

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, PRASStaff@fda.hhs.gov.

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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: asatds@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. 360ll). 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. 360o 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 device 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)(i) 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 hearing 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 hearing 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.

⁹For 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 (cm³) 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-cm³ 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-cm³ 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.

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>.

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

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 pertain 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 Pre-market 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 pmbll., 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, 360o 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: manufacturers, 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(J)(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 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. 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	\$6	\$147	2020	7	10	
	63	6	147	2020	3	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	2	2020	7	10	
	1	1	2	2020	3	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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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.

BILLING CODE 4164-01-C

(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 (cm³) acoustic coupler; or

(ii) When a 2-cm³ 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.

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Dated: August 5, 2022.

Robert M. Califf,

Commissioner of Food and Drugs.

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