Guidance for Industry and FDA Staff

Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products

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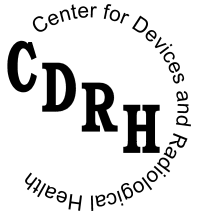

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Ear, Nose, and Throat Devices Branch
Division of Ophthalmic, Neurological and Ear, Nose, and Throat Devices
Office of Device Evaluation

Preface

Public Comment

Written comments and suggestions may be submitted at any time for Agency consideration to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

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Contains Nonbinding Recommendations

Guidance for Industry and FDA Staff

Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

1. Introduction

This guidance document identifies applicable legal requirements under the Food, Drug, and Cosmetic Act (the 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 device[1] that is intended to compensate for impaired hearing. A PSAP is a wearable electronic product[2] that is not intended to compensate for

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[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. Section 201(h)(2), (3) of the 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

impaired hearing, but rather is intended for non-hearing impaired consumers to amplify sounds in the environment for a number of reasons, such as for recreational activities. While some of the technology and function of hearing aids and PSAPs may be similar, the intended use of each article determines whether it is a device or an electronic product. The intended use may be established by labeling materials. Promotional materials that make claims or suggest the use of a PSAP for hearing impaired consumers, such as in the description of the types and severity of hearing loss, establish an intended use that causes the product to be a device and therefore subject to the regulatory requirements for a hearing aid device, as described in this guidance.

The Least Burdensome Approach

The issues identified in this guidance document represent those that we believe need to be addressed before your device can be marketed. In developing the guidance document, we carefully considered the relevant statutory criteria for Agency decision-making. We also considered the burden that may be incurred in your attempt to follow the guidance and address the issues we have identified. We believe that we have considered the least burdensome approach to resolving the issues presented in the guidance document. If, however, you believe that there is a less burdensome way to address the issues, you should follow the procedures outlined in the guidance, **A Suggested Approach to Resolving Least Burdensome Issues**.[3]

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) before marketing. (Section 513(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(a))).

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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 Act (21 U.S.C. 360dd.

[3] http://www.fda.gov/cdrh/modact/leastburdensome.html

Hearing aid devices, as distinguished from cochlear implants, may be class I devices[4] and exempt from premarket review and clearance before marketing, or class II devices, which require premarket review and clearance by FDA before marketing. Procodes for the various types of devices under these classification regulations may be found at:

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

The regulatory definition of a class I 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 class II 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). 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." 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

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[4] In accordance with section 874.9, a hearing aid device is 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 technology than a legally marketed device of that generic type.

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 Branch Chief for Ear, Nose, and Throat Devices at 240-276-4242.

3. Personal Sound Amplification Products (PSAPs)

PSAPs are intended to amplify environmental sound for non-hearing impaired consumers. They are not intended to compensate for hearing impairment. 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, performances). 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 Food, Drug and Cosmetic Act. As such, there is no regulatory classification, product code, or definition for these products. Furthermore, there are no requirements for registration of manufacturers and 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 Electronic Products Branch at 240-276-3291.