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Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products - Draft Guidance for Industry and Food and Drug Administration Staff

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For questions regarding this document, contact the Ear, Nose, and Throat Devices Branch (ENTB) at 301-796-5620.

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



U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Division of Ophthalmic and Ear, Nose, and Throat Devices

Preface

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Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products - Draft Guidance for Industry and Food and Drug Administration Staff

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1. Introduction

This guidance document identifies applicable legal requirements under the 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 our ability to hear sound, but the products have different intended uses, and are therefore subject to different regulatory controls.

A hearing aid is a wearable sound-amplifying device¹ that is intended to compensate for impaired hearing. Hearing aids are usually programmed to address an individual's degree of hearing loss across sound frequencies to improve speech intelligibility. Additionally, hearing aids may be coupled acoustically or wirelessly to external electronic products such as televisions, MP3 players, and telephones. A hearing health professional (such as an audiologist or a hearing aid dispenser) is usually

required to program and optimize the performance of hearing aids with these more complex features. In contrast, a PSAP is a wearable electronic product² that is not intended to compensate for impaired hearing, but rather is intended for non-hearing impaired consumers to amplify sounds in certain environments, such as for hunting or other recreational activities. PSAPs typically are simpler sound amplification devices with fewer features and less functionality than hearing aids, although some of the technology and functionality of hearing aids and PSAPs may be similar.

To clearly distinguish between PSAPs and hearing aids, FDA relies on the intended use of each product to determine whether it is a medical device or an electronic product. The intended use may be established by labeling or promotional materials. Labeling or promotional materials that make claims, or include language that suggests the use of a PSAP for hearing impaired consumers, establish an intended use for the electronic product as a medical device, which would therefore be subject to the regulatory requirements for a hearing aid, as described in this guidance. Examples of such labeling claims and language that would establish an intended use as a medical device include:

- a description of the types and severity of hearing loss
- a description of listening situations that are typically associated with and indicative of hearing loss
- wording to suggest that the product is an alternative to a hearing aid.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

2. Hearing Aids

The regulations define a hearing aid as "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). 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 subject to different types of premarket review requirements than cochlear implants or implantable middle ear hearing devices, which are class III devices, requiring an approved premarket approval (PMA) application before marketing (Section 513(a) of the FD&C Act).

Hearing aid devices, as distinguished from cochlear implants, may be classified as:

- class I devices and exempt from premarket review and clearance before marketing (21 CFR 874.3300(b)(1));
- class II devices, which require premarket review and clearance by FDA before

marketing (21 CFR 874.3300(b)(2) and 21 CFR 874.3950); or

- class II devices that are exempt from premarket review and clearance before marketing (21 CFR 874.3305).³

Product codes for the various types of devices under these classification regulations may be found at:Â

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm>.

The regulatory definition of a hearing aid is codified as follows:

21 CFR 874.3300 Hearing aid.

(a) *Identification.* A hearing aid is wearable sound-amplifying device that is intended to compensate for impaired hearing. This generic type of device includes the air-conduction hearing aid and the bone-conduction hearing aid, but excludes the group hearing aid or group auditory trainer (874.3320), master hearing aid (874.3330), and tinnitus masker (874.3400).

(b) *Classification.* (1) Class I (general controls) for the air-conduction hearing aid. The air-conduction hearing aid is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to 874.9.

(2) Class II for the bone-conduction hearing aid.

The regulatory definition of a wireless air conduction hearing aid is as follows:

21 CFR 874.3305 Wireless air-conduction hearing aid.

(a) *Identification.* A wireless air-conduction hearing aid is a wearable sound-amplifying device, intended to compensate for impaired hearing that incorporates wireless technology in its programming or use.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Appropriate analysis/testing should validate electromagnetic compatibility (EMC) and safety of exposure to non-ionizing radiation;

(2) Design, description, and performance data should validate wireless technology functions; and

(3) Labeling should specify appropriate instructions, warnings, and information relating to EMC and wireless technology and human exposure to non-ionizing radiation.

(c) *Premarket notification.* The wireless air-conduction hearing aid is exempt from the premarket notification procedures in subpart E of part 807 of this

chapter subject to 874.9.

The regulatory definition of a transcutaneous air conduction system is as follows:

21 CFR 874.3950 Transcutaneous air conduction hearing aid system.

(a) *Identification.* A transcutaneous air conduction hearing aid system is a wearable sound- amplifying device intended to compensate for impaired hearing without occluding the ear canal. The device consists of an air conduction hearing aid attached to a surgically fitted tube system, which is placed through soft tissue between the post auricular region and the outer ear canal.

(b) *Classification.* Class II (special controls).Â The special control for this device is FDA's guidance document entitled "Class II Special Controls Guidance Document: Transcutaneous Air Conduction Hearing Aid System (TACHAS); Guidance for Industry and FDA."Â See 874.1 for the availability of this guidance document.

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, date 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 Dispenser" statement).

Additionally, all hearing aids must comply with the required conditions for sale, as stated in 21 CFR 801.421. A prospective hearing aid user must provide to the hearing aid dispenser a written statement from a licensed physician that the prospective user has been medically evaluated and is a candidate for a hearing aid. This evaluation must occur within 6 months prior to the date of purchase of the hearing aid. If 18 years of age or older, the prospective user may waive this requirement for medical evaluation provided that the prospective user signs a waiver statement under the conditions outlined in this regulation. Children (age less than 18 years) are not eligible for a waiver.

Finally, the hearing aid dispenser must retain records of all medical evaluation statements and waivers for a period of three years after dispensing of the hearing aid. These regulatory conditions for sale were established to encourage prospective users to receive proper medical evaluation and treatment for treatable causes of hearing loss. The hearing aid classification regulation specifically excludes the group hearing aid or group auditory trainer (874.3320), master hearing aid (874.3330), and tinnitus masker (874.3400). Therefore, they are not subject to these regulatory requirements for labeling and conditions for sale.

For questions regarding regulatory requirements for hearing aid devices, please

contact the Ear, Nose, and Throat Devices Branch (ENTB) at 301-796-5620.

3. Personal Sound Amplification Products (PSAPs)

PSAPs are intended to amplify environmental sound for non-hearing impaired consumers. They are intended to accentuate sounds in specific listening environments, rather than for everyday use in multiple listening situations. They are not intended to compensate for hearing impairment or to address listening situations that are typically associated with and indicative of hearing loss. 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).¹ Examples of listening situations that are typically associated with and indicative of hearing loss include: difficulty listening to another person nearby, difficulty understanding conversations in crowded rooms, difficulty understanding movie dialogue in a theater, difficulty listening to lectures in an otherwise quiet room, difficulty hearing the phone or doorbell ring, or difficulty listening situations in which environmental noise might interfere with speech intelligibility. Products making these or similar claims should not be considered PSAPs. In addition, products that are sold as an “over the counter” alternative or substitute for a hearing aid should not be considered PSAPs. Because PSAPs are not intended to diagnose, treat, cure or mitigate disease and do not alter the structure or function of the body, they are not devices as defined in the FD&C Act. As such, there is no regulatory classification, product code, or definition 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, under which FDA regulates electronic products that emit sonic vibrations, such as sound amplification equipment. (See also 21 CFR 1000.15.) Manufacturers of PSAPs must report defects and adverse events 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 required under 21 CFR Part 1004.

For questions regarding the requirements for PSAPs, please contact the Branch Chief for the Magnetic Resonance and Electronic Products Branch at 301-796-6503.

¹ 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.Â Section 201(h) (2), (3) of the FD&C Act (21 U.S.C. 321).

² 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 (Section 531(2) of the FD&C Act).

³ In accordance with 21 CFR 874.9, a hearing aid device and a wireless air conduction hearing aid are exempt from premarket notification unless the device:Â 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 technology than a legally marketed device of that generic type.

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