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Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products

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Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

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For questions about this document, contact OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices/DHT1B: Division of Dental and ENT Devices/THT1B3: ENT Devices Team at 301-796-5620.

When final, this guidance will supersede "Guidance for Industry and FDA Staff: Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products," dated February 25, 2009.

FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Preface

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Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products

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Draft Guidance for Industry and Food and Drug Administration Staff

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

This guidance document identifies applicable legal requirements under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) for hearing aids and for personal sound amplification products (PSAPs). Hearing aids and PSAPs both affect a user's ability to hear sound, but the products have different intended uses, and are therefore subject to different regulatory controls. Unlike hearing aids which are intended to aid a person with or compensate for hearing impairment, PSAPs (as defined in Section III) are not intended to diagnose, treat, cure, mitigate, or prevent disease and are not intended to affect the structure or function of the body. Therefore, they are not considered to be "devices" as defined in the FD&C Act.[1]

A lack of clarity between PSAPs and hearing aids has contributed to stakeholder and consumer confusion. This guidance is intended to describe hearing aids, PSAPs, their respective intended uses, and the regulatory requirements which apply to both types of products.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law. FDA guidance documents, including this guidance, should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the

[1] See section 201(h) of the FD&C Act (21 U.S.C. 321(h)).

word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Background

The FDA Reauthorization Act of 2017 (FDARA) (Pub. L. 115-52) directs FDA to establish a category of over-the-counter (OTC) hearing aids through rulemaking, and mandates that FDA establish various requirements for this category of devices. FDA has issued a proposed rule to establish the OTC category of hearing aids and implement the requirements of FDARA ("Proposed Rule").[2] In this Proposed Rule, FDA has also proposed multiple related changes to the overall regulatory framework for hearing aids to harmonize existing regulations with the proposed OTC category while continuing to provide reasonable assurance of safety and effectiveness. Specifically, this Proposed Rule, once finalized, would define OTC hearing aids and establish applicable requirements; amend existing rules for consistency with the new OTC category, and these amended rules will apply to most other hearing aids which will then be regulated as prescription devices (proposed 21 CFR 801.422); repeal the conditions for sale applicable to hearing aids under 21 CFR 801.421; and update regulations relating to decisions on applications for exemption from Federal preemption that may no longer apply.

FDARA also directed FDA to update and finalize the draft guidance entitled "Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products," issued on November 7, 2013.[3] In order to fulfill this FDARA requirement, FDA is issuing this updated draft guidance which supersedes the November 7, 2013 draft guidance. If the Proposed Rule is finalized, there will be a heightened need to appropriately inform consumers by clearly distinguishing PSAPs from OTC hearing aids from a regulatory standpoint. This guidance is intended to accomplish that goal. We intend to continue to take a risk-based approach to enforcing our regulations to protect the public health.

Because we are proposing to change the requirements that apply to hearing aids, this guidance references the current regulations using the current citation in the Code of Federal Regulations (CFR) and to the proposed regulations, which are further described in the Proposed Rule, by citing to the proposed CFR citation, e.g., proposed 21 CFR 800.30(a).

FDA provides additional information regarding hearing aids on the following website: https://www.fda.gov/medical-devices/consumer-products/hearing-aids.

III. Definitions and Scope

[2] "Establishing Over-the-Counter Hearing Aids" (86 FR 58150) available at: https://www.federalregister.gov/d/2021-22473.

[3] See FDARA section 709(c) (Pub. L. 115-52, 131 Stat. 1067).

A hearing aid is "any wearable instrument or device designed for, offered for the purpose of, or represented as aiding persons with or compensating for, impaired hearing" (21 CFR 801.420(a); a similar definition is provided in proposed 21 CFR 800.30(b)). This definition encompasses both air-conduction and bone-conduction devices in a variety of styles (e.g., behind-the-ear, in-the-canal, body worn). Hearing aids are devices as defined by section 201(h) of the FD&C Act.[4] Hearing aids do not include cochlear implants or implantable middle ear hearing devices, which are class III devices that require an approved premarket approval (PMA) application before marketing (section 513(a) of the FD&C Act). In contrast, an electronic product[5] that is intended for non-hearing impaired consumers to amplify sounds in certain environments, such as for hunting or other recreational activities, and is not intended to aid persons with or compensate for impaired hearing, is considered a PSAP. Such PSAPs are not devices as defined in section 201(h) of the FD&C Act and therefore, are not regulated as such.

Currently, hearing aid devices may be classified[6] as:

- class I devices, exempt[7] from premarket notification (510(k)) (21 CFR 874.3300(b)(1));
- class II devices, which require premarket notification (510(k)) and compliance with special controls (if applicable to the specific regulation) before marketing (21 CFR 874.3300(b)(2), 21 CFR 874.3315, 21 CFR 874.3325, and 21 CFR 874.3950); or
- class II devices that are exempt[8] from premarket notification (510(k)), subject to required special controls (21 CFR 874.3305).[9]

[4] A device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term "device" does not include software functions excluded pursuant to section 520(o). See section 201(h) of the FD&C Act (21 U.S.C. 321(h)).

[5] The term "electronic product" means (A) any manufactured or assembled product which, when in operation, (i) contains or acts as part of an electronic circuit and (ii) emits (or in the absence of effective shielding or other controls would emit) electronic product radiation, or (B) any manufactured or assembled article which is intended for use as a component, part, or accessory of a product described in clause (A) and which when in operation emits (or in the absence of effective shielding or other controls would emit) such radiation. See section 531(2) of the FD&C Act (21 U.S.C. 360hh(2)).

[6] Tactile hearing aids, under product code LRA, are currently unclassified devices, subject to premarket notification (510(k)). They are a preamendments device type and do not have a classification regulation.

[7] Refer to 21 CFR 874.9 for the limitations of exemptions from 510(k).

[8] Ibid.

[9] In accordance with 21 CFR 874.9, an air-conduction hearing aid device under 21 CFR 874.3300(b)(1) and a wireless air-conduction hearing aid under 21 CFR 874.3305 are exempt from premarket notification unless the device: 1) is intended for a use different from the intended use of a legally marketed device of that generic type, or 2) if the device operates using a different fundamental scientific technology than a legally marketed device of that generic type.

Product codes for the various types of devices under these classification regulations are listed below:

Table 1 – Relevant Product Codes

Regulation Number[10]	Product Code and Name
21 CFR 874.3300	LRB (Face Plate Hearing Aid)
21 CFR 874.3300	ESD (Hearing Aid, Air Conduction)
21 CFR 874.3300	LDG (Kit, Earmold, Impression)
21 CFR 874.3300	LXB (Hearing Aid, Bone Conduction)
21 CFR 874.3300	MAH (Hearing Aid, Bone Conduction, Implanted)
21 CFR 874.3305	OSM (Hearing Aid, Air Conduction with Wireless Technology)
21 CFR 874.3315	PLK (Tympanic Membrane Direct Contact Hearing Aid)
21 CFR 874.3325	QDD (Self-Fitting Air-Conduction Hearing Aid)
21 CFR 874.3950	NIX (Hearing Aid, Air Conduction, Transcutaneous System)

Although the product codes listed above are current as of the date of issuance of this guidance, new product codes may be created over time for hearing aids regulated under the classification regulations identified above and would fall within the scope of this guidance. We recommend that you reference the product code database (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm) if you are unsure whether this guidance applies to your device and the product code for your device is not already captured in this guidance.

Although the Proposed Rule has proposed amendments to the classification regulations for hearing aids, these proposals do not impact the scope of this guidance. We will ensure that the final version of this guidance aligns and is consistent with the Final Rule when the Proposed Rule is finalized.

This guidance does not apply to the group hearing aid or group auditory trainer (21 CFR 874.3320), master hearing aid (21 CFR 874.3330), and tinnitus masker (21 CFR 874.3400).

IV. Regulatory Requirements

As discussed in Section III, hearing aids are devices under section 201(h) of the FD&C Act and PSAPs (as defined in Section III) are not devices as defined by section 201(h) and therefore, are not regulated as such. This section provides further clarity regarding the intended uses of hearing aids and PSAPs and the regulatory requirements for both types of products.

[10] These are the regulation numbers that currently apply to the product codes identified. These are subject to change as described in the Proposed Rule.

A. Hearing Aids

As devices, hearing aids are subject to applicable device requirements under the FD&C Act and FDA regulations (e.g., adverse event reporting). FDA regulations also include specific requirements for hearing aids that are discussed below. Hearing aids are also electronic products, and therefore, are subject to applicable electronic product requirements under the FD&C Act and FDA regulations (these requirements are discussed in the PSAP section below).

FDA's regulation of hearing aids is intended to provide consumers access to safe and effective hearing aids and ensure that consumers understand how to use available technology and understand when to seek an evaluation by a qualified professional. Specific information in hearing aid labeling is essential in order for consumers and hearing aid dispensers to identify conditions that either may pose a threat to health if left undiagnosed, or avoid unnecessary and inappropriate hearing aid use (e.g., cerumen (earwax) impaction). Specific information in hearing aid labeling will also help consumers and hearing aid dispensers choose appropriate hearing aids that are safe and effective for the consumer's hearing condition. Equipped with this information, consumers can better decide how to address their needs among all options available to them.

Currently, all hearing aids must comply with specific requirements regarding patient and professional labeling identified in 21 CFR 801.420. This regulation includes specific labeling requirements for the hearing aid device itself (e.g., device model, serial number, year of manufacture) as well as the content of the User Instructional Brochure that must be provided to potential hearing aid recipients (e.g., technical data, "Warning to Hearing Aid Dispensers" statement which specifies that the dispenser should advise a prospective user to consult promptly with a licensed physician before dispensing a hearing aid if the dispenser determines that the prospective user has any of the specified conditions).

Additionally, all hearing aids are subject to required conditions for sale, as stated in 21 CFR 801.421. FDA's guidance, "Conditions for Sale for Air-Conduction Hearing Aids" ("Conditions for Sale Guidance"),[11] describes the Agency's current enforcement policy with respect to these conditions for sale. As explained in the Conditions for Sale Guidance, FDA does not intend to enforce the medical evaluation (21 CFR 801.421(a)) or recordkeeping (21 CFR 801.421(d)) requirements prior to the dispensing of certain hearing aid devices to individuals 18 years of age and older. However, as explained in the Conditions for Sale Guidance, FDA intends to continue to enforce 21 CFR 801.421(b) and (c), which require hearing aid dispensers to provide prospective users an opportunity to review and to make available the "User Instructional Brochure," containing specific required labeling, before the sale of a hearing aid. These

[11] For additional details regarding the Agency's enforcement policy, please refer to the FDA guidance "Conditions for Sale for Air-Conduction Hearing Aids," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/immediately-effect-guidance-document-conditions-sale-air-conduction-hearing-aids.

regulatory conditions for sale were established to encourage prospective users to receive proper medical evaluation and treatment for treatable causes of hearing loss/impaired hearing.

Consistent with the Proposed Rule, when finalized, OTC hearing aids, as defined therein, must comply with the requirements for OTC hearing aids (proposed 21 CFR 800.30); in addition, we are proposing to repeal the conditions for sale in 21 CFR 801.421 and amend the labeling requirements in 21 CFR 801.420 (by moving them to proposed 21 CFR 801.422, limiting their scope to prescription hearing aids, and revising them as appropriate to provide consistency with the new labeling requirements for OTC hearing aids in proposed 21 CFR 800.30). Thus, once the Proposed Rule is finalized, prescription hearing aids would need to comply with the hearing aid specific requirements of proposed 21 CFR 801.422, which are similar to the requirements in 21 CFR 801.420.

B. Personal Sound Amplification Products (PSAPs)

This subsection describes PSAPs that fall within the definition provided in Section III of this document. PSAPs are not intended to compensate for hearing impairment. They are intended to accentuate sounds in specific listening environments for non-hearing impaired listeners. Because PSAPs are not intended to diagnose, treat, cure, mitigate, or prevent disease and are not intended to affect the structure or function of the body, they are not devices as defined in the FD&C Act.[12] As such, there is no regulatory classification or product code for these products. Furthermore, there are no requirements for registration of manufacturers or listing of these products with FDA. However, PSAPs are subject to applicable provisions of the Radiation Control for Health and Safety Act of 1968,[13] under which FDA regulates electronic products that emit sonic vibrations, such as sound amplification equipment.[14] Manufacturers of PSAPs must report accidental radiation occurrences under 21 CFR Part 1002, and report defects and take other measures described in 21 CFR Part 1003. Manufacturers of PSAPs must also comply with the requirements to repurchase, repair, or replace electronic products under 21 CFR Part 1004.

Examples of situations in which PSAPs typically are used include hunting (listening for prey), bird watching, listening to lectures with a distant speaker, and listening to soft sounds that would be difficult for normal hearing individuals to hear (e.g., distant conversations).

C. Distinction between PSAPs and Hearing Aids

FDA is aware of confusion in the marketplace over what FDA considers a hearing aid and what it considers a PSAP. While the technology of hearing aids and PSAPs may be similar, FDA considers the intended use of each product to determine whether it is a device or solely an electronic product. A product's intended use refers to the "objective intent" of those legally responsible for the labeling of the product, which may be shown by their oral or written expressions, the design or composition of the product, or by the circumstances surrounding the

[12] See section 201(h) of the FD&C Act (21 U.S.C. 321(h)).
[13] Sections 531 to 542 of the FD&C Act (21 U.S.C. 360hh-ss).
[14] See 21 CFR 1000.15(d).

distribution of the product.[15] This objective intent may be shown, for example, by the claims made in product labeling or advertising, and from other relevant sources.[16,17] Accordingly, FDA may consider, among other things, any written or oral claims or statements in any label, labeling, advertising, and/or promotion of a product by or on behalf of a firm[18] in determining whether a product is a device.

Explicitly or implicitly claiming or stating that a product addresses, mitigates, or improves hearing loss/impaired hearing would be considered an intent to diagnose, treat, cure, mitigate, or prevent disease or to affect the structure or function of the body. The following are examples of explicit or implicit claims or statements that FDA believes would generally cause the product to meet the device definition, in which case the product would be subject to the regulatory requirements applicable to devices, including the specific requirements applicable to hearing aids, as discussed above in this guidance:

- suggestions that the product is for users with certain types or severity of hearing loss/impaired hearing;
- suggestions that the product is indicated for use in situations that are typically associated with and indicative of hearing loss/impaired hearing;
- suggestions that the product is an alternative to a hearing aid (PSAPs are not considered "over-the-counter" alternatives or substitutes for a hearing aid), for example, marketing it as a less expensive alternative to hearing aids or marketing it to consumers who may have hearing loss/impaired hearing and are not yet ready to buy hearing aids;
- information conveyed to the user to optimize the product to their hearing loss/impaired hearing profile (e.g., providing hearing thresholds or a measure of hearing loss/impaired hearing, or using a hearing aid fitting formula or other algorithms to program the product output to match the user's hearing loss/impaired hearing profile).

[15] See 21 CFR 801.4.

[16] See id.

[17] "Labeling" is defined in section 201(m) of the FD&C Act (21 U.S.C. 321(m)) as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." Labeling may include promotional materials.

[18] For the purposes of this guidance document, the term "firm" is used to refer to "persons legally responsible for the labeling of an article (or their representatives)" under 21 CFR 801.4.