent activities solely for that reason.

Such comments cited various reasons, for example, that State regulatory regimes impose obligations on people representing as dispensers, so referring to the term in the OTC Hearing Aid Controls would create an inconsistency with State regulatory requirements. Other comments pointed out that people expect dispensers to have licenses, and FDA's regulations would be inconsistent with such expectations. Still others cited the need for dispensers to acquire and/or demonstrate qualifications prior to dispensing OTC hearing aids.

Similar comments suggested that FDA instead refer to dispensers as ''sellers,'' ''vendors,'' ''merchants,'' or other such terms. These terms, the comments assert, would distinguish salespeople from hearing health care providers.

(Response) FDA is not modifying the scope of the OTC Hearing Aid Controls or the definition of ''licensed person'' to exclude dispensing of OTC Hearing Aids. As we explained in the proposed rule, FDARA lists certain activities that may be undertaken with respect to OTC hearing aids for which a State or locality cannot require the involvement of a licensed person (see 86 FR 58150 at 58158). One such activity that FDARA explicitly lists is the dispensing of OTC hearing aids. This means that, under Federal law, a State or locality cannot require a dispenser of OTC hearing aids to undertake special licensing or equivalent activities because that would in essence require the involvement of a licensed person, contrary to section 709(b)(2)(D) of FDARA and section 520(q)(1)(A)(v) of the FD&C Act.

Additionally, in establishing the OTC category for hearing aids, we have developed requirements to provide reasonable assurance of safety and effectiveness for OTC hearing aids without the involvement of a licensed person (see section 709(b)(2) of FDARA). Imposing special licensing requirements or equivalent activities, therefore, is not necessary to provide reasonable assurance of safety and effectiveness of OTC hearing aids. Although not required, a purchaser of OTC hearing aids can still seek the assistance of a licensed person when selecting a hearing aid.

Since a person may dispense OTC hearing aids without a specialized license or the need to involve a licensed person, referring to dispensers by another term such as ''vendor'' or ''seller'' is not necessary to distinguish dispensing from activities requiring specialized licensure or the involvement of a licensed person. Moreover, we have previously defined dispensers as persons engaged in the sale, lease, or rental of hearing aids (see prior § 801.420(a)(3)). The regulations we are finalizing in this rulemaking use essentially the same definition. In sum, using alternative titles for dispensers may serve to confuse consumers by unnecessarily establishing another term for a legally permissible activity as well as incorrectly implying that FDA's interpretation of the term has changed.

FDA recognizes that State and local requirements sometimes incorporate the term ''dispenser,'' and multiple States impose requirements on account of dispensing hearing aids. However, FDARA section 709(b)(4), to summarize, provides that no State or local government shall continue in effect certain State or local requirements that are different from, in addition to, or otherwise not identical to the

regulations issued under FDARA section 709(b). Thus, regardless of whether a State or locality amends or otherwise updates its requirements, it may not continue in effect the inconsistent requirements prior to their amendment or repeal.

As we explained in the proposal, despite the fact that licensure is not required for dispensing OTC hearing aids, some persons may voluntarily identify as a ''licensed dispenser,'' (see 86 FR 58150 at 58168). Although a State or locality could not require dispensers (or other persons) to undertake special licensing solely on account of commercial activity involving OTC hearing aids, a State or locality could still establish licensure criteria that would apply to those voluntarily identifying as licensed persons. In such a case, the dispenser's identification as a licensed person would imply that the dispenser complies with applicable State or local licensing requirements, albeit voluntarily. (See also the responses to Comment 15, discussing other licensing considerations, and Comment 127, discussing the involvement of a licensed person for prescription hearing aids.)

In sum, in light of Federal statutory and other requirements, including those that provide reasonable assurance of safety and effectiveness of OTC hearing aids, FDA is not narrowing the scope of the OTC Hearing Aid Controls to exclude dispensing. This does not, however, prevent dispensers of OTC hearing aids from voluntarily subjecting themselves to State or local licensing requirements to obtain a license (or its equivalent).

(Comment 14) Comments suggested that OTC hearing aids be available for all degrees of hearing impairment, including degrees greater than moderate. Some of these comments further noted that Medicare does not currently pay for or reimburse the cost of hearing aids. As such, the comments asserted that OTC hearing aids should be usable as lower-cost alternatives to prescription hearing aids for individuals with more-profound impairments.

(Response) For the reasons explained in the response to Comment 10, FDA is establishing requirements for perceived mild to moderate hearing impairment. Thus, the appropriate device output limit that we are establishing would not extend to hearing impairment that would require a greater output than that which is appropriate for perceived moderate hearing impairment.

However, devices of the same type may generally be intended either for prescription or OTC use. For example, a manufacturer marketing an OTC wireless hearing aid could also market another wireless hearing aid with a higher output than that permitted for OTC hearing aids. This higher output would render it a prescription device. As with other products that have differing uses but share manufacturing similarities, a hearing aid manufacturer may be able to realize economies of scale by selling an OTC version and a prescription version of hearing aids that fall within the same type, which in turn could lower the prices for prescription hearing aids. (See also the response to Comment 17 about limitations on FDA's authority to require reimbursement for devices.)

(Comment 15) Some comments suggested FDA define which activities involving hearing aids would require licensure.

(Response) FDA does not generally determine which activities involving medical products require licensure. However, section 709(b)(4) of FDARA lists several activities for which States or localities may not require specialized licensure for, or the involvement of a licensed person in, commercial activity involving OTC hearing aids. These listed activities are the servicing, marketing, sale, dispensing, use, customer support, or distribution of OTC hearing aids through in-person transactions, by mail, or online. As we explained in the proposal, we interpret the listed activities broadly, so for example, the term ''sale'' would include leases or rentals (see 86 FR 58150 at 58165).

States usually determine the requirements for licensure or the involvement of licensed persons. States may still do so with respect to hearing aids when not prohibited by section 709(b)(4) of FDARA (and other applicable laws). Where section 709(b)(4) of FDARA does not list an activity, when construing the terms broadly, a State may require licensure for that activity as it relates to OTC hearing aids. We note that the proposal provided a discussion and some examples (see 86 FR 58150 at 58167–58168). Thus, for example, a State may require a license for a hearing aid fitter, because ''fitting'' is not listed among the activities in section 709(b)(4) of FDARA, and we do not interpret any of the listed activities to include fitting. A person could not be a fitter in that State, even for OTC hearing aids, without a license. However, the State could not require a hearing aid fitting prior to a user purchasing an OTC hearing aid because that would restrict or interfere with commercial activity involving OTC hearing aids. See the response to Comment 13 for further explanation.

Thus, a State may still establish criteria for licensing dispensers should a person voluntarily decide to become a licensed dispenser of OTC hearing aids. In other words, although a State cannot require a license for dispensing OTC hearing aids, a State can establish what a person must do to obtain, and claim to have, a license for dispensing hearing aids. FDA expects that States may wish to continue in effect licensing requirements to dispense prescription hearing aids, and we expect that some hearing aid dispensers may wish to obtain a license in the event they desire to advertise as ''licensed'' and/or to sell prescription hearing aids in addition to OTC hearing aids.

(Comment 16) Some comments urged FDA to limit the scope of OTC availability as much as possible, at least in the beginning. These comments conveyed concerns for the absence of a licensed person in various roles, including education and counseling. One such comment suggested that a more-limited scope would be easier to broaden later than the reverse, limiting a broader scope.

(Response) In the proposed rule, we explained that several barriers likely impede people's access to hearing aids, including among others, Federal and State regulatory requirements (see 86 FR 58150 at 58152, 58154). We are undertaking this rulemaking in part to remove or reduce such barriers to access by establishing requirements that will provide reasonable assurance of safety and effectiveness while encouraging broad availability (see 86 FR 58150 at 58158). Moreover, we received a wealth of thoughtful and nuanced comments about the scope of the OTC Hearing Aid Controls, including this Comment, and we have determined that a more-restrictive approach is not necessary for reasonable assurance of safety and effectiveness of OTC hearing aids. Considering our purpose to broaden access and our determinations regarding reasonable assurance of safety and effectiveness, we do not agree that narrowing the scope of the OTC Hearing Aid Controls, with the intention of considering a broader scope later, is currently an appropriate strategy.

(Comment 17) Some comments noted the role of health insurers, including Medicare, in a person's ability to obtain hearing aids. Comments suggested that FDA focus on payments or reimbursements for hearing aids, potentially including financial incentives.

(Response) FDA does not have authority to require payors to pay for or reimburse the cost of hearing aids or to offer financial incentives to obtain the

devices. However, we intend this rule, among other ends, to broaden access to hearing aids by eliminating certain kinds of requirements that likely add to the cost of accessing the devices. For example, we are establishing rules to make OTC hearing aids available without the involvement of a licensed person.

C. Definitions (§§ 800.30(b) and 801.422(b))

This section focuses on explaining the final definitions. Generally, commenters sought clarity, and we have generally accepted or declined suggestions with the goal of improving clarity of the definitions.

(Comment 18) Multiple comments proposed that FDA use another name to identify OTC hearing aids. For example, some comments proposed ''over-the-counter hearing device,'' ''self-fit over-the-counter hearing device,'' ''hearing amplifiers,'' and ''hearing devices.'' Generally, these commenters sought to avoid confusion with existing devices for both consumers and State regulators. Otherwise, commenters believed, consumers may be misled into believing that OTC hearing aids are equivalent to prescription hearing aids with respect to performance, safety, and effectiveness, and there may be regulatory issues for State licensing boards. Other comments argued that the availability of OTC devices through retailers such as grocery or department stores would suggest that these devices are not hearing aids, so referring to them as such would be inappropriate.

By identifying OTC hearing aids in a different way, consumers, regulators, and other stakeholders would, the comments argued, have a clearer indication of devices subject to the new regulatory category. Many such comments noted that the use of a term other than ''hearing aid'' was recommended by the National Academies of Sciences, Engineering, and Medicine (NASEM) in their report, ''Hearing Health Care for Adults: Priorities for Improving Access and Affordability,'' and by the Hearing Care Associations in their Consensus Paper, ''Regulatory Recommendations for OTC Hearing Aids: Safety & Effectiveness'' (Ref. 7).

(Response) FDA will continue to use the term ''hearing aids'' to refer to the OTC and prescription devices subject to this rulemaking because the use of this term is appropriate. Hearing aids, whether OTC or prescription, are wearable sound-amplifying devices intended to compensate for impaired hearing. The term ''hearing aid'' describes several device types reflected in various classification regulations. Although OTC hearing aids use air-conduction technology, prescription hearing aids may do so as well (for example, an air-conduction hearing aid that provides a higher output than that specified in the OTC Hearing Aid Controls would be prescription). Therefore, the use of the term ''hearing aid'' is appropriate to reflect both OTC and prescription devices that fall within the same device type (for example, wireless air-conduction hearing aids under § 874.3305). Moreover, section 520(q)(1)(A) of the FD&C Act explicitly uses and defines the term ''over-the-counter hearing aid[s],'' and section 709(b)(1) of FDARA requires the establishment of ''a category of over-the-counter hearing aids.'' Thus, referring to the devices by a different name would not only be inconsistent with the applicable classification regulations and statutes, but also FDA expects that doing so would cause confusion and uncertainty for consumers considering purchasing an OTC hearing aid.

Further, we expect this rulemaking to broaden the kinds of retailers that sell OTC hearing aids, helping to increase the availability of the devices. By extension, the availability of OTC hearing aids (by that name) in grocery and department stores would help fulfill one of the purposes of this final rule. Moreover, many technologically similar products are available and go by several names, including ''personal amplifier.'' Based on their intended use(s), some of these may not be devices and/or meet applicable requirements for devices, yet they may appear to some prospective purchasers to be suitable alternatives to safe and effective devices.[7] We expect that consumers are familiar with the name ''hearing aid,'' and using that name will better support broadened use of the devices. At the same time, we expect that introducing yet another name for a similar technology, albeit regulated as a device, would only serve to increase confusion in the marketplace because prospective purchasers may think that a hearing aid could be marketed under other names, including those used for products that do not meet applicable device requirements. Thus, we have determined that the best way to indicate whether the device is subject to this rulemaking is to use the name ''hearing aid'' as used for the device types in the applicable classification regulations, and the name that is established in the FD&C Act and FDARA, OTC hearing aids.

To assist consumers further, as well as ease determining the applicability of the OTC Hearing Aid Controls, we are modifying the labeling and conditions for sale for OTC hearing aids. See Additional Revisions 2 (section III.D.3) and 4 (section III.G), respectively, for further explanation.

Although the technical specifications are different for OTC hearing aids and prescription hearing aids, as explained elsewhere in this document, FDA believes the technical specifications for each category are appropriate. Additionally, information on the technical specifications is required to be provided in the device labeling. FDA believes that OTC hearing aids that comply with § 800.30 and other applicable requirements (for example, Quality System requirements) will have reasonable assurance of safety and effectiveness for people aged 18 and older with perceived mild to moderate hearing impairment.

(Comment 19) A comment suggested that the definition of ''hearing aid'' should include an explicit statement that PSAPs are not hearing aids. The comment mentioned the draft guidance we are finalizing concurrently with this final rule, ''Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products,'' which is published elsewhere in this issue of the **Federal Register** and is also available at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/regulatory-requirements-hearing-aid-devices-and-personal-sound-amplification-products,* and characterized the draft of the guidance as ''provid[ing] essential distinctions between [hearing aids] and PSAPs.''

(Response) FDA agrees that distinguishing between hearing aids (devices) and PSAPs (non-devices) can be an important interest for purchasers, manufacturers, and other stakeholders. We are finalizing requirements for the principal display panel on the package of an OTC hearing aid to bear the marks ''OTC'' and ''hearing aid'' (see Additional Revision 2 in section III.D.3). We are also finalizing a corresponding condition for sale that sellers may only make a hearing aid available OTC when its package bears the requisite marks (see Additional Revision 4 in section III.G). Moreover, we are finalizing the aforementioned draft guidance document, intended to describe hearing aids, PSAPs, their respective intended uses, and the regulatory requirements that apply to both types of products.

[7] FDA is finalizing a guidance alongside this rulemaking to help stakeholders distinguish hearing aids from PSAPs. To summarize, a PSAP is an electronic product intended for non-hearing-impaired people to amplify sounds in certain environments. A PSAP is not intended to aid with or compensate for impaired hearing.

We are not, however, modifying the definition of ''hearing aid'' to state that PSAPs are not hearing aids. As we explained in the proposed rule, the name of a product on its own would not ordinarily demonstrate intended use (86 FR 58150 at 58154). Thus, merely excluding PSAPs from the definition of hearing aid does not remove a product from device regulation under the FD&C Act if, for example, its labeling demonstrated that the product was intended to compensate for hearing loss. We think the actions we are taking will better assist stakeholders to distinguish between products than modifying the definition of ''hearing aid'' in the OTC Hearing Aid Controls.

(Comment 20) Some comments suggested adding definitions to the classification regulation for self-fitting hearing aids (§ 874.3325). For example, comments suggested FDA define ''programming the hearing aid'' and ''self-fitting strategy.''

(Response) FDA is not adding definitions for purposes of the self-fitting air-conduction hearing aid classification at this time. In considering possible definitions to add, including those suggested in the comments, we sought to balance clarity with flexibility. The phrasing of § 874.3325(a) is intended to cover a range of technologies, both present and future, without unduly constraining innovation. For example, the regulation refers to a ''self-fitting strategy,'' rather than a more prescriptive description. Under this regulation, manufacturers could choose different strategies to achieve self-fitting by the user while still being substantially equivalent to other devices of the same type. After considering the comments, we have decided not to constrain the classification further.

However, we recognize that these commenters desired to clarify the classification of different types of air-conduction hearing aids, including the applicability of special controls and premarket notification requirements. We have provided our thinking and expectations in section V.A. of this document to address such concerns. Further, FDA may issue guidance on this subject in the future following our Good Guidance Practices and inviting additional comments (see 21 CFR 10.115).

(Comment 21) Several comments requested that FDA define self-fitting hearing aids in such a way as to clarify that the devices must be manipulable by the general public. Many of these comments showed concern about predatory business practices, through which manufacturers might prevent users from customizing device output, because they did not view self-fitting capability as clearly required for OTC hearing aids.

(Response) FDA agrees that OTC hearing aids must be somehow manipulable by lay users; however, we are not adopting these suggestions.

As explained in the response to Comment 1, not all OTC hearing aids are self-fitting devices classified under § 874.3325. Thus, FDA declines to define self-fitting hearing aids in the way suggested by comments.

Further, modifying the self-fitting hearing aid classification regulation in the suggested way is not necessary. By definition, self-fitting air-conduction hearing aids allow *users* to program their hearing aids, and the devices integrate user input with a *self*-fitting strategy and enable users to *independently* derive and customize their hearing aid fitting and settings. Should users themselves be unable to derive or customize the fitting and settings independently, or program their hearing aids, FDA likely would not consider it a self-fitting air-conduction hearing aid.

More generally, section 520(q)(1)(A)(iii) the FD&C Act defines an OTC hearing aid, in part, as a device that allows the *user* to control the hearing aid and customize it to the user's hearing needs. Should users of a hearing aid be unable to control and customize the device in the manner required, the hearing aid would not be an OTC hearing aid as defined in the FD&C Act or final § 800.30, and thus, would be a prescription device.

FDA also notes that the FD&C Act, the OTC Hearing Aid Controls, and the classification regulation for self-fitting air-conduction hearing aids all refer to the ''user'' of the hearing aid. Referring to manipulation by the general public may not accurately or adequately represent the intended user(s) of a hearing aid because the intended user(s) may differ in significant ways from the general population. However, FDA agrees that manufacturers should generally assume that users are laypeople (not experts) regarding OTC hearing aids, and we are finalizing the definition of ''tools, tests, or software'' as proposed. The definition specifically requires that a lay user be able to control and customize an OTC hearing aid. Further, because OTC hearing aids are not prescription devices (and are not otherwise exempt from certain labeling requirements), the labeling must include adequate directions for use, which are directions under which a layperson can use the device safely and for its intended use(s) (see § 801.5 (21 CFR 801.5)).

(Comment 22) A comment suggested that FDA explicitly require that users have control of the device output to customize the device to their hearing needs. This comment argued the phrasing of the definition for ''tools, tests, or software'' that FDA proposed is ambiguous, potentially allowing manufacturers to restrict control of the device to physical fit but not the sound output.

(Response) As explained in the response to Comment 21, section 520(q)(1)(A)(iii) of the FD&C Act defines an OTC hearing aid as a device that, through tools, tests, or software, allows the user to control the hearing aid and customize it to the user's hearing needs. In final § 800.30(b), we define ''tools, tests, or software'' as components that allow lay users to control the device and customize the device *sufficiently.* As explained in the response to Comment 1, we interpret the requirement for customization to hearing needs to mean that the device must allow the user to cause frequency-dependent changes based on the user's preference, and the requirement for user control to mean that the user can access or select the output characteristics most significant to the user's hearing perception. These elements sufficiently describe the requisite controllability and customization without unnecessarily constraining future technologies that could be available OTC. We are not modifying the OTC Hearing Aid Controls as suggested. However, as explained elsewhere in this document, we added a user-adjustable volume control to the design requirements for OTC hearing aids so users will be able to control this aspect of the sound output.

(Comment 23) Comments suggested that FDA include in the definition of ''used hearing aid'' a stipulation that a bona fide hearing aid evaluation extend through a trial period that might last as long as 90 days. That is, a device would not be considered a ''used hearing aid'' solely because a prospective purchaser wore it for an extended trial period, without the presence of the dispenser or a hearing health professional selected by the dispenser.

(Response) FDA is not adopting this suggestion because purchasers should be aware of use of the device outside of observation to ensure appropriate operating conditions. This is because a device will be in contact with the ultimate user's skin for extended periods, and the device contains sensitive electronics. Without observation, a device that a prospective

user is evaluating may be used in a way that would make the device unsanitary for the ultimate user, or the device could have been subjected to damaging conditions.

However, we are revising the definitions and labeling requirements to clarify labeling terms to convey information better. If a manufacturer inspects and tests a used hearing aid, makes any necessary modifications to the hearing aid to ensure it satisfies applicable requirements to be available OTC, including for labeling, electroacoustic performance, and design, and the manufacturer has adequately reprocessed the hearing aid for the next user, then the manufacturer may describe the device as ''rebuilt'' in the required labeling rather than ''used.''

(Comment 24) Multiple comments proposed that FDA define mild to moderate hearing impairment in terms of objective criteria. For example, these comments suggested that FDA adopt thresholds used by the American Speech-Language-Hearing Association (ASHA) or the World Health Organization (WHO) to categorize hearing impairment. Others suggested more generally that labeling describe hearing impairment in detail so that prospective OTC hearing aid users would ''understand exactly'' their degree of hearing impairment.

(Response) FDA is declining to define hearing impairment for purposes of the OTC Hearing Aid Controls in terms of objective measurements because defining hearing impairment in such a way is neither necessary for, nor consistent with, establishing an OTC category of hearing aids.

Inconsistency would arise because the requirements to establish the OTC category focus on the hearing aid user's perception as well as making devices available without the involvement of a licensed person. Specifically, section 520(q)(1)(A)(ii) of the FD&C Act refers to ''perceived'' impairment in defining the intended use of OTC hearing aids. As explained in the response to Comment 11, the subjective nature of hearing impairment is integral to the regulatory category we must establish for OTC hearing aids.

Further, an objective definition based on measurement of hearing impairment would imply the need to involve a licensed person, such as an audiologist or hearing instrument specialist, to administer a test or otherwise provide an exact understanding. However, OTC hearing aids must be available without the involvement of a licensed person (see 21 U.S.C. 360j(q)(1)(A)(v)), and FDA has determined that an objective measurement of hearing impairment is not necessary for reasonable assurance of safety and effectiveness of OTC hearing aids. Thus, defining the degrees of impairment in objective terms, using one of several available schemes for categorization, would be contrary to the purposes of this final rule as well as unnecessary.

We acknowledge that many licensed persons use audiometric threshold-based hearing loss categories to describe hearing loss severity, and this information may be useful to OTC hearing aid users should they choose to seek it out. However, the perception of hearing difficulties is on a continuum that is not confined to specific audiometric threshold categories. For example, two people with the same audiometric thresholds may have different subjective perceptions of, and different personal preferences for addressing, the impairment. The intended user population will have a broad range of perceptual difficulties and communicative function because of the wide variability and overlap in perception of hearing impairment within and across hearing loss severity.

The ASHA and WHO hearing loss categories each reflect a continuum while providing high-level clinical guidance. These categories do not represent discrete perceptual boundaries for the patient or for the treating professional. Furthermore, these hearing loss categories were not formulated to determine regulatory questions such as whether an individual should have access to OTC hearing aids. We are declining to adapt and apply such a scheme in that way.

Nonetheless, we are establishing labeling requirements to help consumers recognize perceived mild to moderate hearing impairment. See the response to Comment 35 for more on this topic. Further, the labeling encourages users and prospective users to seek professional services in several circumstances, and people who wish to measure their degree of hearing impairment objectively or definitively may still obtain such measurements voluntarily.

(Comment 25) One comment suggested that the definition of ''prescription hearing aid'' be revised to further state that these devices are dispensed by a State-licensed professional.

(Response) FDA declines to revise the definition of ''prescription hearing aid'' as suggested because it is unnecessary. Prescription hearing aids are prescription devices and as such, they are subject to § 801.109. Under § 801.109(a), a prescription device is a device that is: (1) either in the possession of a person, or his agents or employees, regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale or retail distribution of such device or in the possession of a practitioner, such as physicians, dentists, and veterinarians, licensed by law to use or order the use of such device and (2) is to be sold only to or on the prescription or other order of such practitioner for use in the course of his professional practice. Because prescription hearing aids are required to be in the possession of persons lawfully engaged in the retail distribution (or certain other activities) of such devices, and must be sold only to or on the prescription or other order of a licensed practitioner, the revision suggested in the comment is unnecessary.

(Additional Revision 1) After further consideration, FDA is modifying the definition of ''dispenser'' for the purposes of prescription hearing aids under final § 801.422(b). FDA proposed that the term refer to any person engaged in the sale of prescription hearing aids. However, we observed a potential for confusion based on comments we received, because a person engaged in the sale of OTC hearing aids would also be a dispenser. Thus, while the definition of the term in § 801.422(b) is for the purposes of prescription hearing aid labeling, the definition as proposed may have appeared to create an inconsistency with the use of the term outside of § 801.422. To avoid the potential inconsistency and confusion, we are removing ''prescription'' from the final definition of ''dispenser.''

D. Labeling (§ 800.30(c))

FDA received many comments related to labeling for OTC hearing aids. Most of these comments focused on ensuring the information would be easy to understand for most people, that is, people who are not professionals in a field related to hearing impairment. Commenters suggested various means to improve the labeling, including different phrasing, formatting, or positioning. Others provided general feedback and emphasized Plain Language principles, and a need to avoid jargon or overly technical phrasing, to help readers understand information in the labeling. FDA agrees that Plain Language principles apply in the case of labeling for hearing aid users, and that Plain Language will help users to understand the information in the device labeling.

1. User-Friendly Labeling

(Comment 26) Some comments expressed concern that FDA did not validate the labeling of the OTC hearing aids. Many of these comments are concerned that without labeling validation, a consumer's ability to self-diagnose their hearing loss will be hindered. These comments suggested that a requirement for manufacturers to validate labeling will help to ensure that users can properly self-diagnose their hearing loss.

(Response) FDA is declining to adopt labeling validation requirements for OTC hearing aids at this time. The labeling requirements we are finalizing benefitted from extensive input from many sources, including docket comments and public workshops, such as the one convened by NASEM. Additionally, self-fitting air-conduction hearings aids under § 874.3325 are subject to a special control requiring usability testing, which inherently includes testing the directions for use by the user. Further, any device must have labeling bearing adequate directions for use unless subject to an exemption (see section 502(f)(1) of the FD&C Act and § 801.5). This means that the directions for use for an OTC hearing aid must allow a lay user to use the device safely and for its intended purposes (see § 801.5). Given these requirements, and the extensive input we have received for labeling, a requirement for additional validation is not needed for reasonable assurance of safety and effectiveness.

(Comment 27) Multiple comments proposed that labeling refer to an ''Ear-Nose-Throat Doctor,'' ''ENT,'' or similar terms instead of referring to an ''ear specialist.'' These comments suggested that ''ear specialist'' is not specific enough because it might imply somebody besides a physician. For example, it could refer to an audiologist or a hearing aid dispenser, neither of whom need be a physician. As such, ''ear specialist'' may confuse or inadvertently mislead hearing aid users.

(Response) FDA agrees that ''ear-nose-throat doctor'' and ''ENT'' are more descriptive and likely more common than ''ear specialist.'' We have revised labeling throughout to adopt this suggestion when referring to physicians.

(Comment 28) A comment suggested that labeling refer to ''physicians'' rather than ''doctors'' because people who are not physicians may be doctors, for example, people who hold Ph.D.s (philosophical doctors) or chiropractors (some of whom are doctors of chiropractic).

(Response) We are not adopting this suggestion. We are adopting suggestions to refer to ''ear-nose-throat doctors'' instead of ''ear specialists'' to provide better guidance to people who may be unfamiliar with hearing healthcare delivery (see the response to Comment 27). However, we do not expect that people will seek the assistance of philosophical doctors or chiropractors for their hearing needs just because the labeling for OTC hearing aids refers to a ''doctor'' rather than a ''physician.'' Instead, we expect people who seek the assistance of a doctor for their hearing needs will exercise reasonable judgment in discerning which kind of doctor might help them with their hearing needs, in the same way they might exercise reasonable judgment to find appropriate providers when suggested by OTC labeling for other health concerns.

(Comment 29) A comment requested that ''doctor'' and ''physician'' in the labeling be revised to ''licensed healthcare practitioner.'' The comment argued that use of ''licensed healthcare practitioner'' is consistent with FDARA and would ensure that patients see qualified individuals, yet not confuse and limit consumers about whom they can consult.

(Response) FDA is declining to replace all references to ''doctor'' or ''physician'' with ''licensed healthcare practitioner'' because there are certain aspects of hearing care where it is warranted that a patient consult a ''doctor.'' As discussed in the response to Comment 27, FDA is updating the term ''ear specialist'' to ''ear-nose-throat doctor (ENT)'' to avoid confusion as to whom a consumer should consult. Where FDA now uses the term ''ENT'' it is to clarify who is best positioned for a patient to consult on a particular matter. For example, an ENT would generally be the kind of provider who has the necessary qualifications and expertise to conduct an examination for the diagnosis of Red Flag conditions. We acknowledge, however, that not all hearing healthcare providers need to be physicians and there are many situations, such as consumers continuing to have difficulty hearing even after beginning use of OTC hearing aids, where consulting licensed healthcare providers would be necessary or appropriate.

(Comment 30) A few comments recommended rewording the ''red flag'' condition warnings to present the issue first and then the solution. Comments suggested the warning should be updated to read, ''[p]rior to purchasing this device, if you have any of the following you should promptly consult with a licensed physician, preferably, an Ear-Nose-Throat (ENT) doctor.''

(Response) FDA agrees that a different presentation would more effectively communicate the warning. In response to comments proposing rewording to increase readability, we have retitled the warning and reordered the introduction in the manner suggested and adopted slightly different phrasing that we think will be more user-friendly.

(Comment 31) A comment expressed concern about the caution that hearing aids are not hearing protection. Some comments argued that it is impracticable for hearing aid users to take out their hearing aids in situations where a loud sound is passing by. Comments recommended the caution be updated to advise individuals to mute or turn off their hearing aids when experiencing a loud sound and only recommend removal of hearing aids if the hearing aid does not provide any hearing protection.

(Response) FDA is declining to implement this revision. FDA has included information in the labeling requirements to help users have realistic expectations when using hearing aids. This particular caution is intended to assist users in the day-to-day use of their hearing aid and to notify them that they should not rely on their hearing aid for hearing protection. Additionally, the labeling includes a caution that individuals should turn down the volume or remove the device if the sound is uncomfortably loud or painful. These two cautions provide appropriate guidance to help ensure safety when experiencing a loud sound.

(Comment 32) A few comments requested revisions to the note regarding expectations about what a hearing aid can do to use more positive framing. Comments argued that the note was more a notice of what hearing aids cannot do, and a more positive framing would increase readability and product desirability.

(Response) FDA agrees that it is important for users to read and understand the labeling easily, and we have updated the note to include language about the benefits as well as limitations of OTC hearing aids. The language was further updated to provide notice that users may need to wait a few weeks to get used to their hearing aids.

(Comment 33) A few comments requested that FDA require a minimum font size so that consumers can read and understand the particulars of each OTC hearing aid. Comments recommended requiring font sizes from 12–14 points.

(Response) FDA is declining to implement this suggestion. This rule applies to a large number of manufacturers and their various hearing aids so FDA believes some flexibility is

warranted. Additionally, we do not believe a minimum font size is necessary to ensure users can read and understand the labeling for OTC hearing aids because there are requirements that address this. For example, under section 502(c) of the FD&C Act, a device is misbranded if any word, statement, or other information required by or under authority of the FD&C Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use (see 21 U.S.C. 352(c)). Given this and other requirements, and the need for some flexibility as the rule applies to a variety of devices, FDA does not believe a minimum font size is warranted.

(Comment 34) A few comments recommended that the descriptions of functions of the hearing aids include figures and videos alongside text to provide additional clarity on how to use hearing aids.

(Response) To help users after purchase, the inside labeling must include, among other information, a description of accessories; illustration(s) of the OTC hearing aid that indicates operating controls, user adjustments, and battery compartment; adequate directions for use; technical specifications; and a description of commonly occurring, avoidable events that could adversely affect or damage the OTC hearing aid. The labeling requirements will allow a lay user to use the device safely and for its intended purposes (see § 801.5). The additions suggested by comments are not necessary for reasonable assurance of safety and effectiveness.

2. User Education

(Comment 35) A comment suggested that device package labeling describe hearing impairment in terms of common perceptual difficulties. In specific, it proposed that labeling describe mild impairment as having difficulty hearing soft-spoken people and young children. According to the comment, people with mild impairment are often able to hear loud or more-intense vowel sounds but may miss some of the softer consonant sounds. Thus, they may have to ask people to speak up or repeat themselves on occasion. The comment further stated that for someone with typical hearing, this is comparable to placing a finger in one's ears.

The comment proposed that labeling describe moderate impairment as having additional difficulty hearing vowel sounds in addition to missing consonant sounds. According to the comment, this means that when someone is speaking at a normal volume, a person with moderate hearing impairment is unable to hear most of the speech sounds. Accordingly, people with moderate hearing impairment often comment that they hear sounds but cannot always understand speech.

(Response) To help users determine whether they have perceived mild to moderate hearing impairment, FDA has revised the package labeling requirements by simplifying the language and making it less formal. (See the response to Comment 41 for more about these revisions.) However, while we agree that the suggested descriptions may also be useful for prospective users, other factors impact determining the labeling requirements. These factors include, for example, the limited space available for the outside package labeling, as many comments emphasized, and whether the information is necessary to provide reasonable assurance of safety and effectiveness. The descriptions suggested in the comment would add to the length of the material on the outside packaging for OTC hearing aids. Additionally, the required information under final § 800.30(c)(1)(B) sufficiently helps to provide reasonable assurance of safety and effectiveness, without the addition of the suggested text, because it contains enough information for someone to identify whether an OTC hearing aid may be intended for their particular hearing impairment. Therefore, we are not revising this final rule in the way suggested by the comment.

However, as stated above, the additional information described in the comment may still be useful so we intend to add similar information to FDA's website, which has pages focused on hearing aids and hearing loss. You can access the main web page at: *https://www.fda.gov/medical-devices/consumer-products/hearing-aids.* You may also wish to review information from the National Institute on Deafness and Other Communication Disorders. You can access their web pages at: *https://www.nidcd.nih.gov/health/hearing-ear-infections-deafness.* These websites provide more information for people interested in learning about hearing aids and hearing loss.

(Comment 36) A few comments expressed concern that, without proper warnings on the label, purchasers would not be informed on the limitations of OTC hearing aids with regard to their degree of hearing impairment.

(Response) FDA agrees and is finalizing the clear statement that we proposed, with an updated, more user-friendly list of common symptoms of mild to moderate hearing impairment. We are also finalizing the requirement, with similarly improved language, that the labeling describe signs of more severe impairment.

(Comment 37) A few comments expressed concern about the statement that hearing aids will not restore normal hearing and that training and counseling from a hearing healthcare professional may increase satisfaction. Comments argued that these ideas are based upon current limitations of hearing aids and recommended the statement be removed because, they argued, future hearing aids may have the capability to restore hearing to a normal level.

(Response) FDA is declining to remove this statement. The note informs consumers of the limitations and benefits they should expect from an OTC hearing aid. Since many purchasers will be selecting and using OTC hearing aids without the involvement of a licensed person, FDA has included statements, including the one discussed above, to help consumers have realistic expectations about OTC hearing aids. This helps provide reasonable assurance of safety and effectiveness.

(Comment 38) A few comments requested that labeling include a warning of when to stop use of OTC hearings aids. The comments expressed concerns that some hearing aid users may be unaware that they should stop use of OTC hearing aids due to the onset of certain conditions, for example, ear drainage, pain, and balance issues.

(Response) FDA agrees that certain conditions should suggest that users consult with a hearing healthcare provider, but we do not agree that the onset of such conditions necessarily indicates the user should stop using OTC hearing aids. FDA has revised the labeling to make it more general so that it warns users to see a doctor, preferably an ear-nose-throat doctor, if the user experiences any of the listed problems before or after purchase.

(Comment 39) A few comments recommended an additional warning on the inside package labeling to alert individuals that there is potential harm when wearing hearing aids for longer than recommended. Comments proposed a warning to users to exercise special care in the use of the device. It would warn against use of the hearing aid for more than 12 hours a day, for example, and against use if the device becomes uncomfortable, either due to the loudness of sound or the physical fit of the device. Such proposed warnings sought to mitigate the risk of further

impairment if the device was set to the maximum output level and worn for periods of time exceeding these recommendations.

(Response) FDA is declining to implement such suggestions. OTC hearing aids are designed to be worn all waking hours in a variety of listening environments and situations. The labeling required in this rule provides reasonable assurance of safety and effectiveness, including through notices that the hearing aid sound output should be neither uncomfortable nor painful, and that the hearing aid should not cause pain or discomfort when inserting or placing it.

(Comment 40) A few comments expressed concern that the labeling lacked reference to how a hearing healthcare professional can assist and benefit a person purchasing an OTC hearing aid. Comments recommended FDA develop labeling that includes guidance that, due to their specialized knowledge, hearing healthcare professionals are better at assisting in hearing tests and maximizing the benefits of a hearing aid.

(Response) FDA declines to make this addition to the labeling. This rule includes requiring specific language to assist consumers in determining whether an OTC hearing aid best meets their needs and when to consult a licensed professional. As mandated by FDARA, this rule establishes requirements to provide reasonable assurance of safety and effectiveness of OTC hearing aids without the involvement of a licensed person; therefore, while FDA agrees that licensed professionals provide valuable services, FDA will not be incorporating further requirements to include additional information about the benefit of licensed professionals in the labeling.

(Comment 41) FDA proposed that the outside package labeling include a statement that the device may not be useful for more significant hearing loss or complicated hearing needs. Some comments expressed concern that the warning used ''significant hearing loss'' without providing a definition of how to distinguish mild to moderate from significant hearing loss. These comments suggested that FDA further delineate mild to moderate from significant hearing loss, some of them suggesting we use objective criteria rather than more-subjective perceptual terms.

(Response) The final labeling requirements include the signs suggestive of both perceived mild to moderate hearing impairment and more significant hearing impairment. FDA included this information to assist consumers in determining whether OTC hearing aids can meet their needs. We have improved the phrasing of this information to be more understandable to inexperienced hearing aid users, including by removing the phrases the comments characterized as not defined well enough. However, as discussed in the response to Comment 24, FDA is declining to define hearing impairment in terms of objective criteria for the reasons explained in that response. We are continuing to delineate the different degrees of severity with perceptual terms as we believe this will be most useful to the intended users.

(Comment 42) Comments expressed concern that the symptoms suggesting perceived mild to moderate hearing impairment can also be indications of more significant hearing loss.

(Response) FDA infers these comments are concerned that consumers may mistake their degree of hearing loss due to the commonality of symptoms. FDA disagrees. FDA has specified some listening scenarios that represent some of the most common perceptual difficulties a user with perceived mild to moderate hearing impairment may experience. Although these symptoms may apply to multiple types and degrees of impairments, they are most common to perceived mild to moderate hearing impairment and therefore helpful to prospective users of OTC hearing aids. Further, FDA is also requiring that the symptoms commonly experienced by individuals with more significant impairment, with a recommendation to consult with a hearing healthcare professional, be included on the outside package labeling. Although FDA is finalizing more user-friendly language, we are declining to modify the symptoms for perceived mild to moderate hearing impairment. We believe that this information, along with the information required in the labeling to assist people with more severe impairment, will help prospective users determine whether an OTC hearing aid is a good choice for them.

(Comment 43) A few comments suggested labeling requirements include notice to individuals younger than 18 years old who are experiencing hearing issues that they should visit a hearing healthcare provider prior to using hearing aids due to complications that can cause auditory impairment and developmental issues.

(Response) FDA agrees with the concerns expressed by these comments and believes the labeling requirements address these concerns. For example, the labeling requirements in the proposed rule, which are being finalized here, include language that individuals under the age of 18 should consult with a doctor and refrain from using OTC hearing aids. It emphasizes the possible need for medical testing and the potential for hearing impairment in younger people to affect speech and learning.

(Comment 44) A few comments recommended that labeling include an explanation on the differences between prescription hearing aids, OTC hearing aids, and PSAPs to help consumers to select the appropriate device.

(Response) FDA is declining to require in the labeling an explanation of the differences between OTC hearing aids, prescription hearing aids, and PSAPs. Although this information may be helpful to know, it is not necessary for reasonable assurance of safety and effectiveness of OTC or prescription hearing aids. The labeling requirements for OTC hearing aids include common symptoms of those with mild to moderate hearing impairment and symptoms of more significant hearing loss to help consumers decide whether an OTC hearing aid is a good choice for them. Further, as discussed elsewhere in this document, prescription hearing aids must be sold only to or on the prescription or other order of a licensed practitioner (see § 801.109). Therefore, a licensed practitioner will be involved in determining whether a prescription hearing aid is appropriate for an individual with hearing impairment. Additionally, FDA is issuing a guidance with this final rule that will provide additional clarification of the differences between hearing aids and PSAPs. The notification of availability for the guidance appears elsewhere in this issue of the **Federal Register**.

(Comment 45) A few comments requested that OTC hearing aid labeling include a warning that people should not use OTC hearing aids if they have tinnitus. Comments expressed concern that tinnitus can be an indicator of serious medical conditions requiring proper management from a hearing healthcare professional, and failure to seek immediate treatment could cause further harm.

(Response) In the labeling requirements, FDA has included tinnitus in one ear as a condition for which users should seek medical evaluation. FDA is declining to expand upon this labeling requirement to include tinnitus in both ears since bilateral tinnitus often occurs in the presence of any degree of hearing loss. As such, the warning would be overly broad if it were to include bilateral tinnitus.

(Comment 46) A few comments suggested modifying the proposed language recommending users consult a hearing healthcare professional if they remain concerned about their hearing or struggle to use the device. The comments suggested that the labeling recommend users first contact the manufacturer to allow them an opportunity to resolve any issues.

(Response) FDA is declining to implement this suggestion. The statement notifies users that dissatisfaction with the compensation for impaired hearing may call for the attention of a hearing healthcare professional. Although FDA sees the potential benefit in users consulting with manufacturers to resolve certain technical or use questions, the purpose of the note is not to assist with device troubleshooting. Manufacturers may, however, include a troubleshooting section (or similar section) in the user instructions and provide suggestions for when users should consult them for technical or use issues that would not necessarily call for the involvement of a hearing healthcare professional.

(Comment 47) Some comments requested FDA require the labeling on and/or inside the package of OTC hearing aids include information about telecoils. Comments expressed concern that first-time hearing aid purchasers will not be able to make informed decisions about telecoils without an explanation of telecoil capabilities. Specific labeling suggestions varied, but they included statements of whether the device includes telecoils, explanations of what telecoils are, and the benefits telecoils may provide.

(Response) FDA is declining this suggestion because not all OTC hearing aids will have telecoils, and existing requirements would apply, for example for adequate directions for use (see section 502(f)(1) of the FD&C Act and § 801.5). (See also the response to Comment 94 about requiring telecoils.) Including the information about the feature could be confusing to consumers when the device does not include telecoils. Conversely, if a hearing aid includes telecoils, information about them would be necessary to provide adequate directions for use, so the information would have to appear in the labeling (see section 502(f)(1) of the FD&C Act and § 801.5).

(Comment 48) Some comments requested that labeling for OTC hearing aids include a questionnaire to assist consumers in deciding if OTC hearing aids are appropriate for them. Comments recommended the questionnaire to assist consumers in determining if they have a medical condition that requires a visit to a hearing health care provider prior to using OTC hearing aids.

(Response) FDA will not be implementing this suggestion. The labeling requirements we are finalizing, including information on Red Flag conditions and symptoms of more significant hearing loss, are sufficiently informative to provide reasonable assurance of safety and effectiveness without the additional time and effort necessary to complete a questionnaire and assess the results for purposes of deciding whether an OTC hearing aid is appropriate.

(Comment 49) A few comments expressed concern about the note regarding what a hearing aid can do, which includes a statement that, if a user has hearing loss in both ears, use of hearing aids for both ears (bilateral hearing aids) may provide more benefit than just one hearing aid. Comments suggested that this may discourage individuals who wish to begin with only one hearing aid. Comments recommended removing this paragraph from the note.

(Response) FDA disagrees that this statement would deter individuals from using one hearing aid. This statement does not suggest that individuals must use two hearing aids in all cases. This statement in the note simply conveys that two OTC hearing aids may provide more benefit in the case of hearing loss in both ears. Moreover, should individuals with hearing loss in both ears start with one OTC hearing aid and desire more benefit, this information would be useful to help them understand how to achieve greater benefit.

(Comment 50) A few comments requested that the labeling include guidance as to what to do when an eartip gets stuck in the ear canal.

(Response) FDA infers that the information requested by comments is meant to assist users in determining when to consult a healthcare professional. FDA agrees that providing guidance to users on this issue is important. We have updated the labeling to help users decide when to seek medical help (see new § 800.30(c)(2)(iii)(C)).

3. Outside Package Labeling and Purchasing Decisions

(Comment 51) A few comments recommended a statement for individuals with ability limitations, such as a developmental disability, similar to statements directing people under the age of 18 to seek examination and evaluation by hearing healthcare professionals. Commenters implied that, just as with individuals under 18, individuals with ability limitations may not have the same ability to determine their hearing loss or the presence of more serious medical issues; therefore, evaluation by a licensed professional would be necessary.

(Response) FDA is declining to implement this suggestion. The statements addressed to those under age 18 concern hearing healthcare needs that are specific to younger people, such as speech and learning difficulties. Additionally, as explained in the proposal, the use of OTC hearing aids in people younger than 18 presents risks to health beyond those typically associated with use in older people. Whereas hearing loss in older adults is most commonly related to noise exposure and aging, the etiology (causes) of hearing loss in younger people is varied and may result from conditions that warrant prompt diagnosis to avoid serious risks to health (see 86 FR 58150 at 58158). The comments provided no information to support that adults with ability limitations face similar risks to those younger than 18.

Further, we have revised the labeling with more user-friendly terms throughout. We believe the information required in the labeling, including statements identifying Red Flag conditions and advising users to consult with a hearing healthcare professional if they continue to struggle with or remain concerned about their hearing, are appropriate for adults with perceived mild-to-moderate hearing impairment. We do not agree that revising the labeling or limiting purchases for certain adults in the manner suggested by the comments is necessary to provide reasonable assurance of safety and effectiveness of OTC hearing aids.

(Comment 52) A comment requested that FDA standardize the names of hearing aid features so that interested people could compare products more easily. In that vein, multiple comments suggested that FDA develop a rating system to compare features. The commenter expressed that information should be accessible to lay users and that relying on a regulatory guidance document, should FDA issue one in the future, to convey such information is unlikely to assist most consumers, who are not experts in hearing aid technology. Similar comments desired a rating system for device performance in certain conditions, for example, live concerts.

(Response) FDA agrees that interested people should have sufficient information to compare products as easily as possible, and we have made various revisions in this final rule to

improve the usefulness of the required labeling for laypeople. We are also finalizing a requirement for a conspicuous mark identifying the hearing aid as OTC that we expect will help purchasers and others distinguish product categories (see Additional Revision 2 in section III.D.3). Further, FDA's website describes common hearing aid technologies and features to help orient consumers with the technology and terminology, available at: *https://www.fda.gov/medical-devices/hearing-aids/types-hearing-aids.* However, we are not making additional revisions in the final rule to standardize the names of device features.

We note that a number of regulatory requirements will nevertheless assist consumers to compare devices and features. For example, the applicable classification regulation for a device specifies the name of the device type (so is standardized in that way), and the principal display panel on the package of an OTC device must display a statement of identity that includes the common name of the device, in bold typeface (see § 801.61). Further, the labeling must include adequate directions for use that allow a layperson to use the device safely and for its intended purpose(s) (see § 801.5). And for OTC hearing aids, we proposed and are finalizing a requirement under new § 800.30(c)(4) that the labeling include certain technical specifications. Purchasers interested in the electroacoustic performance could use this information to compare across devices.

We acknowledge that manufacturers may use proprietary names for device features, even when other manufacturers offer a similar feature under a different name (perhaps also proprietary). However, FDA expects that hearing aid technology will continue to evolve and that device features will similarly evolve, including the specific capabilities. Precisely identifying, describing, and naming those features and ways to compare them by regulation, even for the present, is neither practical nor necessary. Further, individuals may have different preferences as to which features are more valuable in a hearing aid. For similar reasons, a rating system is neither practical nor necessary. Even with additional standardization of terminology, the import of each feature may still not be apparent to purchasers, and similarly, rating systems may not reflect (rate highly) the features of a device that a given purchaser would value. Thus, finalizing regulatory requirements for such a system of comparison is not likely to communicate useful information to purchasers and may hinder innovation by codifying current characteristics of device features.

To communicate useful information, we expect that manufacturers will describe their devices' features in ways that best appeal to the intended users, and the labeling of a hearing aid will have to be available to prospective users prior to purchase (see new §§ 800.30(c)(2) and 801.422(c)(2)). Moreover, the labeling of a device must not be false or misleading in any particular (see 21 U.S.C. 352(a)(1)). These requirements will help ensure that purchasers have accurate information about a hearing aid and its features in a way that allows them to compare these devices.

As for ratings for device performance in certain conditions, given the subjective nature of user preferences, developing a useful rating system is impracticable. We expect that purchasers will have access to a wealth of opinions from other purchasers, product testers or reviewers, and consumer information organizations. This will allow purchasers to find ratings that reflect their interests more than any possible criteria standardized by regulation. For example, a purchaser may prefer OTC hearing aids that users rate highly for use in a restaurant. Additionally, user preferences may change in the future, so any rating system may become quickly outdated.

Regarding device performance more generally, as we explained in the proposal, we are establishing electroacoustic performance requirements for high-fidelity amplification (see 86 FR 58150 at 58163). A hearing aid must meet these requirements to be available OTC, but the device need not outperform them. By extension, a device need not perform better than a high-fidelity level of amplification. Establishing a rating system for compliant devices, that is, for those that would already have high fidelity, would incorrectly imply some devices are substandard. We are not finalizing requirements for describing how well a device performs beyond the electroacoustic performance specifications in the labeling, the performance itself being required to meet a standard for high fidelity.

(Comment 53) A few comments recommended that information about whether a battery was included, and what type of battery is required, be included on the labeling. Comments recommended the inclusion of this information so that consumers can purchase the necessary batteries at the same time as the OTC hearing aid and adequately compare OTC hearing aids.

(Response) We agree that it is important for manufacturers to include information about the type, as well as the number, of batteries, and whether batteries are included because this is information consumers will need to use the hearing aid. Therefore, FDA is revising the final rule to require this information on the labeling outside the package of the hearing aid so that consumers are aware of the battery requirements prior to, or at the time of, purchase.

(Comment 54) A few comments recommended including a description of any smartphone compatibility requirements to operate the hearing aid on the outside package labeling. Comments argued this would allow consumers to determine if they have the necessary device and programming to operate the hearing aid prior to purchase.

(Response) FDA agrees with the comments that this information is important for consumers to know when comparing OTC hearing aids at the retailer. Similar to the battery information discussed above, information on the control platform is necessary for use of the hearing aid. Therefore, FDA is revising the final rule to require that the outside package labeling indicate whether a mobile device or other non-included control platform is required, such as a smartphone, a remote sold separately, or a personal computer. The labeling also will have to indicate the type of control platform and how the hearing aid connects to the control platform, for example, via Bluetooth and/or USB–C.

(Comment 55) A few comments suggested that the rule require a list of other basic features of each OTC hearing aid (for example, mobile operating system, volume controls, feedback, telecoil, or accessories) on the outside package. Comments expressed concern that, without a list of features, consumers may have difficulty comparing different OTC hearing aids and make an informed decision.

(Response) FDA is declining to implement this suggestion in its entirety. The packaging provides limited space for required labeling, and while we have adopted some such suggestions—see the responses to Comment 53, about batteries, and Comment 54, about smartphone compatibility—we have not determined that the other information is necessary on the outside package labeling to provide reasonable assurance of safety and effectiveness. Additionally, we are finalizing the requirements as proposed

that the inside package labeling, among other requirements, provide illustration(s) of the OTC hearing aid that indicates operating controls, user adjustments, and the battery compartment (see § 800.30(c)(2)(iv)), provide information on the function of all controls intended for user adjustment (see § 800.30(c)(2)(v)), and describe any accessory that accompanies the OTC hearing aid (see § 800.30(c)(2)(vi)). As the inside package labeling must be made available prior to purchase (see § 800.30(c)(2)), consumers will be able to access this information prior to purchase. Further, as discussed in the response to Comment 26, any OTC hearing aid must have labeling that bears adequate directions for use that allow a lay user to use the device safely and for its intended purposes (see § 801.5). In cases where necessary for adequate directions for use, information on other features not specified in § 800.30(c) will have to appear in the labeling, and prospective users will have access to the labeling prior to purchase.

(Comment 56) Some comments expressed concerns for device labeling that states an OTC hearing aid is ''FDA approved,'' ''FDA cleared,'' or otherwise endorsed by the FDA. The comments asserted that such labeling indicates that: FDA has inspected an OTC device for quality and/or compliance with applicable legal requirements, that FDA has approved the device for use by the individual purchaser, and/or that FDA favors the device over others without such labeling. The comments argued that such indications are misleading for purchasers.

(Response) FDA does not endorse particular devices and representations of such in labeling can be false or misleading. The determination of whether ''FDA cleared,'' ''FDA approved,'' or similar language on a device's labeling suggests FDA endorsement of the device or is otherwise false or misleading is made on a case-by-case basis.

Clearance of a device indicates that FDA has determined the device to be substantially equivalent to a class I or II device. It does not in any way denote official approval of a device or in any way imply that the device is in compliance with any other pertinent sections of the FD&C Act (see 41 FR 37458 at 37462, September 3, 1976). Likewise, a grant of a De Novo classification request under 21 CFR 860.260(a)(1) or compliance with registration and listing requirements under part 807 does not denote official approval or imply compliance with other pertinent device requirements. Any representation that creates an impression of official approval of a device due to complying with requirements for premarket notification or registration is misleading and constitutes misbranding (see §§ 807.97 and 807.39, respectively).

The labeling of a device may be false or misleading for other reasons too. For example, if a statement in the labeling creates an impression that FDA officially favors one classified device over another, it would likely be false or misleading. Or, if the labeling uses FDA's logo, creating an impression that FDA has endorsed the product, it would likely be false or misleading.[8] A device would be deemed to be misbranded under section 502(a)(1) of the FD&C Act if its labeling included such false or misleading statements. The FD&C Act prohibits doing or causing certain acts with respect to a misbranded device (see, *e.g.,* 21 U.S.C. 331(a)–(c), (k)).

(Comment 57) A comment requested clarification on the applicability of prescription labeling requirements under new § 801.422 to the implantable components of a bone-conduction hearing aid. The comment argued that applying the labeling requirements to the implantable components is unnecessary because a surgeon has already decided to implant specific components, and the labeling under new § 801.422 is neither necessary nor helpful for the surgeon or the hearing aid user. In contrast, the non-implantable components of a bone-conduction hearing aid, such as the sound processor, are often marketed separately and not necessarily through a physician.

(Response) FDA agrees that the labeling requirements under § 801.422 are not necessary for reasonable assurance of safety and effectiveness with respect to the implantable components of a bone-conduction hearing aid. We have modified the classification regulation to clarify that the labeling requirements for prescription hearing aids apply only to the non-implantable components of a bone-conduction hearing aid. In cases where the implantable components are not sold or distributed with the non-implantable components, the implantable components need not bear the labeling under new § 801.422.

(Comment 58) One comment requested that FDA strike § 801.422(c)(1)(ii)(A). The comment stated that the decision to offer trial rentals or purchase options is a trade issue and does not relate to the safety or effectiveness of the device.

(Response) FDA has decided to retain § 801.422(c)(1)(ii)(A) (in the final rule, this information is in § 801.422(c)(1)(i)(C)). FDA notes that § 801.422(c)(1)(ii)(A) does not require offering a trial-rental or purchase-option program. Instead, this provision just requires that the outside package labeling for a prescription hearing aid include information advising prospective users to inquire about the availability of a trial-rental or purchase-option program.

FDA also notes that § 801.422(c)(1)(ii)(A) is substantially identical to what was already required to be included in the user instructional brochure for a hearing aid under former § 801.420(c)(3). In other words, the information required under § 801.422(c)(1)(ii)(A) is not new and has been required to be in hearing aid labeling for many years. The only differences between §§ 801.420(c)(3) and 801.422(c)(1)(ii)(A) are: § 801.422(c)(1)(ii)(A) applies only to prescription hearing aids, § 801.422(c)(1)(ii)(A) requires that the information be provided on the outside package labeling for a prescription hearing aid, and the required statement under § 801.422(c)(1)(ii)(A) uses language that is easier to understand.

FDA continues to believe that this labeling requirement is necessary to provide reasonable assurance of safety and effectiveness of prescription hearing aids. When FDA included the requirement in former § 801.420(c)(3) to provide information in the user instructional brochure advising prospective users to inquire about the availability of a trial-rental or purchase-option program, FDA acknowledged the difficulty of determining in advance whether an individual will benefit from a hearing aid, and we noted that voluntary trial-rental or purchase-option programs for prospective hearing aid users were available (42 FR 9286 at 9289).

FDA believed that trial-rental or purchase-option programs, which provide prospective hearing aid users the opportunity to wear the selected hearing aid so that the user can make an informed judgment on whether a benefit is obtained from the use of the hearing aid, were important to the welfare of the hearing impaired and therefore, required that the user instructional brochure contain information advising prospective users to inquire about the availability of such program (42 FR 9286 at 9289). FDA explained that this information would help assure that the

[8] FDA's logo is not for use on private sector materials, including device packaging. For more information, you may wish to review FDA's logo policy, available at: *https://www.fda.gov/about-fda/website-policies/fda-logo-policy.*

selected hearing aid would be beneficial and would encourage hearing aid use among those prospective users who lack the motivation to try a hearing aid because of the fear that they will spend a great deal of money with no guarantee of benefit (42 FR 9286 at 9289). FDA believes that the reasons for requiring this information in labeling continue to apply for prescription hearing aids, which are typically sold through licensed hearing aid dispensers, many of whom offer such programs.

(Additional Revision 2) In response to various concerns evident in the comments, we are including in this final rule a requirement that the principal display panel of the outside package labeling of an OTC hearing aid bear the conspicuous marks, ''OTC'' and ''hearing aid.'' FDA intends these marks to clarify for purchasers and others, including retailers and State agencies, whether a product is a hearing aid (regulated as a device), and whether it is available OTC. (See also the response to Comment 18 discussing hearing aid terminology.) However, these marks do not in any way denote official approval of the device, and any representation that creates an impression of official approval because of complying with these marking requirements or with the OTC Hearing Aid Controls would be considered false or misleading and constitute misbranding. (See also the response to Comment 56 regarding other false or misleading statements.) The marking is necessary for reasonable assurance of safety and effectiveness of OTC hearing aids because it provides assurances that non-OTC hearing aids or non-devices will not be confused for OTC hearing aids.

The marks must have the same prominence as required under § 801.61(c) for the device's statement of identity, and a manufacturer may satisfy this new marking requirement if the statement of the device's common name includes both ''OTC'' and ''hearing aid.'' For example, a manufacturer may label its product as a ''Self-Fitting OTC Hearing Aid'' (assuming the device's common name is ''self-fitting hearing aid''). Such a device would meet this new marking requirement as well as the requirement for the common name in the statement of identity. Alternatively, the manufacturer may, for example, label its product without including the marks in the common name of the device, perhaps by placing ''OTC'' in a corner of the principal display panel with the required prominence (assuming the device's common name includes ''hearing aid''). Formatting the marks, for example, by outlining them with a box, would be permissible provided the formatting does not cause the marks to lack the required prominence (see 21 CFR 801.15(a)(6)).

4. Labeling Inside the Package and Technical Matters

(Comment 59) A few comments requested that the frequency response and ANSI S3.22 specifications of OTC hearing aids be included in the user manual.

(Response) FDA infers this request is to assist in selecting an OTC hearing aid with optimal performance. We are not requiring the requested information in OTC hearing aid labeling because, as we explained in the proposal, this information is highly technical and generally not useful to the lay user (see 86 FR 58150 at 58163). However, we are finalizing the proposed requirement that OTC hearing aid labeling include key electroacoustic performance specifications that are more likely to assist prospective lay users in comparing and selecting the devices, including the values for maximum output, full-on gain, total harmonic distortion, self-generated noise, latency, and upper and lower cutoff frequencies for the acoustic bandwidth.

(Comment 60) A few comments expressed concern that requiring summaries of clinical studies conducted by or for the manufacturer on the inside labeling is not practical. Comments suggested that providing a link to an online library of the clinical studies and a summary of each study on the manufacturer's website would suffice.

(Response) FDA disagrees that providing summaries of clinical studies in the labeling inside the package is impractical. While we understand that fully appreciating the outcomes of a study can entail a lengthy technical document, presenting the most important findings regarding the performance of the OTC hearing aid, in a user-friendly format, need not take significant space in the labeling. We are finalizing the requirement as proposed.

(Comment 61) A few comments requested that the labeling include information on how the OTC hearing aid can be fixed or repaired. Comments requested that the information include whether a local hearing healthcare professional can repair the device or if it needs to be sent to the manufacturer. Comments argued this would allow prospective users to make an informed decision when purchasing their devices.

(Response) FDA agrees that manufacturers should provide users with information on how to have their hearing aid repaired because this information may be difficult for users to obtain on their own. The inside package labeling requirements now include information on how and where to obtain repair service or replacements, with at least one specific address where the user can go or send the OTC hearing aid to obtain such repair service or replacements.

(Comment 62) A few comments expressed concern that estimating the expected battery life will be difficult for manufacturers due to inconsistencies between batteries and use conditions. Comments proposed removing this requirement from the labeling inside the package.

(Response) FDA recognizes that battery performance can vary but will retain this requirement in the final rule because this information will help prospective purchasers determine whether a hearing aid will be suitable for their circumstances. Recognizing that performance can vary from device to device, we did not propose, and are not requiring, a specific method of estimating the battery life. However, manufacturers may want to review Clause 4.7 (Battery Life) of ANSI/CTA–2051:2017, which currently provides an acceptable method to estimate the battery life (Ref. 8).

(Comment 63) A comment proposed a requirement for OTC hearing aid labeling to include information about the transport methods for configuration information and other data to and from the OTC hearing aid with all points along the supply chain.

(Response) FDA is not adopting this proposal because such information is focused on the electronic transfer of non-diagnostic data and is not generally necessary for reasonable assurance of safety and effectiveness of all OTC hearing aids. We note, however, that should States establish or continue in effect requirements to disclose such information, and the requirements are not specifically applicable to hearing products, section 709(b)(4) of FDARA likely would not preempt them. However, FDA is not opining on whether such disclosure requirements likely would or would not be preempted under section 521(a) of the FD&C Act. (See also the response to Comment 115 concerning the collection of personal information as part of a sale of an OTC hearing aid.)

(Comment 64) A comment requested that FDA require labeling that specifies the latency of any wireless streaming technologies the OTC hearing aid uses.

(Response) In certain circumstances, latency information in the labeling may be necessary under existing requirements. For example, if the information is necessary to provide adequate directions for use or necessary

for practitioners licensed by law to use the device safely and for its intended purpose(s), then the latency information would have to appear in the device labeling (see §§ 801.5 and 801.109(c), respectively).

However, as a general matter for hearing aids that incorporate wireless streaming technology, FDA has determined that stating the streaming latency is not necessary to provide reasonable assurance of safety and effectiveness. Additionally, a variety of factors can affect wireless streaming latency, including nearby radio interference, distance between the transmitter and receiver, and the presence of materials that absorb certain radiofrequencies. As such, a standardized wireless streaming latency value may not reflect a particular device's design or the environment in which the user wears the hearing aid; and thus, FDA is not adding a requirement to include wireless streaming latency information for all OTC hearing aids in this rule. We note that FDA is finalizing requirements for OTC hearing aid labeling to include manufacturer contact information. If users or prospective users are interested in the streaming latency specifically, they will be able to contact the manufacturer.

(Comment 65) A few comments requested a labeling requirement describing the fitting range across different frequencies (500, 1000, 2000, and 4000 Hertz) to help consumers determine the suitability of different OTC hearing aids to meet their needs.

(Response) FDA understands that traditionally, hearing aids are designed and marketed with a specific fitting range in mind, and manufacturers may maintain this practice. However, OTC hearing aids are intended to be available without the involvement of a licensed person (see 21 U.S.C. 360j(q)(1)(A)(v)). As such, FDA is not using audiometry-defined thresholds or ranges of hearing loss in the final rule. Instead, FDA is using descriptions of common symptoms of mild to moderate hearing impairment in the labeling. As such, describing the fitting ranges across different frequency bands is not necessary for reasonable assurance of safety and effectiveness of OTC hearing aids. However, manufacturers may choose to include this information in device labeling, and prospective users will have access to the manufacturer's contact information prior to purchase should they desire to inquire about the fitting ranges.

5. Adverse Event Reporting

(Comment 66) The proposed labeling included instructions on reporting adverse events through the MedWatch portal, *https://www.fda.gov/Safety/Medwatch,* or by phone, 1–800–FDA–1088. A few comments requested that email and mailing options also be provided for adverse event reporting. Comments further recommended that FDA provide a receipt of the complaint to individuals.

(Response) We are declining to include a mailing address in the labeling because submissions by mail should be on a MedWatch form, for example, the Consumer Voluntary Reporting Form (FDA 3500B), which contains the address along with additional instructions. Reference to just the address in hearing aid labeling may result in reports submitted in an unexpected manner and format, potentially causing confusion, incomplete reports, and significant delays in processing them. However, in addition to reporting events through the MedWatch portal and 1–800–FDA–1088, consumers can submit their adverse event reporting form to FDA by fax or the mailing address according to the instructions on the form. Submitters will receive a reply from FDA after we receive their report. Email is not currently an alternative to the MedWatch online submission system.

(Comment 67) A few comments recommended that in addition to labeling information on reporting adverse events to FDA, contact information for manufacturers should be required so that manufacturers are provided the opportunity to review adverse events. Comments implied that providing manufacturers with awareness about adverse events and opportunity to address them would be beneficial to consumers.

(Response) To help facilitate communications between users and manufacturers, FDA has added the manufacturer's email and mailing address to the labeling requirements (see final § 800.30(c)(1)(i)(E)). Should users wish to report adverse events to the manufacturer, they may use this information to do so. Manufacturers may also include instructions in the labeling, that do not conflict with the labeling requirements, on how to directly report adverse events to them.

(Comment 68) FDA included in the proposed labeling examples of adverse events to be reported to FDA: irritation of the ear canal or outer ear skin, injury from the device (like cuts or scratches, or burns from an overheated battery), pieces of the device getting lodged in the ear canal, and sudden increased severity in hearing loss with the device. Some commenters suggested limiting the list to more-serious conditions to avoid the adverse reporting system being overwhelmed by reports of minor adverse events. Commenters expressed concern that if the labeling were finalized as proposed, more serious adverse events may get lost in the volume of what the commenters see as minor. Commenters recommended adverse event reporting be limited to significant injury and/or death.

(Response) FDA is declining to limit the examples of adverse events, or the reporting of adverse events, to significant injury and/or death. FDA is interested in receiving information on all adverse events to have a better understanding of OTC hearing aid product safety and performance. Additionally, under section 709(d) of FDARA, FDA is required to submit a report to Congress ''analyzing any adverse events related to over-the-counter hearing aids.'' FDA is prepared to review adverse event reports and has experience in sorting through adverse event reporting data to identify safety signals and trends.

(Comment 69) Comments requested that users of prescription hearing aids be able to report adverse events to FDA similar to how OTC hearing aid users can report through the MedWatch portal at *https://www.fda.gov/Safety/Medwatch,* or by phone, 1–800–FDA–1088.

(Response) We agree that prescription hearing aid users should also report adverse events to FDA. We proposed and are finalizing the same note for prescription hearing aids to notify users of how to report adverse events to FDA.

6. Miscellaneous Labeling Considerations

(Comment 70) Some comments recommended that restrictions on the use of OTC hearing aids by individuals under the age of 18 be removed. Comments expressed the need for cost effective hearing aids for individuals under 18. Additionally, comments asserted that individuals under 18 are increasingly suffering from hearing loss as a result of exposure to loud sounds, which they argued is hearing loss that can be addressed by OTC hearing aids.

(Response) FDA is declining to allow the sale of OTC hearing aids to individuals under the age of 18. This condition for sale is consistent with section 709(b)(2)(C) of FDARA and section 520(q)(1)(A)(ii) of the FD&C Act, which establish that OTC hearing aids are only intended for people aged 18 and older. The use of OTC hearing aids

in people younger than 18 presents risks to health beyond those typically associated with use in older people. While FDA appreciates the need for cost effective hearing aids for individuals under the age of 18, the sale of OTC hearing aids will be limited to individuals who are age 18 and older.

(Comment 71) A few comments expressed concern that the manufacturer contact information that FDA proposed to include in the labeling of OTC hearing aids is limiting because the only alternative to a website address was a telephone number. Comments argued that many individuals with hearing loss do not prefer to communicate using the telephone and recommended the inclusion of the manufacturer's email and mailing address on labeling to provide greater access to users.

(Response) FDA agrees that providing additional ways for users to communicate with manufacturers will allow for users to resolve issues with their hearing aids more easily. The labeling requirements have been updated to include the manufacturer's mailing address and email address.

(Comment 72) A few comments noted that hearing aids are physically small and do not have room for a serial number on them. Comments recommended that the serial number be located on an accompanying item, such as on the storage case or registration card.

(Response) FDA is declining to implement this suggestion. Manufacturers have been complying with this long-standing requirement for labeling under § 801.420, which we are revising and renumbering as § 801.422, and marking the serial number on the device itself (since 1977). Additionally, because accompanying items can be misplaced, marking the device itself is essential to the utility of the serial number.

(Additional Revision 3) As noted in the response to Comment 8, we are finalizing labeling requirements for hearing aid software. We expect much of the labeling to be electronic in nature, for example, the graphic and printed matter that appear on a download web page or in electronic display ''cards'' or dialogs in the software's user interface. As such, electronic labeling may have a transitory nature, and we are specifying the occasion and persistence of presentation. For example, we are requiring that the labeling present a warning against use in people younger than 18. In this example, the electronic labeling, perhaps appearing in a modal dialog, need not appear at all times. Rather, we are requiring that the labeling present the warning to the user prior to first use of the software and persist until the user acknowledges it. We are further requiring that the software provide access to all of its labeling for later review, for example, through a Help menu selection.

We intend the software device labeling requirements to correspond with the labeling requirements we proposed for packaged hearing aids to the greatest extent possible. As such, we are requiring that the software device labeling present certain information prior to first use or obtaining payment information for the software (not necessarily the hearing aid or amplification platform), reflective of the nature of the information we are requiring on the packaging, that is, information the prospective user should know prior to purchase, if a purchase is involved. Some labeling is required prior to first use, but it could appear after purchase of the software, if a purchase is involved. Other labeling is required to be accessible in the software, but it need not be presented at any particular time.

We recognize that some of the information required in the labeling under final § 800.30(c)(1) through (4) may not apply to software. For example, specific instructions for cleaning and disinfection likely would not apply to stand-alone software (see final § 800.30(c)(2)(vii)(D)). As another example, an illustration of the battery compartment likely would not apply (see final § 800.30(c)(2)(iv)). To address this, we made it clear that certain information is required to the extent applicable. Thus, in the first example, the software device labeling need not include instructions for cleaning and disinfection if that information is not applicable. In the second example, the software device labeling must include an illustration(s), but not necessarily of the battery compartment if not applicable. Further, in that example, a video would be an adaptation of and suffice for an illustration(s). Although software may not have a principal display panel like a packaged hearing aid, a software-loading or Home screen could serve a similar function to provide the information required under § 800.30(c)(1)(iii).

We have also included requirements for the software device labeling to disclose compatibility requirements as well as any fees or payments. Disclosure of compatibility requirements is necessary for reasonable assurance of safety and effectiveness because this information describes some of the necessary conditions under which the software device will be usable and thus safe and effective. The disclosures of any fees or payments are similarly necessary because they describe necessary conditions under which the software or additional features will start, continue, and/or cease to operate safely and effectively.

The software labeling requirements we are finalizing under new § 800.30(c)(5) are in addition to any other applicable requirement, including special controls. For example, 21 CFR 801.50, regarding labeling requirements for stand-alone software, would still apply to the software when appropriate under that regulation. As another example, the general requirements for adequate directions for use (see section 502(f)(1) of the FD&C Act and § 801.5) would also apply, unless the software device is exempt under § 801.109.

We are adding similar software device labeling requirements in § 801.422.

E. Output Limits (§ 800.30(d))

Generally, comments on the output limits for OTC hearing aids either agreed that FDA's proposed limits were appropriate or comments proposed lower limits. Several comments recommended output limits that depend on device design, for example volume control, compression, or a limit on gain. FDA received many comments on this subject, some of which included references to published scientific literature, consensus standards, stakeholder position papers, and public health guidelines. For the following reasons, we are finalizing lower output limits than we proposed—111 and 117 dB SPL, which are multiples of 3-dB reductions from the proposal—but we are not including a separate gain limit.

1. Finalizing Lower Output Limits

After further considering the potential risk of worsening users' hearing impairments as discussed below, as well as the literature submitted to us in the comments (*e.g.,* Refs. 10 and 11), we have decided to finalize lower output limits than we proposed. We are retaining the conditional structure of the output limits, with the higher output permitted for devices with activated input-controlled compression. (See the response to Comment 87 about requiring a user-adjustable volume control for all OTC hearing aids.) We are also retaining the limits expressed as Output Sound Pressure Level 90 (OSPL90) values rather than A-weighted values as suggested by some comments. OSPL90 values are more common expressions of hearing aid outputs, and they are consistent with the consensus standards we are adopting, which refer to OSPL90 values.

Comments suggested a variety of lower limits, but we are adopting a general limit of 111 dB SPL, which is sufficient to mitigate the greater risk potential from both acute high-output-levels and cumulative exposure that we identified after further consideration. We are correspondingly finalizing the higher conditional limit of 117 dB SPL for devices with activated input-controlled compression.

Many commenters suggested an output limit of 110 dB SPL and considered this output limit sufficient to address even moderate impairment, as each commenter defined the term ''moderate.'' However, as discussed further below, we have applied an equal-energy principle and used a 3-dB exchange rate in revising the general output limit to 111 dB SPL. We do not believe that an output limit of 110 dB SPL would provide any meaningful difference with regard to safety.

The output limits that we are finalizing balance safety and effectiveness without unduly sacrificing either. We are not adopting the even lower limits suggested in some comments because these lower limits would reduce device effectiveness for people with perceived mild to moderate hearing impairment to such a degree that the limits would exclude some intended users from obtaining sufficient benefit of OTC hearing aids. At the same time, progressively lower output limits yield diminishing returns in terms of safety. Thus, lowering the output limit even further as suggested in some comments would begin excluding intended users without achieving meaningful improvements in safety for them. As a result, lowering the output limits even further as suggested in some comments would not provide reasonable assurance of effectiveness for people with perceived mild to moderate hearing impairment, and thus would not be ''appropriate'' for OTC hearing aids per section 709(b)(2)(B) of FDARA.

The reduction in effectiveness and benefit would result primarily because, with even lower output limits, the hearing aid would no longer have a sufficient dynamic range (''headroom'') for high-fidelity amplification. The hearing aid could then apply compression and/or other output limiting measures more often or to a greater degree, resulting in perceptibly lower-fidelity (less effective) amplification. In such circumstances, OTC hearing aids would have significantly reduced effectiveness for the intended users, sometimes even in normally non-hazardous environments. This reduction in effectiveness would be increasingly noticeable for intended users as the device output is reduced.

By way of comparison, a comment urging FDA to adopt an output limit of 102 dB SPL also urged FDA to limit the intended users of OTC hearing aids to people with mild impairment rather than mild to moderate impairment. As we explain in the response to Comment 10, we are not so limiting the OTC category, and an output limit that low would not provide reasonable assurance of safety and effectiveness in addressing perceived mild to moderate hearing impairment. As provided in section 520(q)(1)(A)(ii) of the FD&C Act, OTC hearing aids are ''intended to be used by adults age 18 and older to compensate for perceived mild to moderate hearing impairment.''

Moreover, many comments urging FDA to adopt lower limits than the ones we are finalizing referred to material that stated output levels in root mean square (RMS) terms. The limits we are finalizing are expressed differently—expressed in terms of maximum peak values (implicit in the measurement of OSPL90 values). To derive a peak value based on an RMS level, one would increase the RMS level by an amount that represents the ''crest factor'' of the output. Thus, except in one circumstance that is not applicable to the materials submitted to us, RMS values are lower than peak values for the purposes of considering the sound output of hearing aids, and comparisons between RMS and peak values need to take this difference into account.[9]

As noted, we are also finalizing a lower limit for OTC hearing aids with input-controlled compression activated. This value, 117 dB SPL, is intended to maximize the available headroom for OTC hearing aids while still providing reasonable assurance of safety and effectiveness. As we explained in the proposal, input-controlled compression is an automatic function that dynamically reduces the device's output and helps prevent the device from continuously performing at its output limit (see 86 FR 58150 at 58161–58162). In these ways, the use of input-controlled compression adequately addresses the safety concerns that the increased output can raise. We explain our reasons for finalizing lower output limits in more detail below.

[9] For square wave signals, the peak and RMS values would be the same (a 0-dB difference). However, for the purposes of describing hearing aid performance, a crest factor would be an important element for considering limits as RMS values, for example, to ensure a limit expressed as an RMS value allowed for effective amplification of speech. Crest factors for speech are often 12–17 dB, with 15 dB being a value frequently cited in comments.

We wish to emphasize that, in finalizing lower output limits, we do not intend to reduce the number of intended users for whom the use of OTC hearing aids is safe and effective (in comparison to the proposed limits). Rather, we are lowering final limits to allow sufficient headroom for the same intended users, albeit less headroom than we proposed. As stated above, the output limits that we are finalizing are intended to balance safety and effectiveness without unduly sacrificing either.

In response to comments, we are also revising the final regulation to permit the use of alternative acoustic couplers when a 2-cubic centimeter (cm^3) coupler is not compatible with the device design. See the response to Comment 81 for more on this topic.

Additionally, we are slightly modifying the phrasing of the regulation to clarify that the device may reach the higher limit only while the input-controlled compression is activated. For example, if a user were to deactivate the feature, the device must not exceed the general output limit of 111 dB SPL while the feature is deactivated.

2. Considerations for Appropriateness of Output Limits

In deciding to finalize lower output limits, FDA is primarily considering output limits that will provide reasonable assurance of safety and effectiveness and are ''appropriate'' for OTC hearing aids as section 709(b)(2)(B) of FDARA uses the term. To determine such limits, we are balancing considerations of safety and effectiveness for all intended users of these devices to both protect and promote the public health. As we explained in the proposed rule, too high of an output can be unsafe (see 86 FR 58150 at 58161). However, too low of an output reduces device effectiveness and can lead to poor device performance, and ultimately, can reduce satisfaction and use (see 86 FR 58150 at 58161).

Many comments described the communication needs of hearing aid users and how those interests relate to the output limits and the purposes of establishing the OTC category of hearing aids. FDA agrees that those interests are relevant to safety and effectiveness as well as what would be appropriate. However, balancing the various considerations related to safety and effectiveness is complex and involves the application of scientific judgment. Thus, while FDA agrees with the many thoughtful comments that several factors, discussed further in this section, affect the determination of appropriate output limits, we do not always agree

with the determination reached by commenters.

One of the purposes of this rulemaking is to address a widespread public health need stemming from relatively low adoption and use of hearing aids by people who could benefit from them. More specifically, an underlying goal of this rulemaking is broadening access to these devices, without the involvement of a licensed person, to compensate for perceived mild to moderate hearing impairment in adults. (See the responses to Comments 10–12 for more about the scope of this rulemaking.) FDA is mindful of the need to establish or adopt output limits that would provide sufficient amplification to meet the user's listening needs and thereby bolster user satisfaction, adoption, and use. Moreover, OTC hearing aids need a sufficient output, maximizing the available dynamic range (the headroom), to meet the hearing needs of the breadth of the intended population of adults with perceived mild to moderate hearing impairment. Therefore, the output limits must not be too low.

The appropriateness of output limits for OTC hearing aids should also account for circumstances in which users must determine for themselves when amplification may be excessive and then potentially take action to mitigate or avoid the situation, without the involvement of a licensed person for training or intervention. We are aware that some users of hearing aids who have perceived mild to moderate impairment may have difficulties with such tasks. For example, they may have reduced dexterity or may have difficulty judging their listening environments. Thus, we are also mindful of the need to establish or adopt output limits that provide for reasonable assurance of safety and effectiveness for such users and others. Therefore, the output limits must not be too high. (See also the response to Comment 100 regarding the use of consensus standards.)

FDA has considered quantitative information to inform our consideration of safety and effectiveness. In the proposed rule, we referred to a national workplace safety guideline, ''Occupational Noise Exposure,'' developed by the National Institute for Occupational Safety and Health (NIOSH) (see 86 FR 58150 at 58161–62) (Ref. 9). That guideline, which we will refer to as NIOSH–98, defines, among other subjects, hazardous levels of sound exposure in relation to the duration of exposure. It uses as its basis 85 dBA (A-weighted decibels) over 8 hours (as in, a generic workday) as the maximum non-hazardous exposure level (see paragraph 1.1 of NIOSH–98). Roughly speaking, the difference between A-weighted decibels and decibels of sound pressure level, for present purposes, is about 5 dB. As such, 120 dB SPL, or about 115 dBA, of exposure over 28 seconds would be equivalent to a full workday's allowable exposure for purposes of occupational safety (see table 1–1 of NIOSH–98). To address different levels of exposure besides 85 dBA, NIOSH–98 uses a 3-dB exchange rate (or equal-energy rule), meaning that the allowable time before the exposure is considered hazardous halves for every 3-dB increase (see paragraph 1.1.2 of NIOSH–98). In other words, for louder exposures, NIOSH–98 indicates less allowable time than 8 hours and vice versa for lower exposures.

We have applied an equal-energy principle and used a 3-dB exchange rate as a basis for revising the output limits. This interval, rather than another amount, more clearly reflects our consideration of non-hazardous outputs and the differing output levels. Thus, 117 dB SPL, which is 3 dB less than proposed, represents half the output power of the proposal or twice the time to achieve the same cumulative exposure (when the hearing aid is outputting at the limit). This translates to a lower risk of impairment from using OTC hearing aids. However, half the allowable power does not mean the output will sound ''half as loud.'' As such, not only does 117 dB SPL translate to a lower risk, it also does not unduly sacrifice effectiveness.

For the purpose of illustration, you might think of a person as having a ''budget'' of allowable sound exposure from a hearing aid to avoid further hearing impairment. The rate at which the person goes through the budget depends on the output level, and higher outputs (which have higher power) will use up the budget faster than lower outputs. In other words, because outputs at 117 dB SPL are half the power of those at 120 dB SPL, 117 dB SPL will use up the sound budget more slowly. If a hearing aid user encounters a sound at 117 dB SPL while using hearing aids, the user will thus have more of the budget left over to continue wearing the hearing aid for the rest of the day (without over-exposure) than if the loud sound were at 120 dB SPL. Note, however, that this analogy is merely an illustration of some concepts of cumulative exposure. Hearing healthcare professionals use more technical and precise concepts to describe the effects of sound exposure on hearing abilities.

FDA notes that nothing in this rulemaking is intended to interpret the application of NIOSH–98 for purposes of occupational exposure. Rather, we are considering the effects of cumulative and ongoing exposure in relation to equivalent peak output levels for the purposes of this rulemaking. Conversely, we wish to clarify that referring to NIOSH–98 does not mean that hearing aids should offer an output comparable to occupational noise exposure. (The sound output of a hearing aid is unlikely to reach its output limit regularly.) Nonetheless, NIOSH–98 provides a well-reasoned quantitative approach to the effects of sound exposure on people's hearing.

While many comments agreed that FDA's proposed output limits provided an adequate safety margin, other comments disagreed and called our attention to scenarios in which sound exposure at a relatively high level might be followed by continuing exposure at a relatively modest level. In certain circumstances, the equal-energy principle would imply that the relatively modest exposure could nevertheless be hazardous. In the proposed rule, we used the 3-dB exchange rate to compare the presumable reaction times between 120 dB SPL and 115 dB SPL, explaining that the latter offers about triple the time, an additional 61 seconds (approximately), given the 5-dB difference (see 86 FR 58150 at 58161). This does not imply that a continuous sound output of 115 dB SPL is safe for an extended period of use of an OTC hearing aid. This also does not imply that the user has approximately 89 seconds to intervene (for example, to remove the OTC hearing aid). Experiencing these output levels for long-enough periods of time could place the user at greater risk for further hearing impairment even though the user might judge the follow-on exposures to be modest or normal.

We acknowledge that the statement in ANSI/CTA–2051:2017 that 115 dBA (about 120 dB SPL) is an acceptable listening level for up to 30 seconds might imply that repeated exposures to 115 dBA (about 120 dB SPL) over the course of a day's use of a hearing aid are necessarily acceptable as long as the exposures are shorter than 30 seconds. (Note that a day's use of a hearing aid may be longer or shorter than the generic 8-hour workday that NIOSH–98 uses.) Further, we recognize that referring to the full time as a safety margin did not adequately account for exposure to other sounds throughout the day because using the entire 28-second interval would equate to a day's worth of allowable cumulative exposure. The

28-second interval assumes no other sound exposure during that 8-hour timeframe rather than continuing use (and exposure) at a low-enough level. In consideration of the comments, especially those calling our attention to possible scenarios leading to excess cumulative exposure, we have determined we should reduce the risks of cumulative exposure and do so by finalizing lower output limits than proposed.

Nevertheless, FDA does not expect OTC hearing aids to perform at or near their maximum output capabilities for extended periods of time during the day, if at all. As such, neither our reference to NIOSH–98 nor to ANSI/CTA–2051:2017 should be read to imply that constant outputs at or near 115 dB SPL (about 110 dBA) are necessarily safe. Instead, the limits we are finalizing are meant to be high enough to allow sufficient headroom for high-fidelity amplification for people with perceived mild to moderate hearing impairment, including amplification of occasional peaks necessary to reproduce certain kinds of higher intensity, but infrequent, sounds (see 86 FR 58150 at 58161–62).[10] However, a device's design or software may have sufficient headroom without reaching the maximum allowable output. We intend these output limits to facilitate wide adoption of hearing aids and design flexibility without being unnecessarily prescriptive.

Some comments recommended that FDA adopt a requirement for dosimetry, in essence applying similar principles as those described in NIOSH–98. That is, they suggested that FDA require that OTC hearing aids be able to measure the weekly sound exposure from the use of the device. Instead of limiting peak output, the devices could then limit exposure to a safe cumulative dose. While this approach may be one way to limit exposure, insufficient scientific data exist regarding cumulative exposure with the use of hearing aids by people with perceived mild to moderate hearing impairment. Moreover, as we noted above, this rulemaking and NIOSH–98 contemplate very different contexts, so the quantitative information cannot be directly applied to determining cumulative output limits appropriate for OTC hearing aids. In sum, FDA believes that establishing a dosimetry-based limit for regulatory purposes would be scientifically premature at this time.

[10] The maximum output for a person with greater hearing impairment is likely to be higher than for a person with less impairment; however, this general rule is subject to considerable individual variability.

Indeed, quantitative analyses of safe maximum output limits are generally difficult to apply because the data do not necessarily reflect regulatory considerations. For example, they do not fully reflect the intended users, specifically users with *perceived* mild to moderate hearing impairment, or other considerations for reasonable assurance of safety and effectiveness of OTC hearing aids. Some sources use audiometric threshold-based analyses to quantitatively predict safe maximum output limits (*e.g.,* Ref. 10). However, such analyses use criteria that FDA is not adopting as they have the effect of excluding some people for whom OTC hearing aids would be appropriate. Other references use threshold-based analyses for the maximum output for a hearing aid that is programmed using existing professional fitting formulas, applied to a database of audiograms (*e.g.,* Ref. 11). These results, however, do not fully reflect the intended users of OTC hearing aids, and interpreting the results often involves the application of criteria that FDA is not adopting, for example, the choice and application of threshold-based hearing loss categories.

In either case, these findings are limited for identifying appropriate output limits for OTC hearing aids because this rulemaking is intended to address perceived, not audiometrically quantified, impairment. (See also the response to Comment 24 regarding measurements of hearing loss and incorporating numerical thresholds into this rulemaking.) Moreover, different commenters interpreted the same references differently, demonstrating that even quantitative analyses leave much to interpretation. Well-reasoned, scientific views still exhibited significant diversity. The analyses are instructive, and we have updated our risk assessment based in part on them, but they cannot definitively settle the regulatory questions of this rulemaking. Hence, although we are finalizing lower output limits based on the available information, we are establishing the limits at 111 and 117 dB SPL (peak, not RMS, values) rather than the even lower levels found or suggested in some of the references submitted to us.

Other comments recommended FDA adopt international standards developed jointly by the WHO and the International Telecommunication Union (ITU). These comments identified ITU–T H.870 (2018), ''Guidelines for safe listening devices/systems,'' and ITU–T H.871 (2019), ''Safe listening guidelines for personal sound amplifiers.'' However, the guidelines refer to a WHO-derived standard value for the cumulative sound exposure for non-hearing-impaired adults. In other words, they use a dosimetry-based method, which we do not believe is a suitable basis to establish an appropriate limit, as explained above.

The guidelines do equate this to an output value of 80 dBA for 40 hours per week. However, the rationale underlying the guidelines relies on WHO thresholds and citations to literature that, as explained, FDA is not adopting and does not consider definitive (see the response to Comment 24 about the WHO hearing loss thresholds). Further, as even ITU–T H.871 (2019) explains, Ref. 10 can be read to suggest 90 dB SPL RMS as the maximum sound output for persons with normal hearing (see Appendix II of ITU–T H.871 (2019)). Such maximum sound output recommendations for normal-hearing listeners cannot be used to derive maximum output limits for a hearing aid to compensate for perceived mild to moderate hearing impairment. Thus, FDA is declining to adopt this cumulative exposure limit or the equivalent peak output value.

The lack of sufficient data to establish regulatory limits based on dosimetry does not, however, mean that dosimetry is not a useful feature. Manufacturers that wish to include dosimetry-based features in OTC hearing aids may do so.

Ultimately, as stated previously the output limits that we are finalizing reflect a balancing of safety and effectiveness. By lowering the output limit 3 dB SPL from the proposed rule, these output limits result in a meaningfully lower risk to the intended users, without unduly sacrificing effectiveness.

3. Applying Analyses to Real-World Use of Hearing Aids

As we explain in the responses to Comments 11 and 24, the perception of hearing impairment is conceptually integral to establishing the OTC category of hearing aids, and the application of audiometric thresholds to make regulatory decisions is inconsistent with how the hearing loss categories themselves were formulated. Moreover, audiometric threshold ranges or databases of audiograms do not necessarily reflect the needs and wants of the intended users of OTC hearing aids in a precise way. As such, while quantitative analyses provide useful information, including data on exposure versus stability of hearing impairment, the conclusions have inherent limitations that militate against adopting them wholesale for the regulatory purposes of this rulemaking.

FDA also considered how hearing health care providers fit hearing aids in

a clinical environment. Ordinarily, a fitting algorithm determines the necessary amplification, including the effective output limit of the device for a given user. The provider would then make further, iterative adjustments in consultation with the hearing aid user. These processes effectively guarantee that the device's output will rarely reach the device's maximum capability, if ever.

However, OTC hearing aids may not have features that prevent the user from continuous access to the device's maximum output. Some comments conveyed concerns that users, without the aid of professional judgment, would want to use unnecessarily high amplification on a continual basis; they would tend to prefer higher outputs than a hearing healthcare professional would set. In a worst-case example, the volume control and other features could cause maximum device amplification in a loud environment, and the user does not take action to mitigate the effects. In such a worst-case scenario, the user could suffer further impairment. Although these comments used anecdotes or more general concerns based on professional experience to support their views, we recognize that hearing healthcare providers sometimes recommend lower outputs than hearing aid users might initially prefer. Thus, while we would expect that a device would seldom perform at its maximum, much less continuously, even when set at the applicable output limit, that possibility is greater than for professionally fit devices, for which the audiologist or hearing instrument specialist has, in effect, limited the output. In further consideration of the differences between professionally fit and user-customizable devices, we find additional indications that the safety margin of the proposed output limits is lower than we initially believed regarding the risks of cumulative exposure.

Several comments suggested that FDA also reconsider users' ability to react to loud situations in which continued use of an OTC hearing aid could present significantly increased risks of injury should the user not remove the hearing aids or reduce the output. Some comments observed that users of OTC hearing aids are likely to have characteristics not shared by the general population. For example, OTC hearing aid users may be more likely to have reduced dexterity or experience cognitive difficulties. Such characteristics can hinder adjusting a device in sufficient time, especially if the controls are physically small or require navigation (as in opening a software application on a smartphone to navigate to the correct control interface).

Other comments noted that, while obviously-loud sounds pose risks of further hearing impairment, continuous exposure to lower intensities can pose such risks over a sufficiently long period of device use. Under the proposed limits, overexposure is possible in scenarios where the device is set to its maximum (providing the maximum gain), yet the amplified output does not discomfit the user enough to mitigate the exposure. Such a scenario would entail an increased risk of impairment to residual hearing from use of an OTC hearing aid.

The ability for users to act to protect themselves was an important factor in our proposed output limits (see 86 FR 58150 at 58162), and it remains so for this final rule. FDA recognizes that some OTC hearing aid users may need more time or assistance to react to noticeable overexposure than an average member of the general population. The required design and electroacoustic performance features for OTC hearing aids will significantly reduce such risks for the intended users. For example, a user-adjustable volume control will allow a user to set and maintain the device's output below the maximum. However, after considering the diversity of scientific comments, we are persuaded that our proposal did not adequately account for cumulative exposure to lower-intensity sounds during daily use over an extended period of time—on account of users' ability or desire to intervene as well as the other factors, explained above, that might increase cumulative exposure and the resulting risks. Since a dosimetry-based limit is impractical as discussed above, we are lowering the allowable maximum output to address considerations of cumulative exposure.

4. Declining To Include Gain Limit

Multiple comments, many of which urged FDA to establish or adopt a lower output limit, recommended that FDA also adopt a gain limit. These comments contended that a gain limit would improve device safety by further reducing the risks of over-amplification, primarily due to the device reaching its gain limit and providing no further amplification before it reached its output limit (see 86 FR 58150 at 58162). In effect, a gain limit would lower the output limit.

FDA acknowledges that a gain limit may play a role in the management of risks from overamplification. However, a gain limit reduces the ability to adequately amplify soft sound inputs in some cases, which can lead to decreased device effectiveness and user satisfaction. Moreover, the appropriate gain for a given device will depend on device design and features. Imposing a gain limit may constrain device design and innovation, which could have an undesirable effect on device benefit for intended users.

In addition to preserving flexibility in device design, FDA is not requiring a gain limit in order to maximize access to these devices for the full range of intended users with perceived mild to moderate hearing impairment. Intended users of these devices are a heterogenous population with a range of hearing and communication difficulties and needs. By not requiring a gain limit, the broadest range of intended users will have access to effective devices. This flexibility empowers users to customize their hearing aids to their needs, listening preferences, and communication goals, and it allows for a wider range of options should users' needs, preferences, and goals change over time.

FDA is establishing requirements to provide reasonable assurance of safety and effectiveness of OTC hearing aids for the intended user population, and further reducing the device's output by establishing a gain limit is not necessary for such reasonable assurance. Indeed, a gain limit in this case may detract from such reasonable assurance by broadly reducing the available amplification for the user and limiting the range of intended users of the device. Because the appropriate output limits we are finalizing will sufficiently limit device output, we are not finalizing a gain limit that would further reduce the output. (See also the response to Comment 78, describing how frequency response smoothness helps prevent under- and overamplification of frequency bands, in effect, a more-focused reduction than a gain limit.) This also allows manufacturers the flexibility to design their devices to balance the required output limits with the amplification needs of the intended user population.

F. Other Device Requirements (§ 800.30(e) and (f))

Several comments shared a concern for an influx of unsafe or ineffective devices to the marketplace, for example, devices that do not satisfy the requirements of the OTC Hearing Aid Controls because of lax enforcement and/or manufacturers or sellers evading regulatory controls necessary for reasonable assurance of safety and effectiveness of OTC hearing aids. Such comments tended to focus on the risks to health of violative or non-conforming products, for example, impairment of

remaining hearing from excessive device output, injury stemming from inferior manufacturing practices, or ineffective treatment resulting from the possible difficulty of distinguishing an OTC hearing aid from consumer electronics not intended to compensate for hearing loss.

To provide reasonable assurance of safety and effectiveness of OTC hearing aids, and thereby avoid an influx of unsafe or ineffective devices, we are establishing requirements for, among other things, the design and performance of OTC hearing aids. At the same time, the requirements will not unnecessarily constrain device design or burden manufacturing, which could hinder innovation or impede adoption and use of the devices. Further, compliance with regulatory controls is a concern for all devices, and FDA monitors the marketplace and conducts regular inspections and other postmarket surveillance as part of maintaining reasonable assurance of safety and effectiveness.

1. Electroacoustic Performance

(Comment 73) Some comments urged FDA to adopt the same electroacoustic performance requirements for prescription hearing aids as those for OTC hearing aids.

(Response) While FDA agrees that prescription hearing aids should provide high-fidelity amplification for users, we do not agree that prescription hearing aids should be subject to the same electroacoustic performance requirements as OTC hearing aids. The requirements for OTC hearing aids will provide reasonable assurance of safety and effectiveness without the involvement of a licensed person, such as an audiologist or hearing instrument specialist, to adjust the device output and ensure it performs adequately. However, the requirements we are finalizing for prescription hearing aids presume the involvement of a licensed person: As prescription devices, they may only be sold to or on the prescription or other order of a practitioner licensed by law to use or order the use of the devices (see § 801.109(a)(2)).

The labeling requirements we are finalizing for prescription hearing aids include technical specifications that an audiologist or hearing instrument specialist can use to select and adjust the hearing aid (see 86 FR 58150 at 58164). These requirements are virtually identical to the long-standing labeling requirements for hearing aids in former § 801.420(c)(4) upon which professionals rely. Additionally, we are finalizing a new requirement to state the latency of the prescription hearing aid, measured with a method that is accurate and repeatable to within 1.5 ms. This information will be particularly useful for fitters given evolving hearing aid designs and sound processing capabilities. However, we are not also establishing a latency performance limit for prescription hearing aids. The aforementioned information and the involvement of a licensed person will provide reasonable assurance of safety and effectiveness of prescription hearing aids without the additional performance requirements necessary for OTC hearing aids.

(Comment 74) A comment recommended that the requirements for an OTC hearing aid sold by a licensed person be no different than those for sale by a non-licensed person, and that the final rule should clearly state that preemption would apply to this situation.

(Response) To the extent that this comment recommends that the requirements for the OTC hearing aid itself be no different when sold by a licensed person, versus a non-licensed person, FDA agrees with the comment. The requirements for OTC hearing aids themselves (output limits, electroacoustic performance, labeling, etc.) that we are finalizing apply equally to those sold by licensed and non-licensed persons. To the extent that this comment recommends that State regulation of the activities associated with the sale of OTC hearing aids, for example, via licensing requirements, be preempted, we have addressed that request along with similar comments in the Preemption sections III.H and VIII.

(Comment 75) A comment suggested that prescription hearing aids have the same output limit as OTC hearing aids.

(Response) FDA does not agree that prescription hearing aids should have the same output limit as OTC hearing aids because people with a more severe degree of hearing loss than perceived moderate impairment may need additional gain, and therefore would need a higher output, potentially above limits appropriate for OTC hearing aids. We recognize that people with more severe hearing impairment can still suffer further impairment of their remaining hearing, so the device output must not be too high for them. We are finalizing a requirement, as proposed, that labeling warn dispensers to exercise special care when selecting and fitting a hearing aid with an output that exceeds 132 dB SPL. This warning is nearly the same as the required warning statement in former § 801.420(c)(2). Nevertheless, the output necessary to compensate for more severe hearing impairment safely and effectively, though subject to individual variability, will generally be higher than would be permissible for OTC hearing aids.

(Comment 76) Comments suggested that FDA require input-controlled compression for all OTC hearing aids to help significantly reduce the risk that users could worsen their hearing impairment by using an OTC hearing aid.

(Response) FDA agrees that input-controlled compression can provide multiple benefits for OTC hearing aid users. For example, this feature allows the device to adapt the output dynamically, based on the listening environment. This can reduce the user interaction necessary to adjust the device for different situations. Some users find the feature improves the hearing aid's comfort, contributing to their satisfaction and encouraging continued use. This in turn can help accomplish this rule's purposes of promoting wider adoption and use. However, some users find the feature annoying or distracting, reducing their satisfaction and discouraging them from using their hearing aids. Moreover, the feature is not necessary for reasonable assurance of safety or effectiveness (when the device does not exceed an output of 111 dB SPL). For these reasons, FDA is not requiring input-controlled compression for all OTC hearing aids. (See also the response to Comment 77 about including noise-cancelling technology.)

(Comment 77) A comment suggested requiring that OTC hearing aids include noise-cancelling technology to prevent a loss of benefit from using the devices in noisy environments.

(Response) FDA agrees that noise-cancelling technology can help hearing aid users in certain situations. For example, the feature can help improve the clarity of voices by reducing the volume of only background noise. This can reduce the user interaction necessary to adjust the device for different situations. However, the feature is not generally necessary for reasonable assurance of safety or effectiveness because air-conduction hearing aids can still provide adequate amplification to achieve effectiveness without the feature, so FDA is not requiring noise-cancelling technology for all OTC hearing aids. (See also the response to Comment 76 about including input-controlled compression.)

(Comment 78) Comments requested that FDA remove the frequency response smoothness requirements so, these comments asserted, OTC hearing aids would accommodate all kinds of

perceived mild to moderate hearing impairment, not just individuals with typical age-related, sloping hearing impairment.

(Response) Although FDA agrees that OTC hearing aids should be safe and effective for the breadth of the intended user population with perceived mild to moderate hearing impairments, we are not removing the frequency response smoothness requirements for OTC hearing aids. As we explained in the proposed rule, a smooth frequency response will ensure that an OTC hearing aid does not under- or overamplify certain sounds (see 86 FR 58150 at 58164). A device that does not have a smooth frequency response can, for example, perceptibly distort speech quality (see 86 FR 58150 at 58164).

Moreover, the proposed frequency response smoothness requirements do not limit device output to compensating only for typical age-related, gradually sloping hearing impairment. More specifically, the frequency response smoothness describes the flatness of the output when the device is set to provide constant gain as a function of frequency, that is, when the device is not set to provide frequency shaping. The idea is that the flatter the response when the device is not set to provide frequency shaping, the more consistently the device will achieve any intended frequency shaping to accommodate the user's customization, for example, to compensate for a sloping hearing loss.

This is similar to how a loudspeaker's frequency response is later adjusted by an equalizer, which shapes the input signal. In short, frequency response smoothness does not prevent the device from *appropriately* amplifying lower frequencies. Instead, it helps prevent under- and overamplification at any frequency band that could result from a device that does not appropriately shape the output. We are finalizing the smoothness requirements as proposed.

(Comment 79) Some comments proposed that OTC hearing aids have cutoff limits: if the output were to exceed certain thresholds for a long-enough time, the device would reduce or stop amplification, even if the device never exceeded the allowable output limit.

(Response) FDA agrees that an OTC hearing aid user could experience over-amplification even if the device does not exceed the allowable output limit. As we explain in section V.E of this document, we have considered this possibility further and are correspondingly finalizing output limits lower than we proposed. We also explain in that section that insufficient data exist to establish regulatory limits for exposure over time based on dosimetry. As with implementing dosimetry-based features, manufacturers may establish cutoff limits for their devices, but FDA is not requiring such features for OTC hearing aids.

(Comment 80) A comment requested that FDA allow greater latency for OTC hearing aids, suggesting 25 milliseconds (ms). The comment argued that this delay would still not be perceptible to the user. Other comments requested that FDA address latency for wireless streaming technologies, such as Bluetooth, and other hearing aid designs.

(Response) FDA does not agree that allowing greater latency will be imperceptible. One comment cited for support material that showed four out of nine people perceived a delay of 25 ms. (Two out of nine perceived it at 15 ms.) This does not suggest that allowing greater latency will be equally imperceptible, though such a small sample may not have yielded generalizable results. Regardless, human hearing perception can be sensitive to differences longer than 15 ms, depending on frequencies and conditions, and signal processors for hearing aids can reliably achieve latencies shorter than 15 ms. Given these considerations, we do not agree that greater latency will be imperceptible or that a limit of 15 ms unduly constrains device design. FDA is not revising the latency limit for OTC hearing aids.

Regarding wireless streaming technologies, the latency limit we are finalizing is an electroacoustic performance metric that describes how quickly an OTC hearing aid must produce the output sound relative to the input sound, that is, the *acoustic* input (see 86 FR 58150 at 58164). It does not describe the time necessary for an OTC hearing aid to receive and process a wireless signal after transmission, which can often exceed 15 ms, even under ideal conditions. In contrast to electroacoustic performance, FDA has not determined that a wireless transmission latency limit is generally necessary for reasonable assurance of safety and effectiveness of OTC hearing aids because air-conduction hearing aids compensate for impaired hearing primarily by detecting sounds with on-board microphones. As such, wireless streaming latency does not generally raise the same perceptual concerns as electroacoustic latency. Therefore, we are not establishing a wireless transmission latency limit. (See also the response to Comment 64 regarding labeling for wireless streaming latency.) However, there may be circumstances where, based on the device's design, wireless streaming latency does raise the same perceptual concerns as electroacoustic latency. In such circumstances, manufacturers will likely need to consider wireless transmission latency for devices that incorporate such technology.

As for different device designs regarding acoustic transmission, the latency limit applies. For example, ''open-fit'' devices that allow some incoming sound to bypass the hearing aid would also need to respect the latency limit. Moreover, the latency limit is a performance baseline. Manufacturers may design devices with lower latency should they want to improve electroacoustic performance.

(Comment 81) Some comments suggested that FDA permit different acoustic couplers than proposed for the electroacoustic performance testing requirements. These comments argued that standard 2-cm^3 couplers would not be the most appropriate for some device designs, and performance measurements would more accurately reflect device capabilities if more suitable couplers were permitted.

(Response) FDA agrees that 2-cm^3 couplers may not be compatible with some device designs. We are revising the final regulations to permit use of alternative acoustic couplers that are compatible with the device. The manufacturer would have to document how use of the alternative approach is scientifically valid and technically equivalent.

(Comment 82) A comment requested that FDA prescribe the method to test latency beyond requiring that measurements be accurate and repeatable to within 1.5 ms.

(Response) Although FDA is finalizing standardized test methods to ensure other electroacoustic specifications are comparable across devices, the comparability of latency is less sensitive to the specific method. Latency is a measurement of time, so essentially any scientifically suitable and accurate timing method will produce a result that is comparable to other suitable and accurate methods, even though the methods may differ in the specifics. As such, we are specifying how accurate the timing must be but allowing flexibility for the specific method. Nevertheless, clause 4.8 of ANSI/CTA–2051:2017 suggests two different methods, either of which is acceptable provided the testing equipment is sufficiently accurate and precise.

(Comment 83) A comment observed that FDA considered the electroacoustic performance requirements in ANSI/

CTA–2051:2017, including the self-generated noise limit. However, FDA did not specify A-weighted measurements for the self-generated noise limit in the proposed regulation as the standard does. The comment suggested FDA specify A weighting consistent with the standard.

(Response) FDA agrees that A weighting is more consistent with the standard. We are revising the self-generated noise limit in the final regulation to refer to A-weighted decibels.

2. Design Requirements To Ensure Proper Physical Fit and Prevent User Injury

(Comment 84) Several comments urged FDA to hold OTC hearing aids to the same hardware standards as prescription hearing aids. Some of these comments focused on Quality System requirements (see Comment 95 and our response). Others focused on equivalent electroacoustic performance.

(Response) FDA agrees that OTC and prescription hearing aids should both be held to standards appropriate for medical devices. However, we are not applying all of the same specific rules to both because OTC and prescription hearing aids differ in important respects, for example, the intended uses.

Some of the same rules will apply to both. As we explain in the response to Comment 95, OTC hearing aids will be subject to quality management system requirements that are appropriate for medical devices. The same will be true for prescription hearing aids. Thus, both OTC and prescription hearing aid manufacturers will need to comply with the same Quality System requirements under part 820, even if their individual implementations differ in the details. (See also the response to Comment 96 about a risk-based approach to quality management systems.)

However, some of the requirements will differ, such as those for device performance. We explain in the responses to Comments 73 and 75 that OTC and prescription hearing aids have different intended uses, and therefore, they must satisfy different performance needs. Thus, having reasonable assurance of safety and effectiveness of both categories of hearing aids entails different specific requirements for each category.

(Comment 85) Some comments proposed requiring that eartips for OTC hearing aids be made of ''medical grade'' materials to prevent irritation or damage from the components of the device in contact with the ear canal.

(Response) FDA agrees that contact with substances can cause adverse tissue reactions like skin irritation; however, the design requirements that we are finalizing for OTC hearing aids, along with existing requirements and policies, are sufficient to address the kinds of materials used.

The design requirements that we are finalizing for OTC hearing aids include a requirement that the material for the eartip be atraumatic, which is the same as proposed. As explained in the proposal, atraumatic materials are those that prevent injuries to the skin and bone, and the use of atraumatic materials reduces the chance that daily use or accidental contacts will cause damage to the delicate skin or bone of the ear (86 FR 58150 at 58165). In evaluating the material for the eartip to determine whether it meets this requirement, manufacturers may wish to review FDA's guidance, ''Use of International Standard ISO 10993–1, 'Biological evaluation of medical devices—Part 1: Evaluation and testing within a risk management process,' '' issued September 4, 2020, which describes FDA's approach to biocompatibility evaluation of medical devices, including considerations and recommendations for manufacturers.[11]

As described in the aforementioned guidance, OTC hearing aids (depending on the specific device) would likely be a surface device in contact with intact skin. As such, manufacturers should consider the specific biological effects of cytotoxicity (toxic effects on cells), sensitization (becoming more sensitive to materials over time), and irritation or intracutaneous reactivity (a reaction within the layers of the skin). The use of certain common materials in surface devices contacting intact skin may help manufacturers to pursue least-burdensome methods for evaluating biocompatibility.

Additionally, as we explain in the responses to Comments 95, 96, and 97, OTC hearing aids will be subject to the Quality System requirements, which will also help provide for reasonable assurance of safety and effectiveness.

(Comment 86) Several comments suggested requiring that OTC hearing aids use non-proprietary designs and/or open-platform technology because, in the commenters' views, proprietary designs or closed platforms would limit the compatibility of accessories, availability of replacement parts, or possibility of modifications to the devices.

Other, similar comments proposed that OTC hearing aids have a standard user interface or support a standard application programming interface (API) to allow users to access and modify device settings, perhaps through third-party software, when the manufacturer has not exposed the desired settings to user control. Some comments identified a standard API (or some other standard protocol) as a way to enable device interaction with other electronics of the user's choosing, for example, a smartphone from a different manufacturer.

(Response) While some OTC hearing aid users may desire such features, we do not currently consider them necessary for reasonable assurance of safety and effectiveness of OTC hearing aids generally. Hearing aids that incorporate proprietary designs and interfaces can be safe and effective, without interaction with third-party products. Manufacturers may implement open features, but we are not requiring them.

(Comment 87) Several comments suggested that all OTC hearing aids have a user-adjustable volume control because the feature would be integral to device safety regardless of its output limit. A comment suggested that all hearing aids should have a volume control built into the device itself, separate from a software controller (as in, a ''slider'' in a smartphone application, for example).

(Response) FDA agrees that a user-adjustable volume control should be a design feature of all OTC hearing aids, and we are finalizing such a requirement under new § 800.30(f)(5). However, although FDA understands that a physical (that is, built into the device itself) volume control could provide ready access for some users to adjust the volume, we are declining to adopt this suggestion.

While some users may find a physical volume control useful, several comments that FDA received observed that many users of OTC hearing aids may have limited dexterity, which would in turn limit the usefulness of a hardware controller, for example, a small dial or push buttons on the device. Similarly, we received comments emphasizing hearing aid users' desire for a discreet device, including both its form and its operation. A user interface, perhaps implemented on a remote control or a mobile device, will allow design flexibility for manufacturers to develop and market smaller hearing aids, and adjusting the volume through such an interface may feel more discreet for many users than reaching up to the

[11] The document is available online at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and.*

device to adjust it, perhaps needing additional effort to manipulate physically small controls.

This is consistent with the many comments we received urging that we require the devices to have wireless controls. (See the response to Comment 94 for further discussion on this topic.) For people who are less inclined to use software, they may still purchase a device with a physical volume control or, alternatively, they may still manually limit the sound exposure by, for example, removing the device, covering the microphone, or seeking a quieter environment.

(Comment 88) A comment suggested that all OTC hearing aids have an option for volume limitation and a parental volume control.

(Response) FDA is not adopting these suggestions because the output limits we are finalizing will provide reasonable assurance of safety and effectiveness without requiring an additional feature that would limit the output further. (See also section V.E.4 of this document explaining why FDA is not establishing a separate gain limit.) However, we are finalizing a requirement that all OTC hearing aids have a user-adjustable volume control (see the response to Comment 87).

A parental volume control is likewise not necessary for reasonable assurance of safety and effectiveness, including cases in which the caregiver is not the user's parent. Moreover, establishing a requirement for ''parental control'' may imply that the devices are intended for people younger than 18, which is not the case for OTC hearing aids (see 21 U.S.C. 360j(q)(1)(A)(ii)).

(Comment 89) A comment proposed that the user-adjustable volume control must allow for at least 6 dB of potential adjustment to the device output to ''ensure perceptual functionality.'' This amount, the comment asserted, would help significantly reduce the risk that users could worsen their hearing impairment by using an OTC hearing aid. Other similar comments suggested that FDA specify the performance requirements for the volume control in terms of the range.

(Response) FDA is not requiring that a user-adjustable volume control adjust the volume in 6-dB increments at a minimum, and FDA is not specifying the range for the volume control.

The comment proposing 6-dB increments asserted that a 3-dB change in signal intensity is the average needed for users to perceive a volume difference, thus a 6-dB increment would ensure that users perceive it. However, FDA expects that users will manipulate the control until they perceive not only a difference but a satisfactory output volume, regardless of the size of the increment. Further, a 6-dB minimum increment may force users to increase the volume more than desired, providing unnecessarily high amplification while constraining device design and performance. FDA does not agree that a minimum volume adjustment increment of 6 dB will appreciably reduce risks or increase effectiveness.

As for the range over which the volume control must operate, a specification is not necessary for reasonable assurance of safety or effectiveness, and it may constrain device design unnecessarily. The output of an OTC hearing aid may not exceed the applicable limit under final § 800.30(d) regardless of the performance of the volume control, so establishing an upper limit would be redundant. As for a lower limit, a specific minimum setting would generally depend on the device design. Thus, for similar reasons to not requiring a minimum increment, we are not requiring a minimum volume setting.

(Comment 90) Comments suggested establishing an absolute limit on the maximum insertion depth for OTC hearing aids. There was variability in the range of recommended insertion depth limit ranging from 7.5 mm to 21 mm, though the most frequent recommendation was 15 mm to 17 mm.

(Response) FDA agrees that a fixed limit on the insertion depth of an OTC hearing aid is a better measurement than the anatomical landmark that we proposed (the bony cartilaginous junction). We are finalizing a fixed insertion depth limit relative to the expected distance from the eardrum (tympanic membrane). Note that a ''fixed insertion depth limit'' means a limit that is a specific distance measurement rather than a more relative description. This meaning is different from describing a hearing aid as ''fixed length'' (or similar) in reference to a hearing aid that does not change length. FDA did not propose and is not finalizing a design requirement that hearing aids have a fixed length.

As we explained in the proposal, the length of the ear canal can vary greatly among adults (see 86 FR 58150 at 58165). A fixed insertion depth limit may be too deep for some individuals, potentially resulting in injury. Comments noted that a hearing aid inserted too deeply in the ear canal can cause increased sound pressure levels to be delivered to the eardrum as well as push earwax deeper into the ear canal. However, the same fixed depth limit may be too short for others, potentially reducing device effectiveness. As comments recognized, the hearing aid must be inserted deeply enough for it to stay in place despite jaw movement, and deeper insertion also helps with reducing acoustic feedback and improving gain (amplification). Moreover, deeper insertion can help reduce the cosmetic impact of the hearing aid, that is, help it to be less visible, which may reduce self-consciousness or perceptions of stigma from wearing the device.

Furthermore, we are not aware of any widely accepted method to describe the measurement of the insertion depth of hearing aids. Ear canal anatomy varies across individuals, and methods may not agree on exactly where to start the measurement for various OTC hearing aid designs. These factors may lead to significantly different measurements of insertion depth for the same device.

We proposed a limit based on an anatomical landmark, and several comments characterized the proposal as insufficiently defined and subject to significant variability across individuals. While measurements relative to the individual's anatomy would be ideal, we recognize it is not currently practical, considering the uncertainties stemming from anatomical variability and insertion depth measurement.

As such, following review of all relevant comments, we have determined a limit defined by the distance of the innermost (that is, most medial) component of the hearing aid relative to the eardrum. This should be a generally understandable and consistently measurable way to ensure safe design of the device with respect to placement in the ear canal. Thus, we are limiting the insertion depth to a specific expected distance (''setback'') from the eardrum (tympanic membrane): 10 mm from the innermost component of the device to the eardrum. In establishing this limit, we considered that its primary purpose is to minimize the risk of injury to the tympanic membrane and the skin of the bony portion of the ear canal. We believe that an OTC hearing aid designed to have a 10-mm setback will minimize the risk of injury from inserting the device too deeply while allowing for individual anatomic variability, but without unduly limiting effectiveness.

For adults, the average length of the ear canal has been estimated to be 23–28 mm (Refs. 12 and 13). Using an average length of 25 mm, manufacturers may generally assume that the maximum insertion depth of a hearing aid designed with a setback of 10 mm

from the tympanic membrane would be approximately 15 mm. We acknowledge that an OTC hearing aid design based on this setback limit may result in an actual setback of somewhat less than 10 mm in users with shorter than average ear canals. However, we believe that the limit is conservative enough to ensure safety even in these cases. Some comments pointed out that receiver-in-the-canal hearing aids can have insertion depths of 20–21 mm. However, an audiologist or hearing instrument specialist typically fits such a device. We do not currently consider such insertion depths to be appropriate for OTC hearing aids.

(Comment 91) Some comments proposed either encouraging or requiring that OTC hearing aids use only instant-fit eartips or customized eartips, fabricated based on non-invasive ear scans, to couple the device to the ear canal. A few of these comments further suggested that FDA require a licensed person to fabricate custom earmolds or ear shells.

(Response) FDA is not requiring the use of instant-fit eartips or eartips fabricated based on non-invasive ear scans because currently classified devices to create earmolds and ear shells are not intended for the user of the OTC hearing aid. Instead, earmolds and ear shells are intended for use by a hearing health professional because they often require an impression-making procedure. As some comments noted, improperly taking the impression can leave behind impression material or injure the ear. Separately requiring instant-fit (or non-invasively created) eartips is unnecessary for reasonable assurance of safety and effectiveness of OTC hearing aids.

However, a manufacturer may design an OTC hearing aid intended to be *compatible* with custom earmolds or ear shells, that is, the use of such is optional but not necessary. (A device intended to *rely* on taking impressions would imply the need for a licensed person, hence the device would not be ''available'' over the counter.) We do not wish to preclude this possibility, nor do we wish to limit the kinds of eartips in the future that may be safe and effective for users of OTC hearing aids. Considering the current regulatory framework and a desire to avoid unduly constraining design, we are not adopting this suggestion.

(Comment 92) A comment suggested that OTC hearing aids with removable eartips must have a specific minimum amount of force to remove the eartips from the device. The comment asserted this would help prevent an eartip from falling off the device and lodging in the ear canal.

(Response) FDA is not requiring that eartips have a minimum force to detach them from the device because determining a generally applicable threshold would be impractical and unnecessary. The force exerted on an eartip during normal removal or wear may vary depending on the device design, materials, and the user's anatomy, among other factors. Furthermore, any minimum force requirement would need to ensure that the force was not so great as to hinder the ability of users to change eartips, particularly for users who have limited dexterity. However, we note that manufacturers of devices with removable eartips should consider the risks of accidental separation of an eartip within the canal and ensure their specific designs prevent such adverse events. Although we are not establishing a threshold for force that would apply to all OTC hearing aids, manufacturers should incorporate robust device designs that help provide for safe and effective hearing aids.

(Comment 93) Comments suggested that FDA require a self-administered hearing test to accompany OTC hearing aids because users are not always able to determine whether their hearing loss is mild or moderate.

(Response) While a self-administered hearing test may be one way for users to control OTC hearing aids and customize the devices to their hearing needs, we are not requiring that self-administered hearing tests accompany OTC hearing aids. In some cases, a test is not necessary to achieve safe and effective amplification to compensate for perceived mild to moderate hearing impairment. For example, a self-fitting strategy could do so by guiding the user through a setup process that is not a diagnostic hearing test. Further, users may wish to obtain a hearing test by some other means, for example, by voluntarily visiting an audiologist. The inclusion of a hearing test with the device, in either case, would be unnecessary. Manufacturers may decide to incorporate a validated diagnostic function as appropriate for their device designs, but we do not agree that it should be a requirement for all OTC hearing aids.

(Comment 94) A comment suggested requiring that OTC hearing aids integrate Bluetooth or telecoil technology so users can configure the devices with their smartphones.

(Response) While Bluetooth or other wireless technologies may be desirable for some users of OTC hearing aids, we are not requiring such functionality. We acknowledge that, by definition, a wireless hearing aid will incorporate wireless technology in its programming or use, and we would expect that, with current technologies, most OTC hearing aids will incorporate wireless.

However, we also expect that wireless technology will continue to evolve, and specifying protocols or capabilities may unnecessarily constrain design and hinder innovation. For example, telecoil technology may currently be practical for relatively larger form factor devices, but users may not desire the functionality or the size necessary to incorporate a telecoil, for example, if preferring a smaller device. Other methods of connectivity may also develop, and such devices may be appropriate for OTC availability despite lacking wireless technology. In sum, requiring such features could potentially increase cost while hindering innovation and reducing adoption and use of OTC hearing aids. (See also the response to Comment 87 about requiring a physical control for volume adjustment.)

3. Quality System Requirements

In the proposal, we sought input on the Quality System requirements that would apply to OTC hearing aids but also explained that any changes to the Quality System requirements would be proposed in a separate rulemaking proceeding (86 FR 58150 at 58165). Below we summarize the input that we received and respond to it.

(Comment 95) Many comments supported FDA's proposal that all applicable Quality System requirements under part 820 remain in force for the manufacture of OTC hearing aids. Most of these comments emphasized that hearing aids are medical devices and, as such, should be subject to commensurate manufacturing requirements. Most such comments also opined that the current requirements are not unduly burdensome or unreasonably costly, and in fact, can aid device development. For example, as one such comment stated, the application of Quality System requirements helps manufacturers to identify risks and problems early, helping to focus resources on the most promising new ideas. Such requirements allow manufacturers to identify what works well and effectively investigate what does not. The requirements collectively help reduce costs and time to market.

(Response) We have further considered the applicability of Quality System requirements under part 820, and we are not modifying the applicability of the requirements for

OTC hearing aids. The device quality system requirements are part of the general controls for all devices that help provide for reasonable assurance of safety and effectiveness. In the proposal, we explained that we had previously received conflicting feedback on the possibilities but that we believed a quality management system specific to medical devices was appropriate (see 86 FR 58150 at 58165). Moreover, we consider the Quality System requirements to be interdependent yet inherently flexible (see 86 FR 58150 at 58165). We continue to hold these views, and although we again received conflicting comments, we agree that the requirements are not unduly burdensome. (See also the response to Comment 96, explaining the risk-based nature of the Quality System requirements and the revisions FDA is proposing in a separate rulemaking.)

(Comment 96) A comment proposed that the extent of Quality System controls be based on the risks of device use and the complexity of the device. It suggested that manufacturers be allowed to maintain a Declaration of Conformity, along with supporting documentation, that the manufacturer could provide to FDA upon request.

(Response) As we explained in the proposed rule, the Quality System requirements under part 820 are inherently flexible (see 86 FR 58150 at 58165). We have elsewhere explained that one of the purposes of the flexibility is to allow manufacturers to develop and follow procedures and processes that are appropriate to a given device and according to the state of the art for designing and manufacturing that device (see 87 FR 10119 at 10121, February 23, 2022). Moreover, FDA is proposing to harmonize part 820 with an international consensus standard, International Organization for Standardization (ISO) 13485:2016, ''Medical devices—Quality management systems—Requirements for regulatory purposes,'' that has an even more flexible approach to quality based on risk management (see 87 FR 10119 at 10122). Thus, although FDA agrees that Quality System controls should be based in part on the risks of device use, we are not modifying this final rule because the requirements are already flexible and risk-based, and we are elsewhere proposing to harmonize the risk-based approach with a yet more flexible international consensus standard.

Regarding the use of Declarations of Conformity, section 514(c)(1)(A) of the FD&C Act provides that a person may submit a Declaration of Conformity to an FDA-recognized consensus standard to meet a requirement under the FD&C Act (see 21 U.S.C. 360d(c)(1)(A)). If a person elects to use a Declaration of Conformity in such a way, the person must provide a Declaration of Conformity certifying that the device in question is in conformity with an FDA-recognized consensus standard (see 21 U.S.C. 360d(c)(1)(B)). That is, Declarations of Conformity appertain to devices themselves; to declare that a device is in conformity to a standard for a quality management system is not equivalent to declaring that the quality management system itself conforms to the standard. For more information on using Declarations of Conformity, you may wish to refer to FDA's guidance, ''Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices,'' issued September 14, 2018.[12]

For systems, a certificate (or certification process) is an analogous mechanism to document and declare conformity. However, in our separate proposal regarding harmonization of Quality System requirements with an international consensus standard, we stated that FDA does not intend to exempt from FDA inspections manufacturers that are certified as conforming to the standard (see 87 FR 10119 at 10128). Further, FDA does not intend to develop a certification program or issue such certificates (see 87 FR 10119 at 10128). As explained elsewhere in this document, FDA does not view OTC hearing aids as a unique case for purposes of Quality System requirements. As such, we are declining to modify how manufacturers may use Declarations of Conformity or to accept certifications in lieu of demonstrating compliance under FDA's usual policies for the manufacture of OTC hearing aids. Should FDA determine to follow a different general approach to certifications for purposes of quality management, we will announce such a determination in the final rule based on our proposal to harmonize part 820 with ISO 13485:2016.

(Comment 97) Multiple comments proposed that OTC hearing aids be exempt from the Quality System requirements of part 820. Some of these comments stated that the requirements of the Hearing Aid Restrictions, §§ 801.420 and 801.421, addressed safety concerns with specialized labeling but that modern devices no longer raise these concerns. As such, these commenters viewed the requirements under part 820 as unnecessary.

(Response) FDA does not agree that specialized labeling for, or the diminution of past risks of, hearing aids suggests that the OTC category of hearing aids be exempt from Quality System requirements. Rather, FDA expects that the establishment and continued application of an appropriate Quality System would help reduce device risks and support effectiveness, and are an important control to help provide for reasonable assurance of safety and effectiveness. Further, an appropriate Quality System serves different purposes than labeling, and the two are not substitutes for each other. For example, a Quality System includes production and process controls to ensure that a device conforms to its specifications (see § 820.70(a)). Labeling does not serve this purpose and cannot substitute for production and process controls. We note that the implementation of a Quality System entails risk-based decision-making and that the system's appropriateness is related to the device. The Quality System requirements are inherently flexible, and comments we received agree that a Quality System that complies with part 820 is not unduly burdensome.

4. Choice and Specification of Standards

(Comment 98) Some comments suggested that FDA not specify the exact editions of the standards we are incorporating by reference. In this way, the commenters sought to simplify the process for keeping regulations up to date with new editions of the standards, as the respective organizations develop and publish them.

(Response) While FDA appreciates the value in keeping regulations in sync with consensus standards, we are not adopting this suggestion as doing so would impermissibly allow the standards organizations to change regulatory requirements without FDA going through notice-and-comment rulemaking. In addition, we note that, under the incorporation by reference regulations issued by the Office of the **Federal Register**, incorporation by reference of a publication is limited to a specific edition and ''future amendments or revisions of the publication are not included'' (1 CFR 51.1(f)). Thus, under Federal regulations, we cannot incorporate by reference a specific standard and all future editions of that standard. By incorporating all or parts of a standard by reference, we are referring to those parts exactly as they are in that specific edition, at the time we finalize the rule.

[12] The document is available online at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices.*

(Comment 99) Some comments observed that FDA proposed different consensus standards for regulatory purposes for OTC and prescription hearing aids, specifically ANSI/CTA–2051:2017 and ANSI/ASA S3.22–2014, respectively. These comments raised concerns that the different standards treat the same hearing aid performance aspects differently, which could be confusing or create inconsistencies. They proposed that FDA use only one standard for both OTC and prescription hearing aids.

(Response) FDA does not agree that these standards treat the same performance aspects differently. These standards are not incompatible or divergent for purposes of regulating OTC and prescription hearing aids. Rather, the standards serve different purposes, which is appropriate for regulating different categories of hearing aids.

As we explained in the proposal, ANSI/ASA S3.22–2014 specifies test methods and measurement tolerances, not device performance (see 86 FR 58150 at 58163). For example, ANSI/ASA S3.22–2014 does not specify an output limit. Instead, it describes to manufacturers one way to determine the maximum output, using an OSPL90 curve over a specific bandwidth, and the measurement tolerance for it, that the maximum ''shall not exceed that specified by the manufacturer plus 3 dB,'' (see clause 6.2). ANSI/ASA S3.22–2014 does not help provide for safety and effectiveness by establishing a baseline for performance but rather, in effect, by defining common terms to *describe* device performance.

ANSI/CTA–2051:2017 itself integrates use of those common terms. For example, ANSI/CTA–2051:2017 relies on ANSI/ASA S3.22–2014 to describe test methods by using OSPL90 curves. (However, we note that in one place, the standard refers to ANSI/ASA S3.22–2009, rather than 2014, as a normative reference.) In other words, one standard builds on the other: ANSI/CTA–2051:2017 specifies how well an amplifier should perform instead of leaving it solely to the manufacturer (as ANSI/ASA S3.22–2014 does for hearing aids), but in either case, the specifications are measured and tested based on ANSI/ASA S3.22–2014.

(Comment 100) Some comments objected to the use of ANSI/CTA–2051:2017 for purposes of regulating hearing aids on the basis that an industry group developed the standard rather than a disinterested organization. Other similar comments alternatively or additionally objected that the standard was developed for consumer electronics but not medical devices. In either case or both, these comments argued, the use of the standard is not appropriate for the regulation of OTC hearing aids.

(Response) FDA acknowledges that, in some cases, standards developed specifically for medical devices may be more appropriate for regulatory purposes. For example, we are continuing to apply Quality System requirements specific to manufacturing medical devices, as opposed to a quality management system intended for other kinds of manufacturers. We note that the comments questioning the use of ANSI/CTA–2051:2017, as opposed to a standard specifically for medical devices, generally did not question the test methods or performance specifications specifically—the major exception being the device output limit in clause 4.3, as discussed in the previous section. (Some comments did question the performance specifications on grounds besides being adopted from a consumer-technology standard. See, for example, Comment 78 and the response.)

Some of these comments suggested that FDA use ANSI/ASA S3.22–2014 instead because that standard applies specifically to hearing aids. However, as explained in the response to Comment 99, the standards do not serve the same purposes, so they are not substitutes for each other. Additionally, as explained in response to Comment 99, although ANSI/CTA–2051:2017 specifies how well an amplifier should perform instead of leaving it solely to the manufacturer (as ANSI/ASA S3.22–2014 does for hearing aids), in either case, the specifications are measured and tested based on ANSI/ASA S3.22–2014. Although ANSI/CTA–2051:2017 was intended for personal sound amplification more generally than hearing aids, as discussed elsewhere in this document (see also the discussion in 86 FR 58150 at 58163–64), the performance specifications we are adopting based on that standard will provide reasonable assurance of safety and effectiveness of OTC hearing aids. We are therefore not replacing it with a different standard.

(Comment 101) A comment stated that FDA violated the Information Quality Act by not subjecting the ''CTA Standard'' to pre-dissemination review requirements. This comment argued that FDA cannot therefore use the ''CTA Standard'' in support of the output limits.

(Response) Neither the Information Quality Act (IQA) nor any information quality guidelines require FDA to engage in the pre-dissemination review this comment said is required.

The IQA, or Data Quality Act,[13] required the Director of the Office of Management and Budget (OMB) to issue ''guidelines . . . that provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies.'' Under the IQA, the guidelines OMB issues must require each covered Federal agency to issue guidelines concerning information ''disseminated by the agency,'' and to ''establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency that does not comply'' with OMB's guidelines. OMB's initial guidelines, as corrected, were published in February 2002. ''Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Republication'' (67 FR 8452, February 22, 2002) (''OMB Guidelines''). HHS's guidelines, which include the FDA guidelines, were published in September 2002 and have been periodically updated (''HHS/FDA Guidelines'').[14]

In 2005, OMB published its Final Information Quality Bulletin for Peer Review, which addressed ''peer review of scientific information disseminations that contain findings or conclusions that represent the official position of one or more agencies of the Federal government'' (70 FR 2664 at 2666, January 14, 2005). In 2019, OMB issued a Memorandum entitled ''Improving Implementation of the Information Quality Act'' (''Improving Implementation Memorandum''),[15] the purpose of which was to ''reinforce, clarify, and interpret agency responsibilities with regard to responsibilities under the Information Quality Act (IQA).''

As an initial matter, the IQA ''orders the Office of Management and Budget to draft guidelines concerning information quality and specifies what those guidelines should contain.'' *Salt Inst.* v. *Leavitt,* 440 F.3d 156, 159 (4th Cir. 2006). The IQA does not require pre-dissemination review. Nevertheless, to the extent pre-dissemination review may be required under the OMB Guidelines, it would not apply here, as

[13] Section 515 of the Treasury and General Government Appropriations Act, 2001, Public Law 106–554 (2000) (codified at 44 U.S.C. 3516 note).

[14] These are available at *https://aspe.hhs.gov/reports/hhs-guidelines-ensuring-maximizing-quality-objectivity-utility-integrity-information-disseminated.*

[15] M–19–15 (April 24, 2019).

FDA did not disseminate the referenced information.

The specific source this comment asserted required pre-dissemination review is ANSI/CTA–2051, a voluntary consensus standard established by the ANSI and the CTA. In the proposal, FDA explained that the Agency is basing its proposed output limits on physiological data and stakeholder input. ANSI/CTA–2051:2017 is one of the scientific sources FDA has considered. Other data and scientific sources considered are described in the proposal and include a national workplace safety guideline from the National Institute for Occupational Safety and Health, comments from speakers at a 2017 public workshop meeting held by NASEM, and public comments stemming from a 2016 FDA public workshop (Refs. 14 and 15).

The IQA and associated information quality guidelines concern only information ''disseminated'' by a Federal agency. ANSI/CTA–2051:2017 is not within the scope of the IQA and OMB guidelines because it is disseminated by ANSI and CTA, not a Federal agency. *See, e.g.,* HHS Guidelines section I.D.2.h. (''' 'Dissemination' means agency initiated or sponsored distribution of information to the public.''). Because a Federal agency did not develop or disseminate ANSI/CTA–2051:2017, ANSI/CTA–2051:2017 is not within the scope of the IQA or any information quality guidelines, and is not subject to any pre-dissemination review requirements arising under them.

FDA is committed to using and developing high quality information and follows the applicable requirements and guidelines. *See, e.g.,* 67 FR 8452 at 8459 (''Agencies shall treat information quality as integral to every step of an agency's development of information, including creation, collection, maintenance, and dissemination.''). Additionally, as discussed elsewhere in this document and as discussed in the proposal (see 86 FR 58150 at 58163–64), FDA believes the performance specifications for OTC hearing aids, having taken into account ANSI/CTA–2051:2017, will provide reasonable assurance of safety and effectiveness of these devices.

(Comment 102) A comment stated that FDA has denied the right of a work group, composed of several third-party trade groups and/or professional associations, to seek or secure adoption of a purported voluntary consensus standard it has put forth (''work group's standard''). This comment stated that the National Technology Transfer and Advancement Act, OMB Circular No. A–119, the Administrative Procedure Act, the Information Quality Act, and Executive Order 12866 give this work group that right. The comment further stated that, to remedy the alleged violation(s), FDA must incorporate the work group's standard into an amended notice of proposed rulemaking or the final rule.

(Response) None of the authorities this comment cited require FDA to adopt the work group's standard.

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) states that ''all Federal agencies and departments shall use technical standards that are developed or adopted by voluntary consensus standards bodies'' unless their use is ''inconsistent with applicable law or otherwise impractical.'' Public Law 104–113, section 12(d)(1), (3) (1996). Office of Management and Budget Circular No. A–119, as revised (Circular A–119), implements NTTAA section 12(d) by establishing policies on Federal use of voluntary consensus standards, among other things. Contrary to this comment's assertion, the work group's standard does not fit within Circular A–119's definition of a ''voluntary consensus standard.'' According to this comment, the work group's standard was created by several trade groups and/or professional associations. So the work group's standard is not a voluntary consensus standard within the meaning of Circular A–119, because it was not ''developed or adopted'' by an organization that ''plan[s], develop[s], establish[es], or coordinate[s] voluntary consensus standards using agreed-upon procedures.'' Circular A–119 section 4.A., 4.A.1. But even if the work group's standard were a voluntary consensus standard, nothing in NTTAA or Circular A–119 would require FDA to choose it over ANSI/CTA–2051:2017, the voluntary consensus standard FDA included in the proposal. As explained in the proposal, ANSI/CTA–2051:2017 is, to FDA's knowledge, the first voluntary consensus standard to describe performance characteristics for hearing amplifiers. In the proposal, FDA proposed to establish as requirements a subset of specifications from ANSI/CTA–2051:2017, in conjunction with other proposals. FDA's actions are consistent with NTTAA and Circular A–119. Indeed, Circular A–119 states that it ''does not establish a preference among standards developed in the private sector.'' *Id.* section 6.g.

This comment did not identify any language in the Administrative Procedure Act (APA) or IQA it claimed would require FDA to adopt the work group's standard. And these statutes do not require FDA to adopt any particular standard. These are procedural statutes that do not demand specific substantive outcomes, let alone use by FDA of any commenter's preferred standard.

Finally, this comment asserted that the ''compelling need requirement'' set forth in Executive Order 12866 prohibits FDA's consideration of ANSI/CTA–2051. Under Executive Order 12866, Federal agencies should issue only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling public need, such as material failures of private markets to protect or improve the health and safety of the public, the environment, or the well-being of the American people. Regulatory Planning and Review, section 1, 58 FR 51735 (September 30, 1993). FDA has complied with this provision of Executive Order 12866 because the regulation it is issuing is ''required by law.'' *See* FDARA, section 709(b) (2017). In any event, Executive Order 12866 ''reaffirm[s] the primacy of Federal agencies in the regulatory decision-making process,'' gives ''due regard to the discretion that has been entrusted to the Federal agencies,'' recognizes that ''Federal agencies are the repositories of significant substantive expertise and experience,'' and does not ''displac[e] the agencies' authority or responsibilities, as authorized by law.'' Executive Order 12866 pmbl., sections 2(a), 9; *see In re United Mine Workers of Am. Int'l Union,* 190 F.3d 545, 551 (D.C. Cir. 1999) (stating that Executive Order 12866 ''does not purport'' to ''set aside congressional legislation''). Executive Order 12866 certainly does not prohibit or require adoption of any particular standard. *See Helicopter Ass'n Int'l, Inc.* v. *FAA,* 722 F.3d 430, 439 (D.C. Cir. 2013) (explaining that Executive Order 12866 does not ''create[] private rights'').

(Comment 103) A comment stated that a third party provided a standard to FDA in advance of the proposal, and that FDA's alleged failure to consider that standard before issuing the proposal is arbitrary and capricious and therefore a violation of the Administrative Procedure Act.

(Response) The APA's notice-and-comment procedures provide the requirements that govern this rulemaking, and do not require the kind of pre-proposal special consideration this comment discussed.

Consistent with the APA, FDA published in the **Federal Register**, a ''[g]eneral notice of proposed rulemaking'' that included, among other things, ''the terms or substance of the

proposed rule or a description of the subjects and issues involved.'' 5 U.S.C. 553(b)(3). The APA states that, ''[a]fter notice required'' thereby, the agency ''shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments.'' *Id.* section 553(c). FDA has complied with this provision by, in the proposal, soliciting public comment.

FDA has considered the comments received in response to the proposal, and is in this preamble responding as appropriate. But the APA's notice-and-comment procedures, which require that the public be given an opportunity to participate in the rule making only ''[a]fter'' publication of the notice of proposed rulemaking (NPRM), *id.,* do not require that FDA consider or respond to any comments received in advance of the NPRM.

G. Conditions for OTC Sale (§ 800.30(g))

Many comments on the conditions for sale of OTC hearing aids sought more stringent conditions or enforcement to prevent possible misuses of OTC hearing aids. Although FDA is attentive to these concerns, we are also mindful of unduly impeding access by creating barriers rather than removing them if appropriate (see also 86 FR 58150 at 58166).

(Comment 104) Some comments suggested that FDA require any seller of OTC hearing aids to staff customer support in the United States with licensed persons, for customers to meet with them via telemedicine technology.

(Response) FDA is not adopting these suggestions because this would require the involvement of a licensed person in the sale of an OTC hearing aid, contrary to section 520(q)(1)(A)(v) of the FD&C Act and section 709(b)(2)(D) of FDARA. Further, the requirements in this rulemaking will provide reasonable assurance of safety and effectiveness of OTC hearing aids without the involvement of a licensed person. In any case, FDA would expect such a requirement to entail substantial, perhaps prohibitive, costs for sellers in addition to a significant amount of time to develop or contract for such services. Neither would be compatible with the purposes of this rulemaking, including the purpose of broadening the kinds of sellers that can offer OTC hearing aids.

(Comment 105) Multiple comments proposed a requirement for age verification prior to the sale or delivery of an OTC hearing aid. Similarly, comments proposed a requirement for purchasers to affirm that they are at least 18 years old at the time of purchase. Some of these additionally proposed that purchasers acknowledge or agree that the OTC hearing aid is not for use by anyone younger than 18 years old.

(Response) FDA is not adopting these suggestions. While people younger than 18 should not use hearing aids without the involvement of a licensed person, such as an ear-nose-throat doctor, we do not agree that the risk warrants age verification at this time.

We considered other purchases that require age verification and found that, in such cases, the risks to individuals and the public health were significantly greater than the risks posed by the use of OTC hearing aids by people younger than 18. Furthermore, we do not expect that OTC hearing aids will be as attractive for purchase by people younger than 18 as other age-restricted products that do require verification. Thus, the benefit of mandatory age verification would likely be small relative to the risks posed to the individual by OTC hearing aids compared to the benefit of restricting and risks posed by other age-restricted products.

At the same time, we would expect mandatory age verification, or similar processes like certifications or acknowledgments, to increase the difficulty or complexity of purchases by people who are the intended users, and can benefit from the use, of OTC hearing aids. Since one of the purposes of this rulemaking is to promote the public health by reducing or eliminating barriers to access for such people, we considered which approach is likely to benefit the public health more. In this case, lower-income people or people who live in relatively isolated conditions (for example, in rural areas) are more likely to benefit from broadened access while at the same time being less able to present official documentation of their age (for example, because they lack a driver's license or are buying hearing aids by mail). We have determined that the public health is better served at this time by not imposing requirements for age verification, certification, or acknowledgment.

The above considerations also took into account that we are finalizing requirements to improve the warnings against use of OTC hearing aids by people younger than 18. We are also finalizing the condition for sale that will prohibit sale of OTC hearing aids to or for people younger than 18 under new § 800.30(g)(1). These requirements, along with the others in this rule, will help provide reasonable assurance of safety and effectiveness of OTC hearing aids for the intended users without the need for age verification. We expect that sellers will likely adopt their own practices, tailored to their business models, to prevent violating this condition for sale and/or engaging in a prohibited act. Such practices may, but are not required to, entail age verification by checking a government-issued photographic identification. However, in some cases, the seller may not need to check a government-issued photographic identification, for example, when the seller has personal knowledge of the purchaser's age or may otherwise be certain that the purchaser is 18 or older.

(Comment 106) Several comments proposed that FDA enhance enforcement of legal requirements for labeling, sales, or other provisions for legally marketing hearing aids. Similar comments suggested that FDA enhance enforcement for selling non-compliant products as hearing aids, for example, by making false or misleading statements or improperly avoiding premarket requirements for devices. Other such comments urge in any case that FDA monitor the sales of OTC hearing aids and/or non-compliant consumer electronics marketed as hearing aids.

(Response) FDA intends to apply existing practices for monitoring the market and will take action, including enforcement as necessary and appropriate. Should stakeholders wish to call FDA's attention to potential concerns that we may not otherwise learn, including potential regulatory misconduct, they may file a report sometimes known as a trade complaint. Anyone may file such a report (a complaint), and we encourage people to include supporting and contact information for possible followup questions. However, the reports can be anonymous. More information about the process is available on FDA's website: *https://www.fda.gov/medical-devices/medical-device-safety/reporting-allegations-regulatory-misconduct.* See also the response to Comment 122 regarding the role of State authorities in enforcing requirements applicable to OTC hearing aids.

Moreover, we are finalizing labeling requirements that describe the process of reporting adverse events to FDA (see final §§ 800.30(c)(2)(iii)(F) and 801.422(c)(2)(ii)(E)). Section 709(d) of FDARA directs FDA to report on an analysis of adverse events relating to OTC hearing aids not later than 2 years after the date we issue this final rule. FDA expects this information to be helpful in identifying and analyzing device risk trends, and it will likely inform enforcement prioritization.

(Comment 107) Comments suggested that FDA impose a penalty on persons who sell an OTC hearing aid that is used by a child.

(Response) The FD&C Act sets forth penalties for prohibited acts respecting devices and electronic products as described in section IV of this document (see 21 U.S.C. 331, 333, 360oo and 360pp(b)). Prohibited acts include, among other things, doing or causing a variety of acts involving adulterated and/or misbranded devices (see, *e.g.,* 21 U.S.C. 331(a)–(c), 331(k)). In turn, a device is deemed adulterated and/or misbranded for a variety of reasons (see 21 U.S.C. 351 and 352). For example, an OTC hearing aid sold to or for a person younger than 18 would not, among other deficiencies, bear adequate directions for use for such users. The hearing aid would be deemed misbranded (see 21 U.S.C. 352(f)), and certain activities with respect to the misbranded device (for example, the introduction of the misbranded device into interstate commerce) would be a prohibited act in that example and subject to the penalties under the FD&C Act.

(Comment 108) Several comments suggested that FDA establish a variety of post-sale requirements on manufacturers or sellers of OTC hearing aids. Such proposals included requirements that manufacturers or sellers: accept returns for a certain minimum period (either for money back or credit), warrant certain features or components for a given period, guaranty products or services in some way, and/or provide a minimum rescission period (a period in which a buyer could cancel the purchase).

Many of these comments mentioned user satisfaction and that, if users buy an unsatisfactory device and are unable to return or exchange it, such users could incur unnecessary expenses to obtain a satisfactory OTC hearing aid or forego hearing aid use entirely. Other such comments described a benefit or need to establish a national standard, as opposed to one that varies by State, to encourage broader availability of the devices. The proposed time periods for the application of such requirements varied but were generally 30, 45, 60, or 90 days after purchase.

(Response) FDA is not establishing the suggested post-sale requirements on manufacturers or sellers of OTC hearing aids. We are finalizing a requirement for OTC hearing aid labeling to provide notice of the manufacturer's return policy. We believe this adequately addresses the concern mentioned in the comments that the risk of obtaining an unsatisfactory OTC hearing aid may result in people foregoing hearing aid use entirely, and that additional requirements in this regard are not necessary to provide a reasonable assurance of safety and effectiveness for OTC hearing aids. To the extent the post-sale requirements proposed in the comments are aimed at consumer protection rather than providing a reasonable assurance of safety and effectiveness for OTC hearing aids, we note that there may be other Federal laws, administered by other agencies that provide this type of consumer protection. Likewise, many States have existing requirements that also address these types of consumer protection concerns. See the response to Comment 122 regarding the applicability of State consumer protection requirements.

(Comment 109) A comment proposed that FDA prohibit the resale of OTC hearing aids by consumers. The comment expressed a need for appropriate disinfection of used hearing aids and the need to apply labeling required for used hearing aids. The comment asserted that used OTC hearing aids should be returned by the vendor to the manufacturer for it to take the necessary steps to market a used OTC hearing aid.

(Response) Although FDA agrees that all used hearing aids should be labeled as required and adequately reprocessed regardless of the type of reseller, we are declining to revise the proposed rule to incorporate this suggestion. We are finalizing the requirement that if the OTC hearing aid is used or rebuilt, the outside package must declare that fact, and we have modified the design requirements for OTC hearing aids to specify that if the OTC hearing aid is used or rebuilt, it must be adequately reprocessed for the next user prior to sale. OTC hearing aids must meet these requirements regardless of the type of reseller. We believe that the requirements that we are finalizing for OTC hearing aids provide for reasonable assurance of safety and effectiveness, and prohibiting resale of an OTC hearing aid by a consumer will not add anything and will likely be impractical to enforce.

(Comment 110) Comments proposed that FDA require referrals to physicians for prescription hearing aids when a user or prospective user manifests any of the ''red flag'' conditions. However, one such comment proposed an option for waivers since, it asserted, most people with a ''red flag'' condition have already been advised to seek or previously sought an examination by a physician.

(Response) FDA is declining this suggestion because it would require the involvement of a licensed person in the use of OTC hearing aids in some cases, and it is not necessary for reasonable assurance of safety and effectiveness of OTC hearing aids. We believe that the required prominent warnings and other statements in the labeling of OTC hearing aids are sufficient to advise users and prospective users to consult hearing health care providers, including ENT doctors, in certain circumstances, such as when experiencing certain pathological (''red flag'') conditions. For these reasons, we are not including an examination or waiver requirement for the OTC category of hearing aids.

(Comment 111) Some comments urged FDA to establish generally more-stringent requirements for the sale of OTC hearing aids. These comments reasoned that because hearing aids are medical devices, are technologically complex, and/or intended to compensate for a complex condition, they should not be as easily available as other devices such as bandages (see, *e.g.,* 21 CFR 880.5075, classifying elastic bandages).

(Response) Except as explained elsewhere in this document, FDA is declining this suggestion. We are establishing requirements that are sufficiently stringent to provide reasonable assurance of safety and effectiveness of OTC hearing aids. We have taken into account, among other considerations, the seriousness of hearing impairment as well as the complexity of both the impairment and the technology intended to compensate for it. More stringent requirements are not necessary to provide reasonable assurance of safety and effectiveness, and the requirements we are establishing generally do not depend on the sales environment, provided the environment does not cause the device to be adulterated, misbranded, or otherwise out of compliance with applicable requirements (see, *e.g.,* 21 U.S.C. 351(a)(2)(A) regarding adulteration if held under insanitary conditions).

Moreover, the extent to which the availability of OTC hearing aids is comparable to that of elastic bandages does not suggest the devices themselves are otherwise similar. Similarly, the broad availability of elastic bandages does not cause the devices to be less safe and effective for their intended use(s), and the same would be true for OTC hearing aids. The purposes of this rule include promoting broader availability of OTC hearing aids while establishing requirements that will provide reasonable assurance of safety and effectiveness, which is

incompatible with establishing unnecessarily stringent regulations.

(Comment 112) Comments suggested that sellers of OTC hearing aids be required to keep the devices behind the counter or in a locked cabinet to prevent people younger than 18 from purchasing the devices.

(Response) FDA is declining this suggestion because we are allowing flexibility for sellers to determine how to comply with the condition for sale that prohibits the sale of OTC hearing aids to or for people younger than 18. FDA intends this flexibility to minimize regulatory burdens while promoting access to safe and effective devices. If a seller determines that it can comply with the condition for sale without special storage provisions, then it need not make such storage provisions. Mandating special storage provisions for such sellers of OTC hearing aids would add unnecessary burdens. However, a seller may decide keeping the devices in a locked display case and verifying the purchaser's age with a form of photographic identification will be the most practical approach for its circumstances. (See also the response to Comment 105 regarding age verification.) Although we are not mandating a specific approach to ensure that OTC hearing aids are not sold to people younger than 18, FDA expects that sellers will implement an approach appropriate for their circumstances.

(Comment 113) A comment suggested pairing the purchase of an OTC hearing aid with membership in an organization that could serve first-time hearing aid users, for example, by assisting with or explaining the initial selection and purchase of an OTC hearing aid.

(Response) FDA is not adopting this suggestion as condition for sale of OTC hearing aids. Although such organizations can provide useful and valuable services for users and prospective users of hearing aids, FDA proposed and is finalizing requirements for OTC hearing aids that would provide reasonable assurance of safety and effectiveness without the involvement of a licensed person. Requiring the involvement of such an organization is neither necessary for reasonable assurance of safety and effectiveness nor consistent with the approach we are taking to establish the OTC category for hearing aids to promote broader availability of OTC hearing aids.

Further, as we explained in the proposal, we expect this final rule to lower costs of hearing aids by unbundling the purchase of hearing aids from professional services, including professional advice, fitting, adjustment, or maintenance to make the devices available over the counter (see 86 FR 58150 at 58172). Requiring membership in an organization with the purchase of OTC hearing aids would be contrary to our intent of unbundling services and device purchases. In that vein, we would expect that membership with such an organization would present costs to users, either directly, as in a membership fee, or indirectly, as in increasing the purchase price of a device. Thus, although users and prospective users may choose to seek membership with organizations to obtain related benefits, we do not agree that such membership should be required with the purchase of an OTC hearing aid.

(Comment 114) A comment proposed that FDA require sellers of OTC hearing aids to obtain certifications for relevant standards developed by the ISO as well as comply with appropriate Quality System requirements. For example, dispensers might conform to ISO 21388:2020, ''Acoustics—Hearing aid fitting management.''

(Response) FDA is not requiring sellers of OTC hearing aids that are not manufacturers to comply with part 820 requirements for a Quality System or conform to consensus standards. An OTC hearing aid, by definition, is a device that, among other qualities, allows the user to control and customize it to the user's hearing needs, without the involvement of a licensed person (see 21 U.S.C. 360j(q)(1)(A)(iii) and (v)). Further, multiple provisions of this rule are intended to ensure that persons do not incur special licensing obligations or the equivalent (certifications, for example) on account of commercial activity involving OTC hearing aids (see, *e.g.,* final § 800.30(h)(2)(i)). As such, requiring a seller of OTC hearing aids to be specially licensed or certified is both unnecessary for reasonable assurance of safety and effectiveness of OTC hearing aids and inconsistent with the approach we are taking to establish the OTC category for hearing aids.

Additionally, the scope of part 820 extends to manufacturers of finished devices, as § 820.3(o) defines the term, but generally not other persons (see § 820.1(a)(1)), and the requirements of part 820 are not intended to extend to sellers who are not manufacturers. Instead, part 820 specifies that, among other controls, manufacturers must ensure that device labeling, packaging and shipping containers maintain label and device integrity during customary conditions of processing, storage, handling, and distribution (see §§ 820.120(a) and 820.130).

We likewise observe that the consensus standard ISO 21388:2020 applies to hearing aid fitting management (see clause 1), but not non-licensed persons (*i.e.,* non-hearing aid professionals). As such, this standard is not likely to apply to sellers of OTC hearing aids who are not licensed persons. As we explained above, sellers of OTC hearing aids are not required to have a specialized license or the equivalent.

Nevertheless, FDA acknowledges that quality management may also be useful to many persons who are not manufacturers or hearing aid professionals (as ISO 21388:2020 defines the term). Some concepts in part 820, ISO 21388:2020, or ISO 13485:2016, for example, may help inform such other person's determination of best practices. A number of standards exist for other persons to implement quality management systems, for example, ISO 9001:2015, ''Quality management systems—Requirements,'' and those persons may wish to obtain related certifications and advertise as such. However, FDA has determined that special licensing (or its equivalent) is not necessary, as explained, and we are not requiring sellers of OTC hearing aids that are not manufacturers to comply with part 820 or conform to ISO 21388:2020, ISO 13485:2016, or any other consensus standard.

(Comment 115) A comment proposed that FDA protect consumers from predatory practices throughout the supply chain for OTC hearing aids. It specifically referred to unnecessarily collecting or sharing private information by or with several kinds of persons: manufactures, retailers, medical practitioners, payment processors, service providers, device monitoring and configuration providers, data aggregators, computer hosting services, and platforms.

(Response) FDA is declining this proposal because it is not necessary for reasonable assurance of safety and effectiveness of OTC hearing aids. Moreover, although certain deceptive practices would be prohibited under the FD&C Act, other Federal and State agencies establish and enforce such requirements as those concerning protection of private information. For example, if a seller were to modify the labeling of an OTC hearing aid to mislead prospective purchasers, that would constitute misbranding of a device while held for sale in interstate commerce, which is prohibited under the FD&C Act (see, *e.g.,* 21 U.S.C. 331(k)). Deceiving prospective purchasers in such a way may additionally violate Federal and/or State requirements that FDA is not

responsible for administering or enforcing. For more information about the kinds of health fraud issues FDA addresses, which includes unlawful sales of medical products, you may visit our website: *https://www.fda.gov/consumers/health-fraud-scams.*

However, FDA does not generally administer or enforce requirements respecting predatory commercial practices that do not involve the safety or effectiveness of FDA-regulated products. Should stakeholders wish to raise concerns for deceptive practices not related to requirements that FDA administers or enforces, they should approach the appropriate Federal or State agencies. For example, stakeholders may wish to report fraud to the Federal Trade Commission's Bureau of Consumer Protection. More information is available online: *https://www.ftc.gov/about-ftc/bureaus-offices/bureau-consumer-protection.*

(Additional Revision 4) FDA is finalizing a condition for sale for OTC hearing aids that sellers may not sell the devices over the counter unless the principal display panel of the outside package labeling bear prominent marks identifying the device as ''OTC'' and a ''hearing aid.'' As explained in Additional Revision 2 (section III.D.3), FDA is finalizing a requirement for the outside package labeling to bear the marks to assist purchasers and others, including retailers and State agencies. However, in some cases, purchasers may not view the principal display panel of the package prior to purchase. For example, a person shopping online may filter a list of the devices offered by the seller with ''OTC'' and view only pictures of the device itself. This condition for sale will help ensure that only OTC hearing aids are sold as such, particularly for purchasers who shop online or by mail. This is necessary for reasonable assurance of safety and effectiveness of OTC hearing aids because it provides assurances that non-OTC hearing aids or non-hearing aids will not be sold as or confused for OTC hearing aids.

H. Preemption Provisions (§ 800.30(h))

Most comments on preemption sought clarification on the effects of this rule on State and local requirements, including consumer protections and professional licensing requirements. Many strongly supported preserving States' roles in protecting prospective and current hearing aid users.

(Comment 116) Several comments suggested that FDA define ''restrict or interfere'' in the FDARA preemption provision because these terms are ambiguous. Specifically, one suggestion was that FDA define ''restrict or interfere'' to pertain only to State and local laws that prevent or create an obstacle to a commercial activity involving OTC hearing aids so that State consumer protection laws that pertain to commercial activity involving OTC hearing aids, such as a warranty requirement and mandatory returns for OTC hearing aids, would not be preempted. Another suggestion was that FDA define ''restrict or interfere'' to mean ''present actual legal or procedural impediment to the exclusion of business disincentives.'' One comment expressed concerns that return requirements could be viewed as interfering with distribution of OTC hearing aids because such requirements make distribution chains more complicated and potentially more expensive; warranty requirements would, by mandating servicing of OTC hearing aids, interfere with the servicing of the devices; and both kinds of requirements could be viewed as discouraging the sale of OTC hearing aids by increasing prices for patients.

(Response) FDA declines to include the definitions suggested by comments because the Agency is concerned that the suggested definitions may not be consistent with ''restrict or interfere with'' in section 709(b)(4) of FDARA. For example, the dictionary defines ''restrict'' to mean ''to confine within bounds,'' Merriam-Webster at *https://www.merriam-webster.com/dictionary/restrict,* and this definition seems somewhat different from ''prevent or create an obstacle'' or ''present actual legal or procedural impediments.''

Instead of adopting the definitions proposed by the comments or some other definition, in assessing whether a State or local requirement would ''restrict or interfere with'' commercial activity involving OTC hearing aids, FDA intends to consider, among other things, the ordinary meaning of these terms in the context of section 709 of FDARA, including the objectives of section 709, and the specific facts, such as the specific language of the State or local requirement and the effects of the requirement on commercial activity involving OTC hearing aids.

One of the reasons for the proposed definitions of ''restrict or interfere'' in the comments appears to be the concern that State consumer protection laws, such as those that provide for a return period or warranty for hearing aids, would be preempted under section 709(b)(4) of FDARA. For a discussion of this topic, see the response to Comment 122.

FDA notes that ''restrict or interfere with'' is just one element of the FDARA preemption provision in section 709(b)(4). In other words, there are other elements to consider in assessing whether a State or local requirement is preempted under section 709(b)(4) of FDARA, such as whether the State or local requirement is ''specifically related to hearing products.'' As discussed in the proposal, we do not interpret FDARA to preempt generally applicable requirements, *i.e.,* requirements that relate to other products in addition to hearing products, to services not specific to hearing products, or to unfair trade practices in which the requirements are not limited to hearing products. See 86 FR 58150 at 58167 for further discussion.

(Comment 117) A comment suggested that FDA consider requests from States for exemption from Federal preemption as OTC devices enter the market. Another comment suggested that FDA state in the final rule that the existing processes in § 808.20 (21 CFR 808.20) (which relate to requests for exemption from Federal preemption under section 521 of the FD&C Act) will continue to apply, and that FDA will find against preemption when consistent with the statutory language and ''in the public interest.''

(Response) As discussed in the proposal, section 709(b)(4) of FDARA established preemption specific to OTC hearing aids that is different from the general rule for preemption under section 521 of the FD&C Act. See 86 FR 58150 at 58166. Unlike section 521 of the FD&C Act, section 709(b)(4) of FDARA does not provide for any exemptions for State or local requirements that fall within this provision. Therefore, FDA is unable to provide exemptions from preemption for State or local requirements that fall within the scope of section 709(b)(4).

Section 521 of the FD&C Act does provide for exemption from preemption for State or local requirements that fall within this provision, and the procedures for requesting and granting or denying an exemption are provided in part 808, subpart B (21 CFR part 808, subpart B). Section 808.20 will continue to apply to State or local requirements that fall within section 521 of the FD&C Act, such as requirements for prescription hearing aids. FDA did not propose any changes to § 808.20.

FDA intends to assess preemption consistent with the statutory language of section 709(b)(4) of FDARA for State or local requirements that fall within this provision. We believe this approach to assessing preemption is consistent with the Supreme Court's approach to Federal preemption. *See, e.g., Puerto*

Rico v. *Franklin Cal. Tax-Free Trust,* 579 U.S. 115, 125 (2016) (explaining that ''because the statute contains an express preemption clause, we do not invoke any presumption against preemption but instead focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent.'' (citations and internal quotations omitted)). Additionally, FDA believes that this approach will achieve the objectives of section 709 of FDARA, which include promoting access to safe and effective OTC hearing aids for adults with perceived mild to moderate hearing impairment, and in so doing, will be in the public interest. FDA also intends to assess preemption consistent with section 521 of the FD&C Act for State or local requirements that fall within this provision, and consider exemption from preemption when requested in accordance with § 808.20. As indicated in § 808.20, FDA considers, among other things, information on how the public health may be benefitted if an exemption is granted.

(Comment 118) A comment suggested that FDA set up an informal process by which States could request feedback from the Agency about whether specific requirements are preempted under section 709(b)(4) of FDARA. Another comment requested that FDA specify in the final rule that the process in § 808.5(a) (21 CFR 808.5(a)) apply to State and local requirements concerning hearing products because this process would increase transparency.

(Response) At this time, FDA does not believe it is necessary to set up a separate informal process for States or localities to request feedback from the Agency about whether specific requirements are preempted under section 709(b)(4) of FDARA because there are existing informal processes that States or localities can use to make such requests. For example, State or localities that have questions about preemption may contact the Center for Devices and Radiological Health (CDRH)'s Ombudsman at *cdrhombudsman@fda.hhs.gov* or FDA's Intergovernmental Affairs Staff at *IGA@fda.hhs.gov.* (CDRH's Division of Industry and Consumer Education can also answer general questions regarding device regulation.) Additionally, we note that § 808.5(a) does not set forth a separate process but rather relies on the advisory opinion process in § 10.85 (21 CFR 10.85). States or localities may request an advisory opinion under § 10.85 with respect to whether FDA regards a particular State or local requirement as preempted under section 709(b)(4) of FDARA.

(Comment 119) Two comments noted that part 808 includes a list of the types of State or local requirements that are not preempted, and requested that FDA expand this list with additional examples pertaining to hearing aids, such as requirements that relate to warranties, returns, and the sale of hearing aids for users under 18 years of age.

(Response) The list in part 808 of the types of State or local requirements that are not preempted pertains to preemption under section 521 of the FD&C Act. Specifically, § 808.1(d) provides examples of the types of State or local requirements that are not preempted by section 521 of the FD&C Act, including examples of State or local requirements that are not considered ''requirements applicable to a device'' under section 521 of the FD&C Act.

However, providing general categories of State or local requirement on hearing aids that are not preempted under section 709(b)(4) of FDARA would be challenging because preemption under this section depends in part on whether the requirement would ''restrict or interfere with'' commercial activity involving OTC hearing aids. Whether a State or local requirement would ''restrict or interfere with'' commercial activity involving OTC hearing aids will depend on the specific facts, including the specific language of the State or local requirement and the effects of the requirement.

We note that in the proposal, we did provide specific examples of State or local requirements that we believe would or would not be preempted under section 709(b)(4) of FDARA. See 86 FR 58150 at 58167–68. Additionally, as discussed in the proposal, we do not interpret section 709(b)(4) of FDARA to preempt generally applicable requirements, *i.e.,* requirements that relate to other products in addition to hearing products, to services not specific to hearing products, or to unfair trade practices in which the requirements are not limited to hearing products. See 86 FR 58150 at 58167 for further discussion. However, we noted that if a State or local requirement appears on its face to be generally applicable, but in practice it was specifically related to hearing products and would restrict or interfere with commercial activity involving OTC hearing aids, the requirement would be preempted. See 86 FR 58150 at 58167.

Further, State or local requirements specifically related to hearing products would not be preempted under section 709(b)(4) of FDARA if they would not restrict or interfere with commercial activity involving OTC hearing aids. For example, we believe that reasonable return or warranty requirements for OTC hearing aids would likely promote, rather than restrict or interfere with, commercial activity involving OTC hearing aids by reducing the financial risk to purchasers. For further discussion of this topic, see the response to Comment 122.

We also note that section 709(b)(5) of FDARA specifies, ''[n]othing in this section shall be construed to modify or otherwise affect the ability of any person to exercise a private right of action under any State or Federal product liability, tort, warranty, contract, or consumer protection law.'' Therefore, laws that fall within the scope of this savings clause would not be preempted under section 709(b)(4) of FDARA provided that they do not conflict with the OTC Hearing Aid Controls or frustrate the purposes and objectives of section 709 of FDARA. *See, e.g., Am. Tel. and Tel. Co.* v. *Central Office Tel., Inc.,* 524 U.S. 214, 226 (1998) (holding that a remedies savings clause in the Communications Act of 1934 did not save State laws that were inconsistent with Federal law); *Automobile Importers of America, Inc.* v. *Minnesota,* 871 F.2d 717, 722 (8th Cir. 1989) (although the relevant Federal statute had a broad savings clause, the court stated ''State legislation is preempted if compliance with the state law frustrates the purposes and objectives of federal law'').

States or localities that have questions about preemption may contact CDRH's Ombudsman at *cdrhombudsman@fda.hhs.gov* or FDA's Intergovernmental Affairs Staff at *IGA@fda.hhs.gov,* or they may request an advisory opinion under § 10.85 with respect to whether FDA regards a particular State or local requirement as preempted under section 709(b)(4) of FDARA.

The OTC Hearing Aid Controls in § 800.30 do not apply to hearing aids intended for users under 18 years of age. Hearing aids intended for users under 18 years of age would be considered prescription hearing aids as defined in §§ 800.30(b) and 801.422(b). State or local requirements governing the sale of hearing aids for users under 18 years of age would fall within the scope of section 521 of the FD&C Act, and therefore, that section and part 808 would continue to apply. To the extent that a State or local requirement is preempted under section 521 of the FD&C Act, the State or political subdivision may apply for exemption from preemption in accordance with part 808, subpart B.

(Comment 120) A comment from an association of State Attorneys General

stated that ''the proposed rule includes broad language that could be interpreted to repeal virtually all the state-requested exemptions from preemption issued by the FDA since 1980—even those related exclusively to non-OTC hearing aids'' and that this could create confusion and unnecessary litigation.

(Response) While we are removing most of the regulations codifying the exemption decisions, we are doing so because we are repealing or revising the specific counterpart Federal regulations that preempted State and local requirements respecting devices. In addition, preemption specific to OTC hearing aids would generally nullify the exemptions to the extent the State or local requirements would apply to OTC hearing aids except in certain specific circumstances.

With respect to OTC hearing aids, as discussed in the proposal, section 709(b)(4) of FDARA established preemption specific to OTC hearing aids that is different from the general rule for preemption under section 521 of the FD&C Act. See 86 FR 58150 at 58166. The FDARA preemption provision preempts State and local requirements specifically related to hearing products that would restrict or interfere with commercial activity involving OTC hearing aids, and that are different from, in addition to, or otherwise not identical to regulations issued under FDARA section 709(b). Unlike section 521 of the FD&C Act, section 709(b)(4) of FDARA does not provide for any exemptions for State or local requirements that fall within this provision. Therefore, FDA is unable to continue in effect any previously granted exemptions from preemption for State or local requirements that fall within the scope of section 709(b)(4) of FDARA.

With respect to prescription hearing aids and other State and local requirements for hearing aids not otherwise preempted by FDARA section 709(b)(4), FDA is removing all of the regulations in part 808 related to hearing aids; that is, almost all regulations codifying the previous decisions in §§ 808.53 through 808.101, except for the portions of § 808.55 (California) that do not relate solely to hearing aids. As discussed in the proposal, those exemptions are no longer applicable because this final rule repeals or revises the underlying Federal requirements from which those exemptions were granted. See 86 FR 58150 at 58170. In addition, FDA is aware that several States have modified their requirements that were the subject of the exemption decisions since they applied for exemptions, in which case the exemption decision may no longer be applicable.

We note that removal of these exemptions does not itself mean that those State or local laws are now preempted given that we are repealing or revising the specific counterpart regulations. For example, the repeal of the conditions for sale in § 801.421 means that State or local requirements that differed from, or were in addition to, the repealed counterpart Federal requirements will no longer be preempted under section 521(a) of the FD&C Act (see § 808.1(d)). However, some of the new requirements we are establishing in this rule would implicate preemption under section 521(a) of the FD&C Act. For example, the prescription hearing aid labeling requirements set forth in § 801.422 will preempt certain State or local requirements that are different from, or in addition to, those Federal requirements. These new requirements are similar but not identical to those in § 801.420 and include substantive changes. To the extent that any previously granted petitions for exemptions related to labeling requirements, any such exemptions would be rendered inapplicable due to changes in the underlying Federal requirements from which the exemptions were granted.

States or localities that have questions about preemption may contact CDRH's Ombudsman at *cdrhombudsman@fda.hhs.gov* or FDA's Intergovernmental Affairs Staff at *IGA@fda.hhs.gov,* or they may request an advisory opinion under § 10.85 with respect to whether FDA regards a particular State or local requirement as preempted.

(Comment 121) A comment from the Rhode Island Department of Health noted that Rhode Island General Laws sections 5–49–2.1 and 2.2 contain provisions that would require consumers or purchasers to obtain a certificate of need from a physician who attests that the individual is in need of a hearing aid, and therefore requested that FDA retain § 808.89, which denied Rhode Island's request for exemption from preemption. Doing so, the comment said, would align with FDA's approach of authorizing non-physician licensed hearing professionals to make determinations of need and would also benefit consumers by reducing unnecessary costs and added time to the process of obtaining a hearing aid.

(Response) FDA has decided not to retain § 808.89, because the repeal of the conditions for sale in § 801.421 substantively changes the underlying Federal requirements against which the previous denial of exemption from preemption was made. The repeal of § 801.421 means Rhode Island General Laws sections 5–49–2.1 and 2.2 are no longer preempted under section 521(a) of the FD&C Act, because no counterpart Federal requirement exists (see § 808.1(d)). Without that preemption, the previous denial would have no effect even were we to retain the regulation.

However, section 709(b)(4) of FDARA would separately preempt the Rhode Island provisions to a certain extent, regardless of our previous exemption decisions and whether or not § 808.89 were retained. For example, to the extent the Rhode Island laws require a certificate of need from a physician for the sale of OTC hearing aids, they are now preempted by FDARA section 709(b)(4), because they are specifically related to hearing products, would restrict or interfere with commercial activity involving OTC hearing aids, and are different from, in addition to, or otherwise not identical to, FDA's regulations issued under FDARA section 709(b).

(Comment 122) Some comments expressed concern that State consumer protections would be preempted. For example, one comment stated that many States tie consumer protections, such as return requirements, for purchasers of hearing aids to licensing requirements, and stated that these protections would be preempted under the proposed rule. To address the concern, comments recommended that Federal consumer protections, such as requiring that hearing aid sales be accompanied by a receipt, information relating to warranty, and mandatory return or trial period, be established, for example as conditions for sale under § 800.30(g).

(Response) FDA declines to include the requirements suggested by comments because at this time, the Agency believes requiring that OTC hearing aid sales be accompanied by a receipt, information relating to warranty, and mandatory return or trial period is not necessary to provide reasonable assurance of the safety and effectiveness of OTC hearing aids.

FDA notes that the preemption provision in § 800.30(h)(1) is intended to incorporate the preemption provision in section 709(b)(4) of FDARA. In other words, the preemption provision in § 800.30(h)(1) simply reflects the statute, which expresses clear Congressional intent to preempt certain State and local requirements. As explained in the proposal, FDA decided to codify the FDARA preemption provision in the regulations to assist stakeholders in understanding the legal framework for OTC hearing aids given that the FDARA

preemption provision was not incorporated into the FD&C Act (a process known as U.S. Code classification). 86 FR 58150 at 58166. In this response, FDA focuses on the express preemption provision in section 709(b)(4) of FDARA but notes that there are other types of preemption that may apply such as conflict preemption. *See, e.g., Nat'l Fedn. of the Blind* v. *United Airlines, Inc.,* 813 F.3d 718, 724 (9th Cir. 2016) (describing conflict preemption in addition to express preemption).

Whether a State or local requirement is preempted under section 709(b)(4) of FDARA would depend on the specific facts, including the language of the requirement and the effects of the requirement on commercial activity involving OTC hearing aids. However, FDA believes that many State or local consumer protection requirements would not be preempted under section 709(b)(4) of FDARA because they are not ''specifically related to hearing products'' or would not ''restrict or interfere with'' commercial activity involving OTC hearing aids. As discussed in the proposal, we do not interpret FDARA to preempt generally applicable requirements, *i.e.,* requirements that relate to other products in addition to hearing products, to services not specific to hearing products, or to unfair trade practices in which the requirements are not limited to hearing products. See 86 FR 58150 at 58167. For example, generally, we would not consider a State or local warranty requirement for assistive devices to be ''specifically related to hearing products'' under section 709(b)(4) of FDARA because the requirement relates to other products (*e.g.,* wheelchairs) in addition to hearing products.

Whether a State or local consumer protection requirement that specifically related to hearing products would ''restrict or interfere with'' commercial activity involving OTC hearing aids would depend on the specific facts. However, generally, FDA believes that State or local requirements that provide for a reasonable warranty or return period for hearing aids (*e.g.,* 60-day period) would likely promote, rather than restrict or interfere with, commercial activity involving OTC hearing aids. Such requirements may help to encourage people who could benefit from an OTC hearing aid to purchase the device by reducing their financial risk. As discussed in the proposal, despite the high prevalence and public health impact of hearing loss, only about one-fifth of people who could benefit from a hearing aid seek intervention, likely due to barriers such as high cost. 86 FR 58150 at 58151. An important objective of section 709 is to lower some of the barriers and improve access to these devices for people who could benefit from them. See id.; see also ''FDA User Fee Agreements: Improving Medical Product Regulation and Innovation for Patients, Part I,'' Hearing before the Comm. on Health, Education, Labor, and Pensions, 115th Cong. 115–255 (2017), at 74 (Remarks by Sen. Elizabeth Warren regarding S. 670, the Over-the-Counter Hearing Aid Act of 2017, which was largely incorporated into section 709 of FDARA, indicating that this legislation was intended to improve access and affordability to safe and effective OTC hearing aids for millions of consumers who could benefit from these devices); ''Examining Improvements to the Regulation of Medical Technologies,'' Hearing before the Subcomm. on Health of the H. Comm. on Energy and Commerce, 115th Cong. 115–28 (2017), at 3 (Statement of Rep. Michael C. Burgess regarding H.R. 1652, the Over-the-Counter Hearing Aid Act of 2017, which was largely incorporated into section 709 of FDARA, stating that this bill was introduced ''to safely increase access and affordability in the hearing aid market for millions of Americans from whom it would benefit.'').

Additionally, State or local requirements that provide for reasonable disclosure of the terms of sale in a receipt or similar document would likely promote, rather than restrict or interfere with, commercial activity involving OTC hearing aids by providing important information in writing, such as return or warranty information, to help people with mild to moderate hearing impairment make fully informed purchasing decisions.

Congress also recognized the importance of maintaining certain State consumer protection laws as reflected in section 709(b)(5) of FDARA. Specifically, section 709(b)(5) states, ''Nothing in this section shall be construed to modify or otherwise affect the ability of any person to exercise a private right of action under any State or Federal product liability, tort, warranty, contract, or consumer protection law.'' Therefore, laws that fall within this savings clause would not be preempted unless they conflict with the OTC Hearing Aid Controls or frustrate the purposes and objectives of section 709 of FDARA. *See, e.g., Am. Tel. and Tel. Co.* v. *Central Office Tel., Inc.,* 524 U.S. 214, 226 (1998) (holding that a remedies savings clause in the Communications Act of 1934 did not save state laws that were inconsistent with federal law); *Automobile Importers of America, Inc.* v. *Minnesota,* 871 F.2d 717, 722 (8th Cir. 1989) (although the relevant Federal statute had a broad savings clause, the court stated ''State legislation is preempted if compliance with the state law frustrates the purposes and objectives of federal law'').

With regard to State or local requirements that tie consumer protections to licensing requirements, the consumer protections are not necessarily preempted. As we explained in the proposal, under section 709(b)(4) of FDARA, a State or local government cannot require persons engaged in commercial activity involving OTC hearing aids to undertake special licensing or equivalent activities solely on that basis (see 86 FR 58150 at 58158). However, such persons who voluntarily identify as a licensed person would be subject to corresponding State or local requirements for such licensed persons, including consumer protection requirements, to the extent that the State or local requirements do not restrict or interfere with commercial activity involving OTC hearing aids (see section 709(b)(4) of FDARA; see also the discussion in 86 FR 58150 at 58158).

Therefore, the issue is not necessarily that the consumer protections are preempted, but rather the issue is that the consumer protections are tied to the licensing requirements. Thus, to the extent that consumers purchase OTC hearing aids from non-licensed persons, they may not get the additional consumer protections they would get if they purchased the OTC hearing aid from a licensed person. However, Congress made clear that any State or local requirement for the involvement or intervention of a licensed person for consumers to access OTC hearing aids is preempted under section 709(b)(4) of FDARA. Even if certain consumer protections are not required as part of the sale of OTC hearing aids by non-licensed persons, we do not believe that consumers who purchase OTC hearing aids from non-licensed persons will be left without consumer protections. In addition to consumer protection laws administered by the Federal Trade Commission, many States have generally applicable consumer protection requirements that would not be preempted under section 709(b)(4) of FDARA, such as those that address unfair and deceptive business practices, false or misleading advertising, warranties, etc.

(Comment 123) A comment suggested that FDA preempt State requirements for hearing aids as they apply to OTC hearing aids but that such requirements

should continue to apply to prescription hearing aids. Another comment expressed concern that State hearing aid laws that are not severable could be preempted as applied to all hearing aids.

(Response) If a State requirement does not fall within section 709(b)(5) of FDARA and is preempted under section 709(b)(4) of FDARA, FDA would consider it to be preempted to the extent that it applies to OTC hearing aids. Such State requirement may continue to apply to prescription hearing aids unless the requirement is preempted under section 521 of the FD&C Act.

(Comment 124) A comment noted that there are State statutes and rules that refer to §§ 801.420 and 801.421 or incorporate the same or similar language contained in those provisions, and requested input on whether such State laws would continue to apply or whether they would be preempted by the new Federal rules. The comment also encouraged FDA to consider using the existing sections to capture the new labeling requirements or special controls because using the existing sections may be beneficial for State laws that refer to those sections.

(Response) State laws or rules that incorporate language that is the same as, or substantially identical to, the language contained in former § 801.421 may continue in effect as applied to prescription hearing aids. However, one exception is the statement that was required under § 801.421(a)(2)(iii). Specifically, § 801.421(a)(2)(iii) required that the hearing aid dispenser affords the prospective user the opportunity to sign the following statement: ''I have been advised by (Hearing aid dispenser's name) that the Food and Drug Administration has determined that my best health interest would be served if I had a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing aid. I do not wish a medical evaluation before purchasing a hearing aid.'' State or local laws or rules that require this statement would no longer be in effect because this statement was based on the waiver of the medical evaluation that was required under § 801.421, which FDA is repealing.

Because § 801.420 was issued under section 520(e) of the FD&C Act (among other authorities), and FDA is not relying on this authority for the revised labeling requirements for prescription hearing aids, FDA has decided to establish the revised labeling requirements in new § 801.422. In the labeling requirements for prescription hearing aids in § 801.422, FDA has retained in substance most of the labeling requirements that were in § 801.420 but also made some revisions. Whether State hearing aid labeling requirements that incorporate language from § 801.420 are preempted as applied to prescription hearing aids due to the new labeling requirements in § 801.422 depends on whether they are different from, or are in addition to, the new requirements. If they are equal to, or substantially identical to, the requirements in § 801.422, they would not be preempted as applied to prescription hearing aids. *See* § 808.1(d)(2). State hearing aid labeling requirements incorporating language from § 801.420 would be preempted as applied to OTC hearing aids if they are different from, in addition to, or otherwise not identical to, the OTC hearing aid labeling requirements in § 800.30. See section 709(b)(4) of FDARA.

We note that the requirements in §§ 801.420 and 801.421 were considered general controls that applied to all hearing aids regardless of the device's classification. In other words, these requirements were not special controls under section 513(a)(1)(B) of the FD&C Act. Similarly, the labeling requirements for prescription hearing aids in § 801.422 are considered general controls that apply to all prescription hearing aids regardless of the device's classification. Special controls apply to class II devices and the special controls for a class II hearing aid are specified in the particular classification for the hearing aid (*e.g.,* § 874.3305).

(Comment 125) Comments requested that FDA clarify the types of State or local requirements for an audiological or medical evaluation, prior to purchasing a prescription hearing aid, that this rule would not preempt. Many of these comments conveyed uncertainty about the effects on existing State and local requirements with the withdrawal of previous exemption decisions that allowed States and localities to establish and continue in effect requirements respecting hearing aids.

(Response) State or local requirements that were preempted solely because they differed from or were in addition to the conditions for sale requirements in § 801.421 and for which FDA previously granted exemptions from Federal preemption may continue in effect with respect to prescription hearing aids after the withdrawal of the previous exemption decisions. This is because State or local requirements are preempted under section 521(a) of the FD&C Act only when FDA has established specific counterpart regulations or there are other specific requirements applicable to a particular device that make State or local requirements applicable to the device different from, or in addition to, the specific Federal requirements (see § 808.1(d)). The repeal of § 801.421 will remove this specific counterpart regulation that currently makes State or local requirements different from, or in addition to, the specific Federal requirements therein. As such, the State requirements that were preempted solely because they differed from or were in addition to the requirements in § 801.421 and for which FDA previously granted exemptions will no longer be preempted under section 521(a) of the FD&C Act. They may therefore continue in effect for prescription hearing aids, without an exemption, so FDA is removing the exemption decisions that will become unnecessary.

As a result, if a State establishes or continues in effect a requirement that, for example, people younger than 18 must have a medical evaluation by an ear-nose-throat doctor to obtain a prescription hearing aid, then that requirement would, as a general matter, no longer be ''different from, or in addition to,'' the examination and waiver requirements in § 801.421 that we are repealing. Similarly, a State could establish or continue in effect a requirement, for example, that a licensed hearing instrument specialist refer an adult prescription hearing aid candidate for a medical examination if the specialist observes a Red Flag condition. However, a State could not establish or continue in effect such a referral requirement for OTC hearing aids, as explained elsewhere in this document.

Additionally, as explained elsewhere in this document, FDA is revising the labeling requirements in § 801.420 by, among other things, moving them to new § 801.422 and applying them to prescription hearing aids. State or local requirements with respect to prescription hearing aids that differ from, or are in addition to, the requirements in § 801.422 would be preempted under section 521(a) of the FD&C Act.

I. Repeal of Restrictions and Modifications for Prescription Labeling (§§ 801.420, 801.421, 801.422)

Many comments related to repealing the conditions for sale for hearing aids expressed concerns for maintaining the involvement of a licensed person in the adoption and use of hearing aids. One result of this rulemaking is that non-OTC air-conduction hearing aids will be prescription hearing aids, which will require the order (prescription) of a

practitioner licensed by State law, as we explain elsewhere in this document. Thus, the repeal of § 801.421 does not imply the removal of a licensed person from hearing health care with respect to prescription hearing aids.

Other comments communicated a desire for regulatory consistency and/or continuity. While FDA would agree these are legitimate interests, we generally declined to maintain the restrictions on those bases. However, we note that final § 801.422 retains many of the labeling requirements under § 801.420, and we have made the labeling requirements for prescription hearing aids consistent with that for OTC hearing aids to the extent appropriate.

(Comment 126) One comment expressed concern that with the repeal of the hearing aid restrictions, the previous preemption decisions would no longer apply. The comment stated that while many State laws that had been denied an exemption have since been repealed, some unrepealed laws that have been unenforceable would now be enforceable, including those that would restrict and/or impede the sale of hearing aids.

(Response) FDA is repealing § 801.421 which sets forth the conditions for sale of hearing aids, and revising the labeling requirements under § 801.420 by, among other things, applying them to prescription hearing aids only and moving them to new § 801.422. We assume that the comment is referring to the repeal of § 801.421 given that the labeling requirements, although revised and moved to new § 801.422, would continue to exist and apply to prescription hearing aids. FDA is repealing § 801.421 because the Agency believes these requirements are no longer necessary to provide reasonable assurance of safety and effectiveness of prescription hearing aids. FDA had been exercising enforcement discretion by generally not enforcing most of the requirements in § 801.421 since late 2016. Additionally, we note that prescription hearing aids will require a written or oral authorization from a practitioner licensed by law to administer the device (see § 801.109). This requirement, along with the revised labeling requirements for prescription hearing aids, will help provide reasonable assurance of safety and effectiveness of these devices. State or local requirements that were previously preempted under section 521 of the FD&C Act solely on the basis that they were different from, or were in addition to, the requirements in § 801.421 would no longer be preempted as applied to prescription hearing aids.

We note that State or local requirements would be preempted under section 709(b)(4) of FDARA if they: specifically related to hearing products; would restrict or interfere with the sale of, or other commercial activity involving, OTC hearing aids; are different from, in addition to, or otherwise not identical to, the OTC Hearing Aid Controls; and do not fall within section 709(b)(5) of FDARA.

(Comment 127) Several comments proposed that prescription hearing aids remain restricted devices. Many of these comments expressed concerns about the role of licensed persons in fitting and dispensing hearing aids, and a desire to ensure that prescription hearing aids would only be sold pursuant to the written authorization of a qualified hearing aid professional or, in some cases, a physician specifically. Such comments, sometimes referring to ''special controls,'' also sought to retain oversight of licensed persons.

(Response) Although FDA agrees that the selection and use of prescription hearing aids should involve a licensed person, we are not maintaining the device restrictions because the restrictions are unnecessary to ensure the involvement of a licensed person in the use of prescription hearing aids.

Under final § 800.30(b), a prescription hearing aid is one that does not meet the definition of ''over-the-counter hearing aid'' or does not meet the requirements of the OTC Hearing Aid Controls. Any hearing aid that is not OTC is a prescription device. A prescription hearing aid is subject to § 801.109 regarding prescription devices (explained in the proposal, 86 FR 58150 at 58168). Among other requirements, § 801.109 specifies that prescription devices are those to be sold only to or on the prescription or other order of a practitioner licensed by law to use or order the use of the devices in the course of professional practice (see § 801.109(a)(2)). Further, § 801.109 requires labeling indicating that the device is only for prescription use (see § 801.109(b)(1)). A prescription hearing aid that lacks this labeling would be misbranded (see final § 801.422(c)(6)). Marketing a misbranded device, for example, by introducing it into interstate commerce, and other activities with respect to misbranded devices are prohibited acts (see, *e.g.,* 21 U.S.C. 331(a)–(c), 331(k)).

FDA notes that, in some circumstances, requirements on prescription hearing aids once this rule is in effect may be more stringent than under former § 801.421 which allowed a prospective hearing aid user 18 or older to waive the requirement for a medical evaluation (former § 801.421(a)(2)). Further, as we explained in the proposal, FDA had expressed that we do not intend to enforce the medical evaluation, waiver, or recordkeeping requirements with respect to prospective purchasers who are 18 or older (see 86 FR 58150 at 58154). However, once this rule repeals those restrictions, any hearing aid that meets the definition of a prescription hearing aid will be subject to requirements for prescription devices, such as those in § 801.109(a)(2). That is, such devices may be sold only to or on the prescription or other order of a licensed practitioner. We also note that States, not FDA, generally determine the licensing requirements for practitioners to use or order the use of a prescription device. Thus, States may, for example, require that prescription hearing aids be ordered by physicians (medical doctors) or audiologists, which may involve a medical or audiological evaluation of the prospective user, including someone who is 18 or older. (See also the response to Comment 128.)

(Comment 128) A few comments suggested that FDA apply device restrictions to OTC hearing aids. A comment suggested that FDA make both OTC and prescription hearing aids restricted devices. The comment argued this would ensure regulatory consistency between categories as well as supporting complementary State and local consumer protections.

(Response) FDA is declining to take these suggestions. We are not making OTC hearing aids restricted devices under section 520(e) of the FD&C Act, and we are repealing the existing restrictions on hearing aids. For OTC and prescription hearing aids, at this time we believe the authorities that we are relying on, including those described in section IV of this document, are adequate. Because we are not relying on our restricted device authority at this time, neither OTC hearing aids nor prescription hearing aids would be restricted devices under section 520(e) of the FD&C Act. Therefore, there would be regulatory consistency between these categories in this respect.

Further, to the extent the comment is requesting that FDA maintain the restrictions in § 801.421, the restrictions that we are repealing do not in themselves enable or support complementary State and local consumer protections. Indeed, many of the State requirements for hearing aids for which FDA had granted exemptions from Federal preemption were

preempted because of the restrictions (they were different from, or were in addition to, the restrictions), and the State requirements continued in effect because the States applied for, and FDA granted, exemptions. Absent the restrictions, those State requirements, many of which related to patient or consumer protection, likely would not have been preempted (all else being equal) and could have continued in effect without FDA acting to exempt them.

Moreover, section 709(b)(4) of FDARA would continue to apply to OTC hearing aids and, as described elsewhere, would still preempt certain State and local requirements pertaining to a wide range of commercial activity involving OTC hearing aids, regardless of whether or not OTC hearing aids are restricted devices. Additionally, FDA would not expect that making OTC hearing aids restricted devices would augment State and local consumer protections that would continue in effect. (See also the response to Comment 127.)

(Comment 129) Some comments proposed that prescription hearing aids remain restricted devices to ensure that FDA retain the added regulatory authority over advertising material for restricted devices. These comments asserted that advertising has falsely or misleadingly suggested that products were hearing aids, inducing people to use products that were not safe or effective options to address or compensate for hearing loss. The use of unsafe or ineffective products, instead of hearing aids, has an increased risk of impairing the user's remaining hearing or convincing users not to seek safer, more effective options.

(Response) FDA is not accepting this proposal because as explained in the response above, at this time we believe the authorities that we are relying on, including those described in section IV of this document, are adequate.

Additionally, restricted device authority is not necessary for FDA regulation of products that are marketed as hearing aids but do not comply with applicable requirements. The intended use of an article (not just restricted devices) may be shown by, among other indicia, the circumstances surrounding distribution as well as advertising matter (see § 801.4). Should such circumstances or advertising show that the article is intended to compensate for hearing loss, then it would be subject to labeling and other requirements for hearing aids. Failure to meet these requirements would render the article adulterated and/or misbranded (see 21 U.S.C. 351 and 352). Marketing (for example, by introducing such articles into interstate commerce) and other activities with respect to such articles would constitute prohibited acts even though prescription hearing aids would not be restricted devices (see, *e.g.,* 21 U.S.C. 331(a)–(c), 331(k)).

(Additional Revision 5) FDA has identified additional revisions that would provide for clarity and consistency upon the removal of § 801.420 and the repeal of § 801.421. We proposed to amend § 874.3950 (21 CFR 874.3950), the classification regulation for transcutaneous air-conduction hearing aid systems, by specifying that the devices would be subject to new § 801.422. This would clarify that the devices are prescription hearing aids and subject to corresponding labeling requirements.

However, the regulation currently specifies that transcutaneous air-conduction hearing aid systems are subject to special controls described by the document, ''Class II Special Controls Guidance Document: Transcutaneous Air Conduction Hearing Aid System (TACHAS); Guidance for Industry and FDA,'' issued on November 7, 2002 (see § 874.3950(b)).[16] That document in turn currently refers to §§ 801.420 and 801.421. Further, in reviewing the document for consistency with this rulemaking, we observed that its Scope section refers incorrectly to § 874.3340, which is not the correct citation for the classification regulation for transcutaneous air-conduction hearing aid systems.

For clarity and consistency, in addition to the amendment that we proposed to § 874.3950(a), we are revising the special controls document by replacing references to §§ 801.420 and 801.421 with § 801.422 for both. We also are correcting the reference to the incorrect classification regulation to the correct one, which is § 874.3950. To indicate these revisions, we are adding a statement to the special controls document that we revised the document. We will publish the special controls document with the revisions on or around the effective date of this final rule. However, we are not revising the substance of the special controls document, and as such, we are not updating the date on which the document was issued. The revisions to the special controls document will appear on FDA's website.

[16] The document is available online at: *https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/transcutaneous-air-conduction-hearing-aid-system-tachas-class-ii-special-controls-guidance-document.*

J. Other Amendments

(Comment 130) One comment suggested that FDA include a misbranding provision for OTC hearing aids with respect to labeling, similar to the provision included for prescription hearing aids (final § 801.422(c)(6)).

(Response) FDA declines to include a similar misbranding provision for OTC hearing aids under § 800.30. As provided in §§ 800.30(a) and (b) and 801.422(a) and (b), any hearing aid that does not satisfy the requirements of § 800.30, including the labeling requirements of that section, is a prescription hearing aid, and as such, must meet the requirements of §§ 801.422 and 801.109. In other words, a hearing aid that fails to meet the labeling requirements of § 800.30 would be subject to §§ 801.422 and 801.109. In turn, failure to meet the labeling requirements of §§ 801.422(c) and 801.109 would render the product misbranded, as stated in final § 801.422(c)(6). In other words, hearing aids that fail to comply with the requirements in § 800.30 would be prescription hearing aids and would be misbranded if they fail to comply with §§ 801.422 and 801.109. For example, such a hearing aid would be misbranded under section 502(f)(1) of the FD&C Act in that its labeling would fail to bear adequate directions for use and it would not be exempt from this requirement.

(Comment 131) A comment proposed that FDA develop a national standard to sell prescription hearing aids via telemedicine visits with licensed persons to people who are 18 years of age or older. The comment suggested that the standard could include calibrated in-home tests for both air-conduction and bone-conduction devices.

(Response) Although FDA establishes performance standards for devices, among other general and special controls, in appropriate circumstances, FDA does not generally establish standards for medical practice, including telemedicine. However, we note that in-home hearing tests may meet the definition of ''device'' and be subject to the provisions of, and regulatory controls under, the FD&C Act, including those described in section IV of this document. Classification of a hearing test would establish the controls necessary to provide reasonable assurance of safety and effectiveness of the device for its intended use(s), and these would apply to the devices nationally. (See also section X describing the implications of federalism.)

(Additional Revision 6) FDA has decided not to realign the classification regulations by sound conduction mode as proposed. Combining the existing regulations may have suggested to stakeholders that only a single device type was appropriate for OTC availability or vice versa. However, as explained elsewhere, for example, in the response to Comment 2, that is not the case. To reduce the potential for this kind of confusion, we are keeping the various air-conduction generic types in their existing regulations. However, we are proceeding to separate bone-conduction hearing aids into their own classification regulation, new § 874.3302, including the reassignment of product codes. We are also proceeding with the other proposed minor revisions to the air-conduction classification regulations, including the revisions to the special controls as provided in proposed § 874.3305(b) and clarifying the applicability of requirements under either final § 800.30 or § 801.422 for the various generic types.

VI. Effective and Compliance Dates

(Comment 132) FDA received several comments proposing that the compliance date be the same for hearing aids that have and have not been offered for sale prior to the effective date of this final rule. These comments provided various reasons, including that: new entrants into the hearing aid market need time to make pre-launch adjustments to their marketing and devices they plan to introduce and need more than the 60 days proposed; that FDA takes longer than 60 days to review 510(k)s; and that different compliance dates for different manufacturers would be unfair. Most such comments proposed a compliance date of 240 days after the publication of this final rule.

(Response) FDA is not establishing the same compliance dates because hearing aids that are not offered for sale, that is, not on the market, are not similarly situated as hearing aids offered for sale, that is, on the market, prior to the effective date. The compliance date is not the date by which new entrants must start marketing, and if new entrants find they need additional time prior to marketing their devices, they may take it. Moreover, should a new entrant need to obtain 510(k) clearance, it could not market the device until it obtains clearance, regardless of the compliance date.

We acknowledge that hearing aids on the market will have a different timeframe for compliance. However, the consequences of noncompliance with the new requirements are different for hearing aids that are on the market from those not on the market when this rule takes effect. For hearing aids that are on the market, they are subject to enforcement actions if they do not comply with the new requirements as well as other applicable requirements. Given this, they need sufficient time to come into compliance. Hearing aids that are not on the market do not face these consequences—as discussed above, if such hearing aids do not comply with the new requirements and other applicable requirements, manufacturers may take whatever time they need to bring the devices into compliance. As such, the same compliance timeframe is not appropriate in this case. See the response to Comment 133 about considerations for 510(k)s for marketed devices.

(Comment 133) Some comments regarding marketed devices also raised concerns that FDA may take too long to review 510(k)s, and devices could be out of compliance even if a manufacturer submitted a 510(k) soon after the publication of this final rule. They sought clarification and/or a change in the compliance date.

(Response) In consideration of the comments, for hearing aids legally offered for sale prior to the effective date, FDA intends not to enforce the requirement for a 510(k) in certain situations, as discussed in the compliance date section below.

(Comment 134) Some comments questioned how soon hearing aids could be made available OTC, including whether manufacturers would need to wait 60 days (until the effective date).

(Response) Generally, hearing aids could not be available OTC within the meaning of section 520(q)(1)(A)(v) of the FD&C Act until the effective date of this final rule.

A. Effective Date

This final rule will be effective 60 days after the publication in the **Federal Register**. We are finalizing the following compliance dates:

B. Compliance Date for Hearing Aids Not Legally Offered for Sale Prior to the Effective Date

For hearing aids that have not been offered for sale prior to the effective date of the final rule, or have been offered for sale but are required to submit a new 510(k) under § 807.81(a)(3) due to changes unrelated to this rule (an example of such is the addition of self-fitting technology to a wireless air-conduction hearing aid), compliance with the new or revised requirements applicable to the hearing aid, and obtaining 510(k) clearance if applicable, must be achieved before marketing the device on or after the effective date of this final rule. If a person (*e.g.,* manufacturer) markets such a device without complying with the new or revised requirements or if applicable, obtaining 510(k) clearance, then FDA would consider taking action against such person under our usual enforcement policies.

C. Compliance Date for Hearing Aids Legally Offered for Sale Prior to the Effective Date

For hearing aids that have been legally offered for sale prior to the effective date of the final rule, including those that already have a 510(k) clearance, compliance with the new or revised requirements that apply to the hearing aid must be achieved 180 days after the effective date of the final rule (*i.e.,* 240 days after the publication of the final rule). After that date, if a person (*e.g.,* manufacturer) continues to market such a device but does not comply with the new or revised requirements that apply to the device, then FDA would consider taking action against such person under our usual enforcement policies.

However, FDA does not intend to enforce the requirement to submit a 510(k) and obtain 510(k) clearance where a hearing aid is legally offered for sale prior to the effective date; the changes that require a new 510(k) are made on or before the compliance date and are made solely to satisfy the OTC Hearing Aid Controls; the changes do not adversely affect device safety or effectiveness; the device is otherwise in compliance with applicable requirements; and on or before the compliance date, the manufacturer documents the changes and its determination that the changes do not adversely affect device safety or effectiveness.

At present, legacy and wireless air-conduction hearing aids are exempt from section 510(k) (21 U.S.C. 360(k)) of the FD&C Act, subject to the limitations of exemption described in § 874.9. (Legacy hearing aids are class I devices and are 510(k) exempt under section 510(*l*)(1) of the FD&C Act.) See the response to Comment 5 for more about considerations for when to submit a 510(k).

VII. Economic Analysis of Impacts

We have examined the impacts of this final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us to assess all

costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). This rule is an economically significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the estimated annualized cost over 10 years is $0.009 million per firm, which is unlikely to represent more than three percent to five percent of the revenue of an affected manufacturer, we certify that this final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $165 million, using the most current (2021) Implicit Price Deflator for the Gross Domestic Product. This final rule will result in an expenditure in at least one year that meets or exceeds this amount.

This rule defines a new regulatory category for OTC hearing aids and makes corresponding changes to the existing regulatory framework, including defining hearing aids not meeting the OTC requirements as prescription medical devices, as well as providing new labeling requirements for both OTC and prescription hearing aids. This rule would generate potential cost savings for consumers with perceived mild to moderate hearing impairment who wish to buy lower cost hearing aids not bundled with professional services and not requiring professional advice, fitting, adjustment, or maintenance but who are currently unable to buy such products online because of State regulations or because they do not shop online. This rules also generates costs for hearing aid manufacturers for changing labeling of existing hearing aids as well as for reading the rule and revising internal standard operating procedures in response to the rule. Table 1 summarizes our estimate of the annualized costs and the annualized benefits of this final rule.

TABLE 1—SUMMARY OF BENEFITS, COSTS AND DISTRIBUTIONAL EFFECTS OF FINAL RULE

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered (years)	
Benefits:							
Annualized Monetized $millions/year	$63 63	$6 6	$147 147	2020 2020	7 3	10 10	
Annualized Quantified	.....	.....	.....	.....	7 3	.....	
Qualitative	Potential increase in hearing aid and hearing technology use, leading to associated health benefits, potential fostering of innovation in hearing aid technology. Potential increase in consumer utility, derived from reduced health risks, from inability to buy some existing hearing aids under existing conditions.			.....	.....	.....	
Costs:							
Annualized Monetized $millions/year	1 1	1 1	2 2	2020 2020	7 3	10 10	
Annualized Quantified	.....	.....	.....	.....	7 3	.....	
Qualitative	Potential loss of consumer utility from inability to buy existing hearing aids under existing conditions, including consumers of online hearing aids that do not meet OTC requirements. Costs to manufacturers of hearing aids sold online that do not meet OTC requirements to render their products and sales methods consistent with the requirements of either OTC or prescription hearing aids.			.....	.....	.....	
Transfers:							
Federal Annualized Monetized $millions/year	.....	.....	.....	.....	7 3	.....	
From/To	From:			To:			
Other Annualized Monetized $millions/year	.....	.....	.....	.....	7 3	.....	
From/To	From:			To:			
Effects:							
State, Local or Tribal Government:							
Small Business:							

TABLE 1—SUMMARY OF BENEFITS, COSTS AND DISTRIBUTIONAL EFFECTS OF FINAL RULE—Continued

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered (years)	
Wages:							
Growth:							
Distributional effects are also possible that would favor general retailers and new manufacturers entering into the hearing aid market who do not have relations with current specialty retail suppliers and disfavor specialty retail suppliers and associated workers including hearing healthcare professionals, and established manufacturers with relations with those suppliers.							

We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of this rule. The full analysis of economic impacts is available in the docket for this rule (Ref. 16) and at *https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations.*

VIII. Analysis of Environmental Impact

FDA has carefully considered the potential environmental impact of this final rule and of possible alternative actions. In doing so, the Agency focused on the environmental impacts of its action as a result of increased use and eventual disposal of OTC hearing aids that will need to be handled after the effective date of this final rule.

The environmental assessment (EA) considers environmental impacts related to additional waste to landfills at municipal solid waste (MSW) facilities. The selected action will likely increase the availability and use of hearing aid devices, which would result in additional waste from increased disposal of these devices and their associated batteries, as well as an increase in industrial waste associated with any domestic production to meet market demand for the new devices. Overall, given the current limited use of these devices, projected slow growth with increase in availability, and the small mass of waste material to be disposed or recycled, the selected action is not expected to have a significant impact on MSW, landfill facilities, and the environment.

The Agency has concluded that the final rule will not have a significant impact on the human environment, and that an environmental impact statement is not required. FDA's FONSI and the evidence supporting that finding, contained in an EA prepared under 21 CFR 25.40, are on display with the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.*

IX. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by OMB under the PRA (44 U.S.C. 3501–3521). The title, description, and respondent description of the information collection provisions are shown in the following paragraphs with an estimate of the annual reporting, recordkeeping, and third-party disclosure burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Medical Device Labeling Regulations; OMB Control Number 0910–0485—Revision.

Description: FDA is establishing a regulatory category for OTC hearing aids and making related amendments to update the regulatory framework for hearing aids. Among other amendments described in this rulemaking, we amend the existing labeling requirements for hearing aids. In creating a regulatory category for OTC hearing aids and amending existing rules, we intend to provide reasonable assurance of safety and effectiveness for hearing aids as well as foster access to, and innovation in, hearing aid technology, thereby protecting and promoting the public health.

Description of Respondents: Respondents to the information collection are manufacturers of hearing aids.

We estimate the burden of the collection of information as follows:

TABLE 2—ESTIMATED ONE-TIME BURDEN [1] [2]

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours	Total capital costs
Understanding and implementing new regulatory requirements from hearing aids rule	105	1	105	290	30,450	$4,100,000
Hearing aids relabeling	105	8	840	68	57,120	6,000,000

[1] There are no operating and maintenance costs associated with this collection of information.
[2] Numbers have been rounded to the nearest whole number.

TABLE 3—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1] [2]

Activity; 21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Labeling disclosures under 800.30(c)(2) and 801.422(c)(2); Hearing aids; electronic version of user instructional brochure	105	8	840	1	840

[1] There are no operating and maintenance costs associated with this collection of information.
[2] Numbers have been rounded to the nearest whole number.

TABLE 4—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1] [2]

Activity; 21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
OTC Hearing Aid Controls—800.30	105	7	735	19	13,965
Prescription Hearing Aid Labeling—801.422	105	1	105	19	1,995
Total					15,960

[1] There are no operating and maintenance costs associated with this collection of information.
[2] Numbers have been rounded to the nearest whole number.

Our burden estimate is based on FDA Uniform Registration and Listing System data; FDA's Operational and Administrative System for Import Support data; informal communications with industry; and our knowledge of and experience with information collection pertaining to medical device labeling. We intend the burden estimates to be consistent with our Final Regulatory Impact Analysis (FRIA) for this rulemaking (Ref. 16).

Estimated One-Time Burden: Understanding and implementing new regulatory requirements from hearing aids rule—one-time burden (Recordkeeping): As noted in the FRIA for this rulemaking, we estimate it will take 5 hours each for an executive, a lawyer, and a marketing manager to read and understand the rule. Also included in our estimate is time for revising guidelines or standard operating procedures. We assume this may take up to 25 hours for one executive, up to 100 hours for one marketing manager, and up to 150 hours for one technical writer. Therefore, we estimate a one-time recordkeeping burden of 290 hours for each manufacturer.

Hearing aids relabeling—one-time burden (Third-Party Disclosure): The rulemaking necessitates the relabeling of all current hearing aids (approximately 840). The labeling cost model used in the FRIA suggests, based on a compliance date 240 days after publication of the final rule, a one-time estimated third-party disclosure burden for relabeling of about 68 hours per product.

Estimated Annual Burden: Over-the-Counter Hearing Aid Controls—§ 800.30 (Recordkeeping and Third-Party Disclosure): Section 800.30 sets forth labeling requirements for OTC hearing aids. Section 800.30(c)(1) describes the warnings and other important information that the outside package must bear. Manufacturers must include on the outside package label: certain specified warnings and statements; a weblink to all labeling and any additional resources; contact information to request a paper copy of the labeling; their return policy or absence thereof; if the OTC hearing aid is used or rebuilt, they must declare that fact; the principal display panel must bear the marks ''OTC'' and ''hearing aid''; battery information; and control platform information if applicable.

Section 800.30(c)(2) describes device-specific requirements for labeling, inside the package. Among the labeling requirements listed are a user instructional brochure, an electronic version of which is to be made available for download; additional warnings; caution and notices for users; other specified information; and any other information necessary for adequate directions for use as defined in § 801.5. Also required under proposed § 800.30(c)(2) is the identification of any known physiological side effects associated with the use of the OTC hearing aid that may warrant consultation with a physician; the technical specifications required by § 800.30(c)(4); a description of commonly occurring, avoidable events that could adversely affect or damage the OTC hearing aid; if applicable, information relating to electromagnetic compatibility and wireless technology and human exposure to non-ionizing radiation; information regarding repair service or replacements; and, if applicable, a summary of all clinical or non-clinical studies conducted to support the performance of the OTC hearing aid.

Section 800.30(c)(3) provides requirements for the labeling on an OTC hearing aid itself, specifically, serial number, information regarding the battery and, if the OTC hearing aid is used or rebuilt, the manufacturer must physically attach a removable tag to the hearing aid declaring that fact.

Section 800.30(c)(5) provides requirements related to software device labeling.

We include no estimate for provisions under proposed § 800.30(c)(1)(i)(A) through (D), (c)(2)(i)(A) through (C), and (c)(2)(iii)(A) through (F) because we consider the labeling to be ''public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public,'' consistent with 5 CFR 1320.3(c)(2). Thus, those labeling provisions are not within the definition of collection of information.

The FRIA for this rulemaking estimates that 105 firms manufacture air-conduction hearing aids sold in the United States, based on FDA Medical Device Registration data. We estimate that each manufacturer has an average of eight products that would need relabeling.

For each hearing aid product, we assume a 1-hour annual recordkeeping burden for maintaining the electronic version of the user instructional brochure (under §§ 800.30(c)(2) and 801.422(c)(2)).

The rulemaking would necessitate the relabeling of all current hearing aids (approximately 840) according to either the OTC or prescription hearing aid labeling requirements. While we lack specific data regarding what portion of hearing aids will be relabeled as prescription devices and what portion will be relabeled as OTC hearing aids, for this analysis, we assume that 10 percent will be relabeled as prescription medical devices (about 1 product per manufacturer) and 90 percent as OTC hearing aids (about 7 products per manufacturer). The labeling cost model used in the FRIA suggests an annual estimated third-party disclosure burden of about 19 hours per product.

Prescription Hearing Aid Labeling—§ 801.422 (Third-Party Disclosure): Section 801.422(c) sets forth labeling requirements for prescription hearing aids. However, as with some of the provisions under proposed § 800.30(c), we include no estimate for provisions under § 801.422(c)(1)(i)(A) through (C), (c)(2)(i)(A) through (C), and (c)(2)(ii)(A) through (F) because we consider the labeling to be ''public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public,'' consistent with 5 CFR 1320.3(c)(2).

Section 801.422(c)(1) provides the warnings and notice that must be on the

outside package labeling; if applicable, that the prescription hearing aid is used or rebuilt; battery information; and if applicable, control platform information.

Section 801.422(c)(2) describes requirements for prescription hearing aid labeling, inside the package. Among the labeling requirements listed are a user instructional brochure, an electronic version of which is to be made available for download; warnings; caution and notices for users; and additional information that must be included in the user instructional brochure.

Section 801.422(c)(3) provides the requirements for the labeling on a prescription hearing aid itself, specifically, serial number; information regarding the battery if applicable; and if the prescription hearing aid is used or rebuilt, the manufacturer must physically attach a removable tag to the hearing aid declaring that fact.

Section 801.422(c)(4) provides the technical specification elements that must appear in the user instructional brochure or in separate labeling that accompanies the device.

Section 801.422(c)(5) provides requirements related to software device labeling.

The FRIA estimates that 105 firms manufacture air-conduction hearing aids sold in the United States, based on FDA Medical Device Registration data. We estimate that each manufacturer has an average of eight products that would need relabeling.

For each hearing aid product, we assume a 1-hour annual recordkeeping burden for maintaining the electronic version of the user instructional brochure (under §§ 800.30(c)(2) and 801.422(c)(2)).

The rulemaking would necessitate the relabeling of all current hearing aids (approximately 840) according to either the OTC or prescription hearing aid labeling requirements. While we lack specific data regarding what portion of hearing aids will be relabeled as prescription devices and what portion will be relabeled as OTC hearing aids, for this analysis, we assume that 10 percent will be relabeled as prescription medical devices (about 1 product per manufacturer) and 90 percent as OTC hearing aids (about 7 products per manufacturer). The labeling cost model used in the FRIA suggests an annual estimated third-party disclosure burden of about 19 hours per product.

As required by section 3506(c)(2)(B) of the PRA, FDA provided an opportunity for public comment on the information collection requirements of the proposed rule.

We received more than 1,000 comments on the proposed rule. We describe and respond to the comments in section V of this document, ''Comments on the Proposed Rule and FDA's Responses.'' Comments and responses related to the provisions that underlie the information collection are described in the following sections: III.B, regarding scope; III.D, regarding labeling; and III.F, regarding other device requirements. We have not made changes to the estimated burden as a result of those comments.

We also received a comment relating to the information collection burden estimate. The comment expressed concern that, for a small business, the ''cost for building a system from scratch'' and for reading and understanding the rule, without a lawyer or a marketing manager, is overly burdensome.

Included in our estimate of 290 hours for ''Understanding and implementing new regulatory requirements from hearing aids rule,'' is an average of 5 hours each for an executive, a lawyer, and a marketing manager to read and understand the rule. Therefore, we estimate 15 hours for reading and understanding the rule. We assume that a manufacturer who does not employ a lawyer or marketing manager, would take approximately the same amount of time to read and understand the rule. This is consistent with the comment's statement that it took ''at least 8 hours to read through and understand this rule.''

While it is not clear what is meant by ''building a system from scratch'' in this context, included in our estimate is time for revising guidelines or standard operating procedures. We assume this may take up to 25 hours for one executive, up to 100 hours for one marketing manager, and up to 150 hours for one technical writer; a total of 275 hours for revising guidelines or standard operating procedures. Our estimate assumes that, as a standard business practice and in compliance with the existing requirements, a company has guidelines or standard operating procedures in place and that the burden estimate represents only the time to revise existing documentation to be consistent with the rulemaking. We believe this estimate reflects an appropriate amount of time for understanding and implementing the new regulatory requirements.

Additionally, the comment expressed concern about the time to write ''the user instructional brochure from scratch.''

We have included a 68-hour, one-time burden estimate for the relabeling necessitated by the rulemaking. This estimate includes, among other things, time for updating the user instructional brochure and providing the required content online. Our recordkeeping burden estimate of 1 hour for ''Labeling disclosures under §§ 800.30(c)(2) and 801.422(c)(2); Hearing aids; electronic version of user instructional brochure'' is an annual estimate, intended to reflect the maintenance of records associated with the requirement in §§ 800.30(c)(2) and 801.422(c)(2) to make an electronic version of a user instructional brochure available for download.

We have not revised our burden estimate based on this comment.

The information collection provisions in this final rule have been submitted to OMB for review as required by section 3507(d) of the Paperwork Reduction Act of 1995.

Before the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. 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.

X. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive order requires Agencies to ''construe . . . a Federal statute to preempt State law only where the statute contains an express preemption provision or where there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.'' Federal law includes an express preemption provision that preempts certain State requirements ''different from, or in addition to, any requirement applicable under'' the FD&C Act that is applicable to devices. (See section 521 of the FD&C Act; *Medtronic* v. *Lohr,* 518 U.S. 470 (1996); and *Riegel* v. *Medtronic,* 552 U.S. 312 (2008).) Federal law also preempts State or local laws ''specifically related to hearing products that would restrict or interfere with the servicing, marketing, sale, dispensing, use, customer support, or distribution of [OTC hearing aids] through in-person transactions, by mail, or online, that [are] different from, in addition to, or otherwise not identical to, the regulations promulgated under'' section

709(b) of FDARA (see section 709(b)(4) of FDARA).

Section 521(b) of the FD&C Act provides that the Commissioner of Food and Drugs may, upon application of a State or local government, exempt a requirement from preemption, if the State or local requirement for the device is more stringent than the requirement under the FD&C Act, or if the requirement is necessitated by compelling local conditions and compliance with it would not cause the device to be in violation of a requirement under the FD&C Act. Following this process, a State or local government may request an exemption from preemption for those State or local requirements pertaining to hearing aid products that are preempted by the Agency's final rule under section 521 of the FD&C Act. However, because FDARA does not provide a parallel mechanism to exempt State or local requirements from its express preemption provision, FDA is not considering exemptions under section 709(b)(4) of FDARA for OTC hearing aids.

Thus, this final rule will create requirements that fall within the scope of section 521 of the FD&C Act and/or section 709(b)(4) of FDARA. It also amends § 801.420 and repeals § 801.421, and such changes affect many of the decisions on applications for exemption from preemption that were issued in relation to these two regulations under section 521(b) of the FD&C Act, resulting in the removal of the regulations codifying such decisions, as discussed further in section V.I. above. The scope of preemption of this final rule is discussed in more detail in sections III.G through I, above.

XI. Consultation and Coordination With Indian Tribal Governments

We have analyzed this rule in accordance with the principles set forth in Executive Order 13175. We have determined that the rule does not contain policies that would have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Accordingly, we conclude that the rule does not contain policies that have tribal implications as defined in the Executive order and, consequently, a tribal summary impact statement is not required.

XII. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only with the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

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4. Maharani, A., P. Dawes, et al., ''Longitudinal Relationship Between Hearing Aid Use and Cognitive Function in Older Americans.'' *Journal of the American Geriatrics Society,* 66(6):1130–1136, 2018.
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7. NASEM, ''Hearing Health Care for Adults: Priorities for Improving Access and Affordability.'' Board on Health Sciences Policy, Committee on Accessible and Affordable Hearing Health Care for Adults; Blazer, D.G., S. Domnitz, and C.T. Liverman, Eds., 2016. DOI: 10.17226/23446. Available at: *https://www.nap.edu/catalog/23446/hearing-health-care-for-adults-priorities-for-improving-access-and.*
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10. Johnson, E.E., ''Safety Limit Warning Levels for the Avoidance of Excessive Sound Amplification to Protect Against Further Hearing Loss.'' *International Journal of Audiology,* 56(11):829–836, 2017.
11. Tedeschi, T., C. Jones, and E. Stewart. ''Real World Evidence on Gain and Output Settings for Individuals with Mild-to-Moderate Hearing Loss.'' *Hearing Review,* 27(7):9–11, 2020.
12. Ahmad, I., W.C. Lee, and J.D. Binnington. ''External Auditory Canal Measurements: Localization of the Isthmus.'' *Otorhinolaryngologia Nova,* 10:183–186, 2000.
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14. NASEM, ''Over-The-Counter Hearing Devices Discussion: Safety and Quality Requirements and Considerations Session.'' MP3, 1:15:39 (English). *National Academies' Hearing Health Care Report: June 2017 Dissemination Meeting;* Washington, DC, 2017.
*15. FDA, ''Streamlining Good Manufacturing Practices (GMPs) for Hearing Aids,'' public workshop. Silver Spring, MD; April 21, 2016. Available at: *https://wayback.archive-it.org/7993/20171114234227/https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm480336.htm.*
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List of Subjects

21 CFR Part 800

Administrative practice and procedure, Medical devices, Ophthalmic goods and services, Packaging and containers, Reporting and recordkeeping requirements.

21 CFR Part 801

Labeling, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 808

Intergovernmental relations, Medical devices.

21 CFR Part 874

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 800, 801, 808, and 874 are amended as follows:

PART 800—GENERAL

■ 1. The authority citation for part 800 is revised to read as follows:

Authority: 21 U.S.C. 321, 334, 351, 352, 355, 360e, 360i, 360j, 360k, 361, 362, 371.

Section 800.30 also issued under Sec. 709, Pub. L. 115–52, 131 Stat. 1065–67.

■ 2. Add § 800.30 to subpart B to read as follows:

§ 800.30 Over-the-counter hearing aid controls.

(a) *Scope.* This section specifies the requirements for over-the-counter (OTC) air-conduction hearing aids. Air-conduction hearing aids that satisfy the requirements in paragraphs (c) through (f) of this section are considered ''available'' over the counter as section 520(q)(1)(A)(v) of the Federal Food, Drug, and Cosmetic Act uses the term. Air-conduction hearing aids that do not meet the definition in section 520(q) of the Federal Food, Drug, and Cosmetic Act or do not satisfy the following requirements are prescription hearing aids. Unless otherwise specified, the requirements in this section are in addition to other applicable requirements, including but not limited to special controls found in the applicable classification regulation in part 874 of this chapter.

(b) *Definitions for the purposes of this section.* This section uses the following definitions:

Air-conduction hearing aid. An air-conduction hearing aid is a hearing aid that conducts sound to the ear through the air.

Hearing aid. A hearing aid is any wearable device designed for, offered for the purpose of, or represented as aiding persons with or compensating for, impaired hearing.

Licensed person. A licensed person is a person as defined in section 201(e) of the Federal Food, Drug, and Cosmetic Act that holds a license or degree for the diagnosis, assessment, or treatment of hearing loss; or that holds a license to sell or distribute hearing aids. A person that must meet generally applicable licensing or operating requirements such as annual health and safety inspections, provided the generally applicable licensing or operating requirement is consistent with this section and other applicable requirements under the Federal Food, Drug, and Cosmetic Act, is not a ''licensed person'' solely for that reason. A person that represents as a marketer, seller, dispenser, distributor, or customer support representative (or an equivalent description) is not a ''licensed person'' solely by making such representations.

Over-the-counter hearing aid. An over-the-counter (OTC) hearing aid is an air-conduction hearing aid that does not require implantation or other surgical intervention, and is intended for use by a person age 18 or older to compensate for perceived mild to moderate hearing impairment. The device, through tools, tests, or software, allows the user to control the hearing aid and customize it to the user's hearing needs. The device may use wireless technology or may include tests for self-assessment of hearing loss. The device is available over-the-counter, without the supervision, prescription, or other order, involvement, or intervention of a licensed person, to consumers through in-person transactions, by mail, or online, provided that the device satisfies the requirements in this section.

Prescription hearing aid. A prescription hearing aid is a hearing aid that is not an OTC hearing aid as defined in this section or a hearing aid that does not satisfy the requirements in this section.

Rebuilt hearing aid. An OTC hearing aid is ''rebuilt'' if the manufacturer has inspected and tested the device, made any necessary modifications to ensure it meets applicable regulatory requirements, including the requirements in this section to be available OTC, and adequately reprocessed the device for the next user.

Sale. Sale includes a lease, rental, or any other purchase or exchange for value.

Tools, tests, or software. Tools, tests, or software are components of the device that, individually or in combination, allow a lay user to control the device and customize it sufficiently, such as the device's output, to meet the user's hearing needs.

Used hearing aid. A hearing aid is ''used'' if a user has worn it for any period of time. However, a hearing aid shall not be ''used'' merely because a prospective user wore it as part of a bona fide hearing aid evaluation to determine whether to select that particular hearing aid for that prospective user. A hearing aid evaluation is ''bona fide'' if it was conducted in the presence of the dispenser or a hearing health professional selected by the dispenser to assist the prospective user in making a determination.

(c) *Labeling.* An OTC hearing aid shall bear all of the following in the labeling:

(1) *Outside package labeling.* The outside package of an OTC hearing aid shall bear all of the following:

(i) *Warnings and other important information.* All of the following shall appear on the outside package:

(A) (A) *Warning against use in people younger than 18.*

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WARNING: If you are younger than 18, do not use this.

You should go to a doctor, preferably an ear-nose-throat doctor (an ENT), because your condition needs specialized care. Over-the-counter hearing aids are only for users who are age 18 or older.

(B) Symptoms suggesting perceived mild to moderate hearing loss.

This hearing aid is for adults with signs of mild to moderate hearing loss. How do you know if you have this?

- You have trouble hearing speech in noisy places
- You find it hard to follow speech in groups
- You have trouble hearing on the phone
- Listening makes you tired
- You need to turn up the volume on the TV or radio, and other people complain it's too loud

(*C) Advice of availability of professional services.*

Some people with hearing loss may need help from a hearing healthcare professional. How do you know if you need to see one?

- You can't hear speech even if the room is quiet
- You don't hear loud sounds well, for example, you don't hear loud music, power tools, engines, or other very noisy things

If your hearing loss makes it hard to hear loud noises, this hearing aid may not be your best choice without help from a professional. If this hearing aid does not help you enough, ask for help from a hearing healthcare professional.

(D) ''*Red flag*'' *conditions.*

WARNING: When to See a Doctor

If you have any of the problems listed below, please see a doctor, preferably an ear-nose-throat doctor (an ENT).

- Your ear has a birth defect or an unusual shape. Your ear was injured or deformed in an accident.
- You saw blood, pus, or fluid coming out of your ear in the past 6 months
- Your ear feels painful or uncomfortable
- You have a lot of ear wax, or you think something could be in your ear
- You get really dizzy or have a feeling of spinning or swaying (called vertigo)
- Your hearing changed suddenly in the past 6 months
- Your hearing changes: it gets worse then gets better again
- You have worse hearing in one ear
- You hear ringing or buzzing in only one ear

(E) *Notice of contact information.*

This information and other labeling, including the user instructional brochure, are available on the internet at: [weblink to all labeling and any additional resources]

You may also call [telephone number] or write to [email address] or [postal address] to request a paper copy of this information and other labeling.

(F) *Notice of manufacturer's return policy.*

Manufacturer's return policy: [succinct, accurate statement of return policy or absence of return policy]

(ii) *Statement of build condition.* If the OTC hearing aid is used or rebuilt, the outside package shall declare that fact. A sticker under and visible through the outer wrapper will suffice to declare such fact.

(iii) *Statement of OTC availability.* The principal display panel shall bear the marks ''OTC'' and ''hearing aid'' with the same prominence required under § 801.61(c) of this chapter for the device's statement of identity. The device's common name on the principal display panel may satisfy all or part of this requirement to the extent the common name includes the marks.

(iv) *Indication of battery information.* The outside package shall indicate the type and number of batteries and whether batteries are included in the package.

(v) *Indication of control platform.* The outside package shall indicate whether a mobile device or other non-included control platform is required. The indication must include the type of platform and how the platform connects to the device.

(2) *Labeling, inside the package.* The manufacturer or distributor of an OTC hearing aid shall include a user instructional brochure inside the package and shall make an electronic version available for download without site or customer registration and without requiring purchase of any product or service. The user instructional brochure shall include all of the following:

(i) The following warnings, which shall appear in the following order and prior to any content except the cover page:

(A) *Warning against use in people younger than 18.*

WARNING: If you are younger than 18, do not use this.
You should go to a doctor, preferably an ear-nose-throat doctor (an ENT), because your condition needs specialized care. Over-the-counter hearing aids are only for users who are age 18 or older.

This OTC hearing aid is for users who are 18 and older. People who are younger than 18 with hearing loss should see a doctor, preferably an ENT, because they may need medical testing and management. Hearing loss can affect speech and learning, so professional fitting and continuing care are also important.

(B) ''*Red flag*'' *conditions.*

WARNING: When to See a Doctor

If you have any of the problems listed below, please see a doctor, preferably an ear-nose-throat doctor (an ENT).

- Your ear has a birth defect or an unusual shape. Your ear was injured or deformed in an accident.
- You saw blood, pus, or fluid coming out of your ear in the past 6 months
- Your ear feels painful or uncomfortable
- You have a lot of ear wax, or you think something could be in your ear
- You get really dizzy or have a feeling of spinning or swaying (called vertigo)
- Your hearing changed suddenly in the past 6 months
- Your hearing changes: it gets worse then gets better again
- You have worse hearing in one ear
- You hear ringing or buzzing in only one ear

(C) *Warning about pain from device placement.*

WARNING: This hearing aid should not cause pain when inserting it.

Remove this device from your ear if it causes pain or discomfort when you insert or place it. To try again, make sure to follow the instructions. If you feel pain or discomfort again, contact the manufacturer. If your pain or discomfort doesn't go away, contact your hearing healthcare professional. You can also report this to FDA as an adverse event according to the instructions that appear later.

(ii) Any additional warnings the manufacturer may include prior to the cautions and notices to users in paragraph (c)(2)(iii) of this section.

(iii) The following cautions and notices for users, which shall appear prior to any content except the cover page and the warnings under paragraphs (c)(2)(i) and (ii) of this section:

(A) *Caution about hearing protection.*

Caution: This is not hearing protection.

You should remove this device if you experience overly loud sounds, whether short or long-lasting. If you're in a loud place, you should use the right kind of hearing protection instead of wearing this device. In general, if you would use ear plugs in a loud place, you should remove this device and use ear plugs.

(B) *Caution about excessive sound output.*

Caution: The sound output should not be uncomfortable or painful.

You should turn down the volume or remove the device if the sound output is uncomfortably loud or painful. If you consistently need to turn the volume down, you may need to further adjust your device.

(C) *Caution about components lodging in ear.*

Caution: You might need medical help if a piece gets stuck in your ear.

If any part of your hearing aid, like the eartip, gets stuck in your ear, and you can't easily remove it with your fingers, get medical help as soon as you can. You should not try to use tweezers or cotton swabs because they can push the part farther into your ear, injuring your eardrum or ear canal, possibly seriously.

(D) *Advice to seek professional services.*

Note: If you remain concerned, consult a professional.

If you try this device and continue to struggle with or remain concerned about your hearing, you should consult with a hearing healthcare professional.

(E) *Note about user expectations.*

Note: What you might expect when you start using a hearing aid

A hearing aid can benefit many people with hearing loss. However, you should know it will not restore normal hearing, and you may still have some difficulty hearing over noise. Further, a hearing aid will not prevent or improve a medical condition that causes hearing loss.

People who start using hearing aids sometimes need a few weeks to get used to them. Similarly, many people find that training or counseling can help them get more out of their devices.

If you have hearing loss in both ears, you might get more out of using hearing aids in both, especially in situations that make you tired from listening—for example, noisy environments.

(E) *Note about reporting adverse events to FDA.*

Note: Tell FDA about injuries, malfunctions, or other adverse events.

To report a problem involving your hearing aid, you should submit information to FDA as soon as possible after the problem. FDA calls them "adverse events," and they might include: skin irritation in your ear, injury from the device (like cuts or scratches, or burns from an overheated battery), pieces of the device getting stuck in your ear, suddenly worsening hearing loss from using the device, etc.

Instructions for reporting are available at https://www.fda.gov/Safety/MedWatch, or call 1-800-FDA-1088. You can also download a form to mail to FDA.

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(iv) An illustration(s) of the OTC hearing aid that indicates operating controls, user adjustments, and the battery compartment.

(v) Information on the function of all controls intended for user adjustment.

(vi) A description of any accessory that accompanies the OTC hearing aid, including but not limited to wax guards and accessories for use with a computer, television, or telephone.

(vii) Specific instructions for all of the following:

(A) Instructions for sizing or inserting the eartip of the OTC hearing aid to prevent insertion past the depth limit and damage to the tympanic membrane.

(B) The tools, tests, or software that allow the user to control the OTC hearing aid, including self-selection and self-checking the performance of the OTC hearing aid, and customize it to the user's hearing needs, including information about properly fitting eartips.

(C) Use of the OTC hearing aid with any accompanying accessories.

(D) Maintenance and care of the OTC hearing aid, including how a lay user can clean, disinfect, and replace parts or how to seek replacements, as well as how to store the hearing aid when it will not be used for an extended period of time.

(E) If the battery is replaceable or rechargeable, how to replace or recharge the battery, including a generic designation of replacement batteries.

(F) Expected battery life.

(G) Any other information necessary for adequate directions for use as defined in § 801.5 of this chapter.

(viii) Identification of any known physiological side effects associated with the use of the OTC hearing aid that may warrant consultation with a physician, referring to an ear-nose-throat doctor when preferable, including if applicable, skin irritation and accelerated accumulation of cerumen (ear wax).

(ix) The technical specifications required by paragraph (c)(4) of this section.

(x) A description of commonly occurring, avoidable events that could adversely affect or damage the OTC hearing aid, including but not limited to, as applicable, ear wax buildup, drops, immersion in water, or exposure to excessive heat.

(xi) If the hearing aid incorporates wireless technology in its programming or use, appropriate warnings, instructions, and information relating to electromagnetic compatibility and wireless technology and human exposure to non-ionizing radiation.

(xii) Information on how and where to obtain repair service or replacements, including at least one specific address where the user can go or send the OTC hearing aid to obtain such repair service or replacements.

(xiii) If clinical or non-clinical studies were conducted by or for the manufacturer to support the

performance of the OTC hearing aid, a summary of all such studies.

(3) *Labeling on the device.* The labeling on an OTC hearing aid itself shall bear all of the following clearly and permanently, except as provided in paragraph (c)(3)(iii) of this section:

(i) The serial number.

(ii) If the battery is removable, a ''+'' symbol to indicate the positive terminal for battery insertion unless the battery's physical design prevents inserting the battery in the reversed position.

(iii) If the OTC hearing aid is used or rebuilt, the manufacturer shall physically attach a removable tag to the hearing aid declaring that fact.

(4) *Technical specifications.* All of the following technical specifications shall appear in the user instructional brochure that accompanies the device. You may additionally include it on the outside package:

(i) The maximum output limit value (Output Sound Pressure Level 90 (OSPL90)).

(ii) The full-on gain value, which is the gain with a 50 decibel (dB) Sound Pressure Level (SPL) pure-tone input and volume set to full on.

(iii) The total harmonic distortion value.

(iv) The self-generated noise value.

(v) The latency value.

(vi) The upper and lower cutoff frequencies for bandwidth.

(5) *Software device labeling.* OTC hearing aid software that is not distributed with the hearing aid or amplification platform shall meet all of the following labeling requirements. With respect to the information required under paragraphs (c)(1) through (4) of this section, the information must be provided in the software device labeling, as specified in paragraphs (c)(5)(i) through (v) of this section, rather than the locations (*e.g.,* outside package labeling) specified in paragraphs (c)(1) through (4):

(i) Prior to first use of the software or obtaining payment information for the software, whichever occurs first, the labeling must clearly and prominently present all of the following to the prospective user. For each, the labeling must remain visible until the user dismisses it or proceeds to the next step:

(A) Compatibility and minimum operating requirements for the software device.

(B) Disclosures of any fees or payments after first use or initial payment, including but not limited to any fees or payments relating to subscriptions, add-on features, or continued access to features or services. The disclosures must name and briefly describe what each fee or payment covers.

(C) The information required under paragraphs (c)(1)(i), (iii), and (v) of this section.

(ii) Prior to first use of the software, the labeling must clearly and prominently present all of the following to the prospective user:

(A) The information required under paragraph (c)(2)(i)(A) of this section, and it must remain visible until the user acknowledges it.

(B) The information required under paragraphs (c)(2)(i)(B) and (C), (c)(2)(ii), (iii), and (v), (c)(2)(vii)(B) and (G), and (c)(2)(viii) and (ix) of this section, and the information must remain visible until the user dismisses it or proceeds to the next step.

(C) All other information required under paragraph (c)(2) of this section, to the extent applicable, and the information must remain visible until the user dismisses it or proceeds to the next step.

(iii) The software device labeling must include the information required under paragraphs (c)(3)(i) and (c)(4) of this section.

(iv) All of the software device labeling must be accessible for review after acknowledgment, dismissal, or proceeding to the next step.

(v) If there are changes to any of the labeling required under paragraph (c)(5) of this section, the labeling with the changed information must be presented to the user until the user dismisses it.

(d) *Output limits.* The output limit for an OTC hearing aid shall be the device maximum acoustic output sound pressure level (SPL) with an acoustic coupler as described in paragraph (e)(6) of this section when the device input is a 90 dB SPL pure-tone, and the gain/volume control is full on. An OTC hearing aid shall not exceed the following limits at any of the frequencies at which the device is intended to operate:

(1) *General output limit.* An OTC hearing aid shall not exceed an output limit of 111 dB SPL at any frequency except as provided in paragraph (d)(2) of this section.

(2) *Output limit for a device with activated input-controlled compression.* An OTC hearing aid that has input-controlled compression activated shall not exceed an output limit of 117 dB SPL at any frequency.

(e) *Electroacoustic performance limits.* An OTC hearing aid shall perform within all of the following electroacoustic limits. Measure each electroacoustic performance characteristic using an acoustic coupler as described in paragraph (e)(6) of this section, where applicable:

(1) *Output distortion control limits.* Test the output distortion of the OTC hearing aid as follows to ensure that it does not exceed the limit specified in paragraphs (e)(1)(i) through (iii) of this section.

(i) The total harmonic distortion plus noise shall not exceed 5 percent for output levels within one of the following sets of levels, depending on the test method:

(A) Using sine wave-based testing, measure at 70 dB SPL and 100 dB SPL; or

(B) Using a 500-hertz (Hz) one-third-octave pulsed-noise signal, measure at 67 dB SPL and 97 dB SPL.

(ii) You must measure the total harmonic distortion using a 500-Hz input tone with an analyzer that has a bandwidth at least as wide as the frequency limits of the OTC hearing aid.

(iii) You must measure the output distortion at the OTC hearing aid's maximum volume and the input sound level to the OTC hearing aid adjusted to produce the required outputs.

(2) *Self-generated noise level limits.* Self-generated noise shall not exceed 32 dBA. You must disable any methods that artificially lower the apparent noise floor for the measurement. Such methods would include but are not limited to auto-muting and downward expansion.

(3) *Latency.* Latency shall not exceed 15 ms. You must measure the latency with a method that is accurate and repeatable to within 1.5 ms.

(4) *Frequency response bandwidth.* The lower cutoff frequency shall extend to 250 Hz or below, and the upper cutoff frequency shall extend to 5 kHz or greater. You must measure the frequency response bandwidth as specified in the Method for clause 4.1 in ANSI/CTA–2051:2017.

(5) *Frequency response smoothness.* No single peak in the one-third-octave frequency response shall exceed 12 dB relative to the average levels of the one-third-octave bands, two-thirds octave above and below the peak. You must measure the frequency response smoothness using values for a diffuse field and the corrected one-third-octave frequency insertion response as specified in the Method for clause 4.1 in ANSI/CTA–2051:2017.

(6) *Acoustic coupler choice.* Where applicable, use one of the following acoustic couplers to measure electroacoustic performance:

(i) When compatible with the device design, a 2-cubic centimeter (cm^3) acoustic coupler; or

(ii) When a 2-cm^3 acoustic coupler is not compatible with the device design, an acoustic coupler that is a scientifically valid and technically equivalent alternative. You must document the rationale for using an alternative acoustic coupler.

(f) *Design requirements.* An OTC hearing aid must conform to all of the following design requirements:

(1) *Insertion depth.* The design of an OTC hearing aid shall limit the insertion of the most medial component so that, when inserted, the component is reasonably expected to remain at least 10 millimeters (mm) from the tympanic membrane.

(2) *Use of atraumatic materials.* The material for the eartip of an OTC hearing aid shall be atraumatic.

(3) *Proper physical fit.* The design of an OTC hearing aid shall enable consumers to readily achieve a safe, customized, acoustically favorable, and comfortable physical fit in the ear canal and/or external ear.

(4) *Tools, tests, or software.* The OTC hearing aid shall, through tools, tests, or software, permit a lay user to control the device and customize it to the user's hearing needs.

(5) *User-adjustable volume control.* The OTC hearing aid shall have a user-adjustable volume control.

(6) *Adequate reprocessing.* If the OTC hearing aid is used or rebuilt, it must be adequately reprocessed for the next user prior to sale.

(g) *Conditions for sale of an OTC hearing aid.* The sale of an OTC hearing aid is subject to all of the following conditions:

(1) *Age minimum.* Sale to or for a person younger than 18 years of age is prohibited.

(2) *Statement of OTC availability.* Sale of an OTC hearing aid is prohibited unless its labeling bears the statement of OTC availability required under paragraph (c)(1)(iii) of this section.

(h) *Effect on State law.* Any State or local government requirement for an OTC hearing aid is preempted to the following extent:

(1) *Preemption.* No State or local government shall establish or continue in effect any law, regulation, order, or other requirement specifically related to hearing products that would restrict or interfere with the servicing, marketing, sale, dispensing, use, customer support, or distribution of OTC hearing aids through in-person transactions, by mail, or online, that is different from, in addition to, or otherwise not identical to, the regulations promulgated under section 709(b) of the FDA Reauthorization Act of 2017, including any State or local requirement for the supervision, prescription, or other order, involvement, or intervention of a licensed person for consumers to access OTC hearing aids.

(2) *Professional requirements*—(i) *General rule.* The servicing, marketing, sale, dispensing, customer support, or distribution of OTC hearing aids, or an equivalent activity, whether through in-person transactions, by mail, or online, shall not cause, require, or otherwise obligate a person providing such services to obtain specialized licensing, certification, or any other State or local sanction unless such requirement is generally applicable to the sale of any product or to all places of business regardless of whether they sell OTC hearing aids. However, although a State or local government may not require the order, involvement, or intervention of a licensed person for consumers to access OTC hearing aids, a licensed person may service, market, sell, dispense, provide customer support for, or distribute OTC hearing aids.

(ii) *Sale of OTC hearing aids is not an exemption.* The servicing, marketing, sale, dispensing, customer support, or distribution of OTC hearing aids does not exempt a person from any State or local government's professional or establishment requirements that are consistent with this section.

(iii) *Representations may create professional obligations.* A person shall not incur specialized obligations by representing as a servicer, marketer, seller, dispenser, customer support representative, or distributor (or an equivalent description) of OTC hearing aids. However, a person representing as any other defined professional or establishment, or as a State licensed dispenser, is subject to applicable State and local requirements even if the person undertakes commercial or professional activities only in relation to OTC hearing aids.

(3) *Private remedies.* This section does not modify or otherwise affect the ability of any person to exercise a private right of action under any State or Federal product liability, tort, warranty, contract, or consumer protection law.

(i) *Incorporation by reference.* ANSI/CTA–2051, ''Personal Sound Amplification Performance Criteria,'' dated January 2017 (ANSI/CTA–2051:2017), is incorporated by reference into this section with the approval of the Director of the Office of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. This material is available for inspection at the Food and Drug Administration and at the National Archives and Records Administration (NARA). Contact the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500. For information on the availability of this material at NARA, email: *fr.inspection@nara.gov,* or go to: *www.archives.gov/federal-register/cfr/ibr-locations.html.* The material may be obtained from Consumer Technology Association (CTA), Technology & Standards Department, 1919 S Eads Street, Arlington, VA 22202; phone: 703–907–7600; fax: (703) 907–7693; email: *standards@ce.org,* website: *www.cta.tech*.

PART 801—LABELING

■ 3. The authority citation for part 801 is revised to read as follows:

Authority: 21 U.S.C. 321, 331–334, 351, 352, 360d, 360i, 360j, 371, 374.

§ 801.420 [Removed]

■ 4. Remove § 801.420.

§ 801.421 [Removed]

■ 5. Remove § 801.421.

■ 6. Add § 801.422 to subpart H to read as follows:

§ 801.422 Prescription hearing aid labeling.

(a) *Scope.* This section specifies the labeling requirements for prescription hearing aids. Any hearing aid that does not satisfy the requirements of § 800.30 of this chapter shall be a prescription device. Unless otherwise specified, the requirements in this section are in addition to other applicable requirements, including but not limited to special controls found in the applicable classification regulation in part 874 of this chapter. This section does not apply to group auditory trainers.

(b) *Definitions for the purposes of this section.* This section uses the following definitions:

Dispenser. A dispenser is any person, as defined in section 201(e) of the Federal Food, Drug, and Cosmetic Act, engaged in the sale of hearing aids to any member of the consuming public or any employee, agent, salesperson, and/or representative of such a person.

Hearing aid. A hearing aid is any wearable device designed for, offered for the purpose of, or represented as aiding persons with or compensating for, impaired hearing.

Prescription hearing aid. A prescription hearing aid is a hearing aid that is not an over-the-counter (OTC) hearing aid as defined in § 800.30 of this chapter or a hearing aid that does not satisfy the requirements in § 800.30 of this chapter.

Rebuilt hearing aid. A prescription hearing aid is ''rebuilt'' if the manufacturer has inspected and tested the device, made any necessary modifications to ensure it meets applicable regulatory requirements, including the requirements in this section, and adequately reprocessed the device for the next user.

Sale. Sale includes a lease, rental, or any other purchase or exchange for value.

Used hearing aid. A hearing aid is ''used'' if a user has worn it for any period of time. However, a hearing aid shall not be ''used'' merely because a prospective user wore it as part of a bona fide hearing aid evaluation to determine whether to select that particular hearing aid for that prospective user. A hearing aid evaluation is ''bona fide'' if it was conducted in the presence of the dispenser or a hearing health professional selected by the dispenser to assist the prospective user in making a determination.

(c) *Labeling.* A prescription hearing aid shall bear all of the following labeling:

(1) *Outside package labeling.* The outside package of a prescription hearing aid shall bear all of the following:

(i) *Warnings and other important information.* All of the following shall appear on the outside package:

(A) *Warning against use in people younger than 18 without prior medical evaluation.*

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WARNING – Medical evaluation for people younger than 18: The use of a hearing aid in people younger than 18 years old without a medical evaluation may worsen impairment or disability. A prospective hearing aid user who is younger than 18 should have a recent medical evaluation from a doctor, preferably an ear-nose-throat doctor (an ENT). Prior to purchase, a doctor should determine that the person is a candidate for the use of a hearing aid.

(B) ''*Red flag*'' *conditions.*

WARNING: When to See a Doctor

If you have any of the problems listed below, please see a doctor, preferably an ear-nose-throat doctor (an ENT).

- Your ear has a birth defect or an unusual shape. Your ear was injured or deformed in an accident.
- You saw blood, pus, or fluid coming out of your ear in the past 6 months
- Your ear feels painful or uncomfortable
- You have a lot of ear wax, or you think something could be in your ear
- You get really dizzy or have a feeling of spinning or swaying (called vertigo)
- Your hearing changed suddenly in the past 6 months
- Your hearing changes: it gets worse then gets better again
- You have worse hearing in one ear
- You hear ringing or buzzing in only one ear

(C) *Note about device trial options.*

Note: Ask about trial-rental or purchase-option programs.

If you're unsure about your ability to get used to using a hearing aid, you should ask about a trial-rental or purchase-option program. Many hearing instrument specialists offer programs that allow you to wear a hearing aid for a short time, at a nominal fee, before you decide to buy the hearing aid.

(ii) *Statement of build condition.* If the prescription hearing aid is used or rebuilt, the outside package shall declare that fact. A sticker under and visible through the outer wrapper will suffice to declare such fact.

(iii) *Indication of battery information.* The outside package shall indicate the type and number of batteries and whether batteries are included in the package.

(iv) *Indication of control platform.* That outside package shall indicate whether a mobile device or other non-included control platform is required. The indication must include the type of platform and how the platform connects to the device.

(2) *Labeling, inside the package.* The manufacturer or distributor of a prescription hearing aid shall include a user instructional brochure inside the package and shall make an electronic version available for download without site or customer registration and without requiring purchase of any product or service. The user instructional brochure shall include all of the following:

(i) The following warnings, which shall appear in the following order and prior to any content except the cover page:

(A) *Warning against use in people younger than 18 without prior medical evaluation.*

WARNING: People younger than 18 should go to a doctor before using this. People younger than 18 years old need specialized care, and using this without a medical evaluation may worsen impairment or disability. A hearing aid user who is younger than 18 should have a recent medical evaluation from a doctor, preferably an ear-nose-throat doctor (an ENT). Before using this, a doctor should determine that the use of a hearing aid is appropriate.

(B) ''*Red flag*'' *conditions, addressed to dispensers.*

WARNING to Hearing Aid Dispensers:

You should advise a prospective hearing aid user to consult promptly with a doctor, preferably an ear specialist such as an ENT, before dispensing a hearing aid if you determine through inquiry, actual observation, or review of any other available information concerning the prospective user, that the prospective user has any of the following conditions:

- Visible deformity of the ear, either congenital or traumatic
- Fluid, pus, or blood coming out of the ear within the previous 6 months
- Pain or discomfort in the ear
- History of excessive ear wax or suspicion that something is in the ear canal
- Dizziness, either recent or long-standing
- Sudden, quickly worsening, or fluctuating hearing loss within the previous 6 months
- Hearing loss or ringing (tinnitus) only in one ear or a noticeable difference in hearing between ears
- Audiometric air-bone gap equal to or greater than 15 dB at 500 Hz, 1000 Hz, and 2000 Hz

(C) *Warning to dispensers about very high-output devices.*

WARNING to Hearing Aid Dispenser, Outputs over 132 dB SPL:

You should exercise special care in selecting and fitting a hearing aid with a maximum output that exceeds 132 dB SPL because it may impair the remaining hearing of the hearing aid user.

(D) *Additional warnings.* Any additional warnings the manufacturer may include prior to the cautions and notices to users in paragraph (c)(2)(ii) of this section.

(ii) The following cautions and notices for users, which shall appear prior to any content, except the cover page and the warnings under paragraph (c)(2)(i) of this section:

(A) *Caution about hearing protection.*

Caution: This is not hearing protection.

You should remove this device if you experience overly loud sounds, whether short or long-lasting. If you're in a loud place, you should use the right kind of hearing protection instead of wearing this device. In general, if you would use ear plugs in a loud place, you should remove this device and use ear plugs.

(B) *Caution about excessive sound output.*

Caution: The sound output should not be uncomfortable or painful.

You should turn down the volume or remove the device if the sound output is uncomfortably loud or painful. If you consistently need to turn the volume down, you may need to further adjust your device.

(C) *Caution about components lodging in ear.*

Caution: You might need medical help if a piece gets stuck in your ear.

If any part of your hearing aid, like the eartip, gets stuck in your ear, and you can't easily remove it with your fingers, get medical help as soon as you can. You should not try to use tweezers or cotton swabs because they can push the part farther into your ear, injuring your eardrum or ear canal, possibly seriously.

(D) *Note about user expectations.*

Note: What you might expect when you start using a hearing aid

A hearing aid can benefit many people with hearing loss. However, you should know it will not restore normal hearing, and you may still have some difficulty hearing over noise. Further, a hearing aid will not prevent or improve a medical condition that causes hearing loss.

People who start using hearing aids sometimes need a few weeks to get used to them. Similarly, many people find that training or counseling can help them get more out of their devices.

If you have hearing loss in both ears, you might get more out of using hearing aids in both, especially in situations that make you tired from listening—for example, noisy environments.

(E) *Note about reporting adverse events to FDA.*

Note: Tell FDA about injuries, malfunctions, or other adverse events.

To report a problem involving your hearing aid, you should submit information to FDA as soon as possible after the problem. FDA calls them "adverse events," and they might include: skin irritation in your ear, injury from the device (like cuts or scratches, or burns from an overheated battery), pieces of the device getting stuck in your ear, suddenly worsening hearing loss from using the device, etc.

Instructions for reporting are available at https://www.fda.gov/Safety/MedWatch, or call 1-800-FDA-1088. You can also download a form to mail to FDA.

(F) *Note about hearing loss in people younger than 18 and fitting devices.*

Note: Hearing loss in people younger than 18

- People younger than 18 should see a doctor first, preferably an ear-nose-throat doctor (an ENT), because they may have different needs than adults.
- The doctor will identify and treat medical conditions as appropriate.
- The doctor may refer the person to an audiologist for a separate test, a hearing aid evaluation.
- The hearing aid evaluation will help the audiologist select and fit the appropriate hearing aid.

A person who is younger than 18 years old with hearing loss should have a medical evaluation by a doctor, preferably an ENT, before buying a hearing aid. The purpose of a medical evaluation is to identify and treat medical conditions that may affect hearing but that a hearing aid won't treat on its own.

Following the medical evaluation and if appropriate, the doctor will provide a written statement that the hearing loss has been medically evaluated and the person is a candidate for a hearing aid. The doctor may refer the person to an audiologist for a hearing aid evaluation, which is different from the medical evaluation and is intended to identify the appropriate hearing aid.

The audiologist will conduct a hearing aid evaluation to assess the person's ability to hear with and without a hearing aid. This will enable the audiologist to select and fit a hearing aid for the person's individual needs. An audiologist can also provide evaluation and rehabilitation since, for people younger than 18, hearing loss may cause problems in language development and educational and social growth. An audiologist is qualified by training and experience to assist in the evaluation and rehabilitation of hearing loss in people younger than 18.

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(iii) An illustration(s) of the prescription hearing aid that indicates operating controls, user adjustments, and the battery compartment.

(iv) Information on the function of all controls intended for user adjustment.

(v) A description of any accessory that accompanies the prescription hearing aid, including but not limited to wax guards, and accessories for use with a computer, television, or telephone.

(vi) Specific instructions for all of the following:

(A) Use of the prescription hearing aid with any accompanying accessories.

(B) Maintenance and care of the prescription hearing aid, including how a user can clean, disinfect, and replace parts or how to seek replacements, as well as how to store the hearing aid when it will not be used for an extended period of time.

(C) If the battery is replaceable or rechargeable, how to replace or recharge the battery, including a generic designation of replacement batteries.

(D) Expected battery life.

(vii) Identification of any known physiological side effects associated with the use of the prescription hearing aid that may warrant consultation with a physician, referring to an ear-nose-throat doctor when preferable, including if applicable, skin irritation and accelerated accumulation of cerumen (ear wax).

(viii) The technical specifications required by paragraph (c)(4) of this section unless such specifications appear in separate labeling accompanying the prescription hearing aid.

(ix) A description of commonly occurring, avoidable events that could adversely affect or damage the prescription hearing aid, including but not limited to, as applicable, ear wax buildup, drops, immersion in water, or exposure to excessive heat.

(x) If the hearing aid incorporates wireless technology in its programming or use, appropriate warnings, instructions, and information relating to electromagnetic compatibility and wireless technology and human exposure to non-ionizing radiation.

(xi) Information on how and where to obtain repair service or replacements, including at least one specific address where the user can go or send the prescription hearing aid to obtain such repair service or replacements.

(xii) If clinical or non-clinical studies were conducted by or for the manufacturer to support the performance of the prescription hearing aid, a summary of all such studies.

(3) *Labeling on the device.* The labeling on a prescription hearing aid itself shall bear all of the following clearly and permanently, except as

provided in paragraph (c)(3)(iii) of this section:

(i) The serial number.

(ii) If the battery is removable, a ''+'' symbol to indicate the positive terminal for battery insertion unless the battery's physical design prevents inserting the battery in the reversed position.

(iii) If the prescription hearing aid is used or rebuilt, the manufacturer shall physically attach a removable tag to the hearing aid declaring that fact.

(4) *Technical specifications.* You must determine the technical specification values for the prescription hearing aid labeling in accordance with the test procedures of ANSI/ASA S3.22–2014 (R2020), except as provided in paragraph (c)(4)(ix) of this section for latency. Technical specifications and their associated values that are useful in selecting, fitting, and checking the performance of the prescription hearing aid shall appear in the user instructional brochure or in separate labeling that accompanies the device, including all of the following:

(i) Saturation output curve (Saturation Sound Pressure Level (SSPL) 90 curve).

(ii) Frequency response curve.

(iii) Average saturation output (High Frequency (HF)-Average SSPL 90).

(iv) Average full-on gain (HF-Average full-on gain).

(v) Reference test gain.

(vi) Frequency range.

(vii) Total harmonic distortion.

(viii) Equivalent input noise.

(ix) Latency, measured using a method that is accurate and repeatable to within 1.5 ms.

(x) Battery current drain.

(xi) Induction coil sensitivity (telephone coil aids only).

(xii) Input-output curve (only for hearing aids with automatic gain control).

(xiii) Attack and release times (only for hearing aids with automatic gain control).

(5) *Software device labeling.* Prescription hearing aid software that is not distributed with the hearing aid or amplification platform shall meet all of the following labeling requirements. With respect to the information required under paragraphs (c)(1) through (4) of this section, the information must be provided in the software device labeling, as specified in paragraphs (c)(5)(i) through (v) of this section, rather than the locations (*e.g.,* outside package labeling) specified in paragraphs (c)(1) through (4).

(i) Prior to first use of the software or obtaining payment information for the software, whichever occurs first, the labeling must clearly and prominently present all of the following to the prospective user. For each, the labeling must remain visible until the user dismisses it or proceeds to the next step:

(A) Compatibility and minimum operating requirements for the software device.

(B) Disclosures of any fees or payments after first use or initial payment, including but not limited to any fees or payments relating to subscriptions, add-on features, or continued access to features or services. The disclosures must name and briefly describe what each fee or payment covers.

(C) The information required under paragraphs (c)(1)(i) and (iv) of this section.

(ii) Prior to first use of the software, the labeling must clearly and prominently present all of the following to the prospective user:

(A) The information required under paragraph (c)(2)(i)(A) of this section, and it must remain visible until the user acknowledges it.

(B) The information required under paragraphs (c)(2)(i)(B) through (D) and (c)(2)(ii), (iv), (vii), and (viii) of this section, and the information must remain visible until the user dismisses it or proceeds to the next step.

(C) All other information required under paragraph (c)(2) of this section, to the extent applicable, and the information must remain visible until the user dismisses it or proceeds to the next step.

(iii) The software device labeling must include the information required under paragraphs (c)(3)(i) and (c)(4) of this section.

(iv) All of the software device labeling must be accessible for review after acknowledgment, dismissal, or proceeding to the next step.

(v) If there are changes to any of the labeling required under paragraph (c)(5) of this section, the labeling with the changed information must be presented to the user until the user dismisses it.

(6) *Misbranding.* A prescription hearing aid that is not labeled as required under this section and § 801.109 is misbranded under sections 201(n), 502(a), and/or 502(f) of the Federal Food, Drug, and Cosmetic Act.

(d) *Incorporation by reference.* ANSI/ASA S3.22–2014 (R2020), ''AMERICAN NATIONAL STANDARD Specification of Hearing Aid Characteristics,'' dated June 5, 2020, is incorporated by reference into this section with the approval of the Director of the Office of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. This material is available for inspection at the Food and Drug Administration and at the National Archives and Records Administration (NARA). Contact the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500. For information on the availability of this material at NARA, email: *fr.inspection@nara.gov,* or go to: *www.archives.gov/federal-register/cfr/ibr-locations.html.* The material may be obtained from the Acoustical Society of America (ASA), 1305 Walt Whitman Road, Suite 300, Melville, NY 11747; phone: (631) 390–0215; fax: (631) 923–2875; email: *asastds@acousticalsociety.org.*

PART 808—EXEMPTIONS FROM FEDERAL PREEMPTION OF STATE AND LOCAL MEDICAL DEVICE REQUIREMENTS

■ 7. The authority citation for part 808 is revised to read as follows:

Authority: 21 U.S.C. 360j, 360k, 371. Section 808.1 also issued under Sec. 709, Public Law 115–52, 131 Stat. 1065–67.

■ 8. In part 808, remove the words ''the act'' and add in their place ''the Federal Food, Drug, and Cosmetic Act''.

■ 9. In § 808.1, add headings to paragraphs (a) through (f) and add paragraph (g) to read as follows:

§ 808.1 Scope.

(a) *Introduction.* * * *

(b) *General rule for State and local requirements respecting devices.* * * *

(c) *Exempting from preemption certain State or local requirements respecting devices.* * * *

(d) *Meaning of ''requirements applicable to a device.''* * * *

(e) *Determination of equivalence or difference of requirements applicable to a device.* * * *

(f) *Applicability of Federal requirements respecting devices.* * * *

(g) *Exemptions not applicable to certain State or local government requirements specifically related to hearing products.* An exemption under this part shall not apply to any State or local government law, regulation, order, or other requirement specifically related to hearing products, including any requirement for the supervision, prescription, or other order, involvement, or intervention of a licensed person for consumers to access over-the-counter hearing aids, that:

(1) Would restrict or interfere with the servicing, marketing, sale, dispensing, use, customer support, or distribution of over-the-counter hearing aids, as defined under section 520(q) of the Federal Food, Drug, and Cosmetic Act, through in-person transactions, by mail, or online; and

(2) Is different from, in addition to, or otherwise not identical to, the

regulations issued under section 709(b) of the FDA Reauthorization Act of 2017.

■ 10. Revise § 808.3 to read as follows:

§ 808.3 Definitions.

Compelling local conditions includes any factors, considerations, or circumstances prevailing in, or characteristic of, the geographic area or population of the State or political subdivision that justify exemption from preemption.

More stringent refers to a requirement of greater restrictiveness or one that is expected to afford to those who may be exposed to a risk of injury from a device a higher degree of protection than is afforded by a requirement applicable to the device under the Federal Food, Drug, and Cosmetic Act.

Political subdivision or *locality* means any lawfully established local governmental unit within a State which unit has the authority to establish or continue in effect any requirement having the force and effect of law with respect to a device intended for human use.

State means any State or Territory of the United States, including but not limited to, the District of Columbia and the Commonwealth of Puerto Rico.

Substantially identical to refers to the fact that a State or local requirement does not significantly differ in effect from a Federal requirement.

§ 808.53 [Removed and Reserved]

■ 11. Remove and reserve § 808.53.

■ 12. Revise § 808.55 to read as follows:

§ 808.55 California.

The following California medical device requirements are preempted under section 521(a) of the Federal Food, Drug, and Cosmetic Act, and FDA has denied them exemption from preemption:

(a) *Medical devices; general provisions.* Sherman Food, Drug, and Cosmetic Law, Division 21 of the California Health and Safety Code, sections 26207, 26607, 26614, 26615, 26618, 26631, 26640, and 26441, to the extent that they apply to devices; and

(b) *Ophthalmic devices; quality standards.* California Business and Professions Code, section 2541.3 to the extent that it requires adoption of the American National Standards Institute standards Z–80.1 and Z–80.2.

§§ 808.57 through 808.101 [Removed and Reserved]

■ 13. Remove and reserve §§ 808.57 through 808.101.

PART 874—EAR, NOSE, AND THROAT DEVICES

■ 14. The authority citation for part 874 continues to read as follows:

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

■ 15. Revise § 874.3300 to read as follows:

§ 874.3300 Air-conduction hearing aid.

(a) *Identification.* An air-conduction hearing aid is a wearable sound-amplifying device intended to compensate for impaired hearing that conducts sound to the ear through the air. An air-conduction hearing aid is subject to the requirements in § 800.30 or § 801.422 of this chapter, as applicable. The air-conduction hearing aid generic type excludes the group hearing aid or group auditory trainer, master hearing aid, and the tinnitus masker, regulated under §§ 874.3320, 874.3330, and 874.3400, respectively.

(b) *Classification.* Class I (general controls). This device is exempt from premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 874.9.

■ 16. Add § 874.3302 to read as follows:

§ 874.3302 Bone-conduction hearing aid.

(a) *Identification.* A bone-conduction hearing aid is a wearable sound-amplifying device intended to compensate for impaired hearing and that conducts sound to the inner ear through the skull. The non-implantable components of a bone-conduction hearing aid, such as the external sound processor, are subject to the requirements in § 801.422 of this chapter.

(b) *Classification.* Class II.

■ 17. In § 874.3305, add a sentence at the end of paragraph (a) and revise paragraph (b) to read as follows:

§ 874.3305 Wireless air-conduction hearing aid.

(a) * * * A wireless air-conduction hearing aid is subject to the requirements in § 800.30 or § 801.422 of this chapter, as applicable.

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

(1) Performance data must demonstrate the electromagnetic compatibility (EMC), electrical safety, and thermal safety of the device;

(2) Performance testing must validate safety of exposure to non-ionizing radiation; and

(3) Performance data must validate wireless technology functions.

* * * * *

■ 18. In § 874.3315, revise paragraph (a) to read as follows:

§ 874.3315 Tympanic membrane contact hearing aid.

(a) *Identification.* A tympanic membrane contact hearing aid is a prescription wearable device that compensates for impaired hearing. Amplified sound is transmitted by vibrating the tympanic membrane through a transducer that is in direct contact with the tympanic membrane. A tympanic membrane contact hearing aid is subject to the requirements in § 801.422 of this chapter.

* * * * *

■ 19. In § 874.3325:

■ a. Add a sentence at the end of paragraph (a);

■ b. Revise paragraph (b)(5); and

■ c. Remove paragraph (b)(7).

The addition and revision read as follows:

§ 874.3325 Self-fitting air-conduction hearing aid.

(a) * * * A self-fitting air-conduction hearing aid is subject to the requirements in § 800.30 or § 801.422 of this chapter, as applicable.

(b) * * *

(5) If the device incorporates wireless technology:

(i) Performance testing must validate safety of exposure to non-ionizing radiation; and

(ii) Performance data must validate wireless technology functions.

* * * * *

■ 20. In § 874.3950, add a sentence at the end of paragraph (a) to read as follows:

§ 874.3950 Transcutaneous air conduction hearing aid system.

(a) * * * A transcutaneous air conduction hearing aid system is subject to the requirements in § 801.422 of this chapter.

* * * * *

Dated: August 5, 2022.

Robert M. Califf,

Commissioner of Food and Drugs.

[FR Doc. 2022–17230 Filed 8–16–22; 8:45 am]

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