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MEMORANDUM

DATE: January 31, 2017

TO: Hearing and Speech Board Members
Washington State Department of Health

FROM: Joyce A. Roper, Senior Assistant Attorney General
Agriculture and Health Division

SUBJECT: **FDA Guidance -- Immediately in Effect Guidance Document: Conditions for Sale for Air-Conduction Hearing Aids (Issued on December 12, 2016)**

BACKGROUND

On December 1, 2016, Senators Warren and Grassley introduced Senate Bill (SB) 9, titled "To Provide for the Regulation of Over-the-Counter Hearing Aids." [1] The bill would void the November 7, 2013 Draft Guidance issued by the FDA, entitled "Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products," and reinstate a February 25, 2009 Guidance until a new guidance, consistent with the SB 9,can be adopted.[2] Since the December 1 introduction, no action in Congress has been taken on SB 9.

However, on December 12, 2016, the FDA issued a guidance entitled "Immediately in Effect Guidance Document: Conditions for Sale for Air-Conduction Hearing Aids," purportedly containing nonbinding recommendations.[3] The substantive items in this guidance are similar to those contained in SB 9.

SUMMARY OF DECEMBER 12, 2016 GUIDANCE

FDA will not enforce its federal rule requiring a medical evaluation prior to dispensing two categories of hearing aids to patients over the age of 18.[4] In addition, no enforcement will be taken with respect to the record keeping requirement for documentation of the medical

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[1] A copy of SB 9 is attached as Attachment 1 for ease of reference.

[2] The November 7, 2013 Guidance is attached as Attachment 2, and the February 25, 2009 Guidance is attached as Attachment 3 for ease of reference.

[3] The December 12, 2016 Guidance is attached as Attachment 4 for ease of reference.

[4] 21 C.F.R. § 801.421(a).

evaluations for those patients.[5] The two categories of hearing aids are class I air-conduction hearing aids[6] and class II wireless air-conduction hearing aids[7] and only for patients who are 18 years of age and older.

FDA is continuing to enforce existing labeling requirements, which read as follows:

> The User Instructional Brochure shall contain the following notice:
>
> **IMPORTANT NOTICE FOR PROSPECTIVE HEARING AID USERS**
>
> Good health practice requires that a person with a hearing loss have a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing aid. Licensed physicians who specialize in diseases of the ear are often referred to as otolaryngologists, otologists or otorhinolaryngologists. The purpose of the medical evaluation is to assure that all medically treatable conditions that may affect hearing are identified and treated before the hearing aid is purchased.[8]

AND

> **Warning statement. The User Instructional Brochure shall contain the following warning statement:**
> **Warning to Hearing Aid Dispensers**
> A hearing aid dispenser should advise a prospective hearing aid user to consult promptly with a licensed physician (preferably an ear specialist) before dispensing a hearing aid if the hearing aid dispenser determines 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:
> (i) Visible congenital or traumatic deformity of the ear.
> (ii) History of active drainage from the ear within the previous 90 days.
> (iii) History of sudden or rapidly progressive hearing loss within the previous 90 days.
> (iv) Acute or chronic dizziness.
> (v) Unilateral hearing loss of sudden or recent onset within the previous 90 days.
> (vi) Audiometric air-bone gap equal to or greater than 15 decibels at 500 hertz (Hz), 1,000 Hz, and 2,000 Hz.
> (vii) Visible evidence of significant cerumen accumulation or a foreign body in the ear

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[5] 21 C.F.R. § 801.421(d).

[6] 21 C.F.R. § 874.3300(b)(1)

[7] 21 C.F.R. § 874.3305

[8] 21 C.F.R. § 801.420(c)(3)

canal.
(viii) Pain or discomfort in the ear.

Special care should be exercised in selecting and fitting a hearing aid whose maximum sound pressure level exceeds 132 decibels because there may be risk of impairing the remaining hearing of the hearing aid user. (This provision is required only for those hearing aids with a maximum sound pressure capability greater than 132 decibels (dB).)[9]

This guidance does not apply to:

- Class II bone-conduction hearing aids[10]
- Hearing aids labeled for prescription-use only
- Hearing aids for persons younger than 18 years of age

FDA'S NEXT STEPS

The guidance is based on two reports:

1) an October 2015 report by the President's Council of Advisors on Science and Technology (PCAST), and
2) a June 2, 2016 study co-sponsored by the FDA, other federal agencies and consumer advocacy groups entitled "Hearing Health Care for Adults: Priorities for Improving Access and Affordability," prepared through the National Academies of Sciences, Engineering and Medicine (NAS).

The PCAST report recommended:

- the FDA should approve a class of hearing aids for over-the-counter sale, without the requirement for consultation with a credentialed dispenser, and
- the requirement for a medical examination or a written waiver provides little patient benefit and acts as a barrier to access for those needing hearing assistance.

The NAS report concluded:

- the health risk of missed diagnosis for treatable causes of hearing loss is low
- the waiver presented a barrier to access without enhancing patient safety
- the majority of consumers sign the waiver in lieu of a medical evaluation.

The two reports contained other recommendations, which the FDA intends to consider and address in the future, such as a regulatory framework for hearing aids to be sold directly over-the-counter to consumers without the requirement for consultation with a credentialed dispenser.

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[9] 21 C.F.R. § 801.420(c)(2)

[10] 21 C.F.R. § 874.3300(b)(2)

The FDA intends to reexamine 21 C.F.R. § 801.421 to amend it in the usual federal rulemaking process. Presumably, this includes both the provisions not being enforced based on this guidance (21 C.F.R. § 801.421(a) and (d)), and the other subsections, such as the opportunity to review the availability and notice language in the User Instructional Brochure in 21 C.F.R. § 801.421(b) and (c).

STATE LAW REQUIREMENTS

The state statute and rules regulating hearing aid specialists and audiologists refer to medical evaluations for persons over 18 years of age prior to dispensing hearing aids in three provisions. First, RCW 18.35.110(1)(e)(i) declares disciplinary action may be taken when a licensee or interim permit holder fails to advise the prospective hearing aid user, in writing, that the user should first consult a licensed physician prior to dispensing the hearing instrument ***IF***, from observations by the licensee or permittee or on the basis of information provided by the user, any of the following conditions are found or should have been found to exist:

- visible congenital or traumatic deformity of the ear, including perforation of the eardrum;
- history of, or active drainage from the ear within the previous 90 days;
- history of sudden or rapidly progressive hearing loss within the previous 90 days;
- acute or chronic dizziness;
- any unilateral hearing loss;
- significant air-bone gap when generally acceptable standards have been established by the FDA;
- visible evidence of significant cerumen accumulation or foreign body in the ear canal;
- pain or discomfort in the ear; or
- any other conditions established by the Board in rule.

Referral is not required if the service provided is solely for replacement of a lost or damaged hearing instrument within 12 months of purchase. RCW 18.35.110(1)(e)(i) also requires a signed statement from the user if the user waives the medical examination and the waiver must inform the user that waiving the examination is not in his or her best health interest. The waiver or documentation of medical evaluation must be maintained for three years after purchase of the hearing instrument.

The two other provisions are in the administrative rules for audiologists and hearing instrument fitting and dispensing, which also require documentation of referrals in WAC 246-828-095(1)(a) and -100(1)(a), respectively. WAC 246-828-100(4) states that a hearing aid specialist or audiologist may not sell a hearing instrument unless the prospective patient or client provides a statement that his or her hearing loss has been medically evaluated in the preceding six months and the patient or client may be considered a candidate for a hearing instrument. Patients and clients who are 18 years of age or older may waive the medical evaluation and the waiver must be retained in the audiologist or hearing aid specialist's records.

EFFECT OF FEDERAL GUIDANCE ON STATE LAW

The requirement in RCW 18.35.110(1)(e)(i) is not inconsistent with the federal guidance because it requires a referral for medical evaluation only when the licensee or permittee knew or should have known that one of the listed conditions exists or likely exists. While the federal guidance dispenses with the federal standards of requiring a medical evaluation referral for the sale of class I air-conduction hearing aids and class II wireless air-conduction hearing aids, the mandated warnings, including the referral recommendations when specific conditions are suspected or found, remain in effect. Those conditions are the same as the conditions listed in RCW 18.35.110(1)(e)(i).

The Board's administrative rules, WAC 246-828-095(1)(a) and -100(1)(a) do not list specific conditions but instead refers generically to documentation of medical evaluation referrals or, in the alternative, documentation of signed waivers from patients 18 years of age and older. The rules could be read in the context of the Board's statutory authority on referrals for medical evaluations, i.e. RCW 18.35.110(1)(e)(i). Or, the Board could construe the rules to require documentation of medical evaluations or signed waivers for every patient or client, including those receiving class I air-conduction hearing aids and class II wireless air-conduction hearing aids.

The federal guidance is non-binding and there is nothing in the federal law upon which the guidance is based that preempts state law. Unless the federal law preempts state law, the state laws continue to apply to persons regulated by the Hearing and Speech Board.

The opinions in this memo are those of the author only and do not represent the opinion of the State of Washington Office of the Attorney General.

JAR/BL
Attachments
cc: Janette Benham, Program Manager, DOH
Trina B. Crawford, Executive Director, DOH

II

114TH CONGRESS
2D SESSION

S. 9

To provide for the regulation of over-the-counter hearing aids.

IN THE SENATE OF THE UNITED STATES

DECEMBER 1, 2016

Ms. WARREN (for herself and Mr. GRASSLEY) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To provide for the regulation of over-the-counter hearing aids.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Over-the-Counter Hearing Aid Act of 2016".

SEC. 2. REGULATION OF OVER-THE-COUNTER HEARING AIDS.

(a) IN GENERAL.—Section 520 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j) is amended by adding at the end the following:

"(o) REGULATION OF OVER-THE-COUNTER HEARING AIDS.—

"(1) DEFINITION.—In this subsection, the term 'over-the-counter hearing aid' means a device—

"(A) that uses the same fundamental scientific technology as air conduction hearing aids (as defined in section 874.3300 of title 21, Code of Federal Regulations) (or any successor regulation) or wireless air conduction hearing aids (as defined in section 874.3305 of title 21, Code of Federal Regulations) (or any successor regulation);

"(B) that is intended to be used by adults to compensate for perceived mild to moderate hearing impairment;

"(C) that includes tools to allow the user to control the over-the-counter hearing aid and customize it to the user's hearing needs;

"(D) that may—

"(i) use wireless technology; or

"(ii) include tests for self-assessment of hearing loss; and

"(E) that 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.

"(2) REGULATION.—An over-the-counter hearing aid shall be subject to the regulations promulgated in accordance with section 2(b) of the Over-the-Counter Hearing Aid Act of 2016 and shall be exempt from sections 801.420 and 801.421 of title 21, Code of Federal Regulations (or any successor regulations).".

(b) REGULATIONS TO ESTABLISH CATEGORY.—

(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the "Secretary"), not later than 3 years after the date of enactment of this Act, shall promulgate proposed regulations to establish a category of over-the-counter hearing aids, as defined in subsection (o) of section 520 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j) as amended by subsection (a), and, not later than 180 days after the date on which the proposed regulations are issued, shall issue such final regulations.

(2) REQUIREMENTS.—In promulgating the regulations under paragraph (1), the Secretary shall—

(A) include requirements that provide reasonable assurances of the safety and efficacy of

over-the-counter hearing aids, such as appropriate consumer labeling; and

(B) describe the requirements under which the sale of over-the-counter hearing aids is permitted, without the supervision, prescription, or other order, involvement, or intervention of a licensed person, to consumers through in-person transactions, by mail, or online.

(3) PREMARKET NOTIFICATION.—The Secretary shall make findings under section 510(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(m)) to determine whether over-the-counter hearing aids (as defined in section 520(o) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(o)), as amended by subsection (a)) require a report under section 510(k) to provide reasonable assurance of safety and effectiveness.

(4) EFFECT ON STATE LAW.—No State or local government shall establish or continue in effect any law, regulation, order, or other requirement related to the manufacturing, marketing, sale, customer support, or distribution of over-the-counter hearing aids (as defined in section 520(o) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(o)), as amended by subsection (a)) through in-person

transactions, by mail, or online, that is different from, in addition to, or otherwise not identical to, the regulations promulgated under this subsection.

(c) GUIDANCE.—

(1) WITHDRAWAL OF GUIDANCE.—

(A) WITHDRAWAL.—Effective as of the date of enactment of this Act, the Secretary shall not use the draft guidance of the Department of Health and Human Services entitled, "Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products", issued on November 7, 2013, as the basis for any premarket review under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or for any related compliance or enforcement decisions or actions.

(B) INTERIM GUIDANCE.—Until such time as new final guidance is issued under paragraph (2) to replace the guidance described in subparagraph (A), the draft guidance entitled "Guidance for Industry and FDA Staff: Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products," issued on February 25, 2009, shall be in effect.

(2) NEW GUIDANCE ISSUED.—Not later than the date on which final regulations are issued under subsection (b), the Secretary shall update the draft guidance described in paragraph (1)(A). Such updated guidance shall clarify which products, on the basis of claims or other marketing, advertising, or labeling material, meet the definition of a device, as defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) and which products meet the definition of a personal sound amplification product, as set forth in such guidance.

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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

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.
Document issued on: November 7, 2013

You should submit comments and suggestions regarding this draft document within [90] days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.regulations.gov. Identify all comments with the docket number listed in the notice of availability that publishes in the Federal Register.

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
Ear, Nose, and Throat Devices Branch

Preface

Additional Copies

Additional copies are available from the Internet. You may also send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the guidance or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number (1832) to identify the guidance you are requesting.

Contains Nonbinding Recommendations

Draft - Not for Implementation

Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products

Draft Guidance for Industry and Food and Drug Administration Staff

This draft guidance, when finalized, will represent 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 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 device[1] 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

[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 FD&C Act (21 U.S.C. 321).

wearable electronic product[2] 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).

[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).

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: 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] 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: 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.

(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). 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 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). 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.

Guidance for Industry and FDA Staff

Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products

Document issued on: February 25, 2009

For questions regarding this document, contact Eric A. Mann, M.D., Ph.D. at 240-276-4242 or via email at eric.mann@fda.hhs.gov .

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

Additional copies are available from the Internet at: http://www.fda.gov/cdrh/ode/guidance/1696.pdf . You may also send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the guidance or send a fax request to 240-276-3151 to receive a hard copy. Please use the document number (**1696**) to identify the guidance you are requesting

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

[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.

Contains Nonbinding Recommendations

Immediately in Effect Guidance Document: Conditions for Sale for Air-Conduction Hearing Aids

Guidance for Industry and Food and Drug Administration Staff

Document issued on December 12, 2016.

For questions about this document, contact Eric Mann at (301) 796-5620.

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 (DOED)

Preface

Public Comment

You may submit electronic comments and suggestions at any time for Agency consideration to http://www.regulations.gov. Submit written comments to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Identify all comments with the docket number FDA-2016-D-3466. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

Additional copies are available from the Internet. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please use the document number GUD-16-041 to identify the guidance you are requesting.

Contains Nonbinding Recommendations

Immediately in Effect Guidance Document: Conditions for Sale for Air-Conduction Hearing Aids

Guidance for Industry and Food and Drug Administration Staff

This guidance represents 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 describes one part of FDA's effort to create a flexible and adaptive regulatory approach to the oversight of hearing aids to increase availability and accessibility of these devices.

Hearing loss is estimated to affect 30 million people in the United States[1] and can have a significant impact on communication, social participation, and overall health and quality of life.[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.[3] Several barriers may contribute to the low use of hearing aids in hearing impaired individuals such as high cost, stigma of being perceived as old or debilitated, and value (hearing benefit relative to price).[4]

FDA regulations regarding conditions for sale have also been cited as a potential barrier to availability and accessibility of hearing aids.[5,6] FDA is issuing this guidance to communicate to

[1] Lin FR, Niparko JK, Ferrucci L. *Hearing loss prevalence in the United States.* Archives of Internal Medicine 2011;171(20):1851-1853.
[2] Dalton DS. *The impact of hearing loss on quality of life in older adults.* The Gerontologist 2005;43(5):661-668.
[3] World Health Organization Deafness and hearing impairment. Fact sheet No. 300. 2006 http://www.who.int/mediacentre/factsheets/fs300/en/index.html.
[4] McCormack A, Fortnum H. *Why do people fitted with hearing aids not wear them?* International Journal of Audiology 2013;52(5):360-368.
[5] President's Council of Advisors on Science and Technology (PCAST) Report on *Hearing Aids: Aging America & Hearing Loss: Imperative of Improved Hearing Technologies*, October 2015 available at https://www.whitehouse.gov/sites/default/files/microsites/ostp/PCAST/pcast_hearing_tech_letterreport_final.pdf.
[6] National Academies of Sciences, Engineering and Medicine (NAS) Report on *Hearing Health Care for Adults: Priorities for Improving Access and Affordability.* June 2016 available at

consumers, hearing aid dispensers, hearing aid manufacturers, and hearing health professionals that FDA does not intend to enforce certain conditions for sale of hearing aid devices that are required per FDA regulation. Specifically, 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, FDA will 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.

This guidance is being implemented without prior public comment because the Agency has determined that prior public participation is not feasible or appropriate (Section 701(h)(1)(C)(i) of the FD&C Act and 21 CFR 10.115(g)(2)). FDA has determined that this guidance document presents a less burdensome policy that is consistent with public health. Although this guidance is immediately in effect, FDA will consider all comments received and revise the guidance document as appropriate.

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.

II. Background

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. In light of this, FDA has previously taken regulatory actions intended to promote the availability and accessibility of hearing aid devices to consumers. For example, the Agency has exempted certain hearing aids from premarket notification, including those regulated as air-conduction hearing aids under 21 CFR 874.3300(b)(1) and 21 CFR 874.3305. However, other FDA regulations that require specific labeling and conditions for sale, initially implemented in the late 1970's, have been cited as a potential barrier to access.[7,8] The labeling regulation (21 CFR 801.420) outlines requirements for a User Instructional Brochure for all hearing aid devices which must include: 1) general labeling instructions (e.g., instructions for device use, maintenance and service, and a statement that hearing aids will not restore normal hearing), 2) a "Warning to Hearing Aid Dispensers" which advises a dispenser to promptly refer any prospective user to a licensed physician (preferably an ear specialist) if the dispenser detects certain listed medical conditions which may indicate a medically treatable cause of hearing loss, 3) an "Important Notice for Prospective Hearing Aid Users" which stresses the importance of a medical evaluation (preferably by a specialist in ear disorders), and 4) technical data useful in

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http://www.hearingreview.com/2016/06/national-academies-sciences-release-report-hearing-aid-accessibility-affordability/.

[7] Gudmundsen petition, 2003, Docket No. FDA-2003-P-0342, http://www.fda.gov/ohrms/dockets/dailys/03/aug03/081203/03p-0363-cp00001-vol1.pdf.

[8] FDA enacted regulations regarding "Hearing aid devices; professional and patient labeling" (21 CFR 801.420) and "Hearing aid devices; conditions for sale" (21 CFR 801.421).

selecting, fitting and checking the performance of a hearing aid. In part, the "Conditions for Sale" regulation (21 CFR 801.421(a)) requires that all prospective hearing aid users must have a medical evaluation by a licensed physician within the 6 months prior to the hearing aid dispensation. Individuals 18 years of age and older may waive the requirement for a medical evaluation by signing a waiver statement.

Two recent reports issued recommendations intended to facilitate hearing aid innovation and to improve affordability and patient access. A report in October 2015 by the President's Council of Advisors on Science and Technology (PCAST) recommended that, "FDA should approve [a] class of hearing aids for over-the-counter (OTC) sale, without the requirement for consultation with a credentialed dispenser." The report also concluded that "the requirement for a medical examination (or a written waiver of such examination) provides little patient benefit, while acting as a barrier to access for the millions of Americans needing hearing assistance."[5] In addition to the PCAST report, FDA and other federal agencies and consumer advocacy groups co-sponsored a study entitled, "Hearing Health Care for Adults: Priorities for Improving Access and Affordability," through the National Academies of Sciences, Engineering and Medicine (NAS).[6] The NAS published the study report on June 2, 2016, which recommends that the medical evaluation requirement be removed for adults. After a review of the literature and relevant clinical databases from the U.S. Department of Defense and the U.S. Department of Veterans Affairs, NAS concluded that the health risk of missed diagnosis of treatable causes of hearing loss is low, and "the regulation provides no clinically meaningful benefit, and the waiver presents a barrier to access with no substantial enhancement of patient safety." Finally, it has been reported that a majority of consumers today are signing the waiver in lieu of a medical evaluation.[9]

Based on the information described above, and in an effort to improve the accessibility of hearing aid devices to consumers, FDA is issuing this guidance to communicate that it does not intend to enforce certain conditions for sale applicable to hearing aids. In addition to recommendations about the medical evaluation and recordkeeping requirements addressed in this guidance, the PCAST and NAS reports provide other recommendations regarding FDA's regulation of hearing aids. FDA does intend to consider and address those recommendations in the future as appropriate, including those regarding a regulatory framework for hearing aids that can be sold directly OTC to consumers, without the requirement for consultation with a credentialed dispenser. FDA intends to solicit additional public input from stakeholders before adopting such an approach.

III. Scope

This guidance applies to the subset of hearing aids that are regulated as class I air-conduction hearing aids under 21 CFR 874.3300(b)(1) and class II wireless air-conduction hearing aids under 21 CFR 874.3305, where hearing aids mean "any wearable instrument or device designed for, offered for the purpose of, or represented as aiding persons with or compensating for, impaired hearing," as defined in 21 CFR 801.420(a)(1).

[9] Adams, SB. *Who will hear? An examination of the regulation of hearing aids.* Journal of Contemporary Health Law & Policy 1995;11(2):505-521.

This guidance does not apply to class II bone-conduction hearing aids as identified in 21 CFR 874.3300(b)(2). Bone-conduction hearing aids are generally used for specific types of hearing loss (e.g., conductive/mixed hearing loss, unilateral hearing loss), and are commonly used for patients with important medical conditions (e.g., chronic draining ears, atresia or deformity of ear canal) which require medical attention. Also, hearing aids labeled for prescription-use only, e.g., those that are inserted deep in the ear canal by a hearing health professional, should continue to be sold only as directed.

This guidance does not apply to hearing aid users younger than 18 years of age. FDA will continue to enforce the medical evaluation requirement for all prospective hearing aid users younger than 18 years of age.

IV. Approach to Conditions for Sale

As described above, recent expert reports and recommendations from PCAST and NAS, as well as public comments to the dockets[10,11] for the guidance entitled "Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products - Draft Guidance for Industry and Food and Drug Administration Staff" (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm373461.htm) and FDA's workshop on "Streamlining Good Manufacturing Process for Hearing Aids" (http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm480336.htm), have provided FDA with new information and perspective on the current regulatory scheme for hearing aids. The PCAST and NAS reports in particular reach a similar conclusion that the medical examination and waiver requirements are providing little public benefit for users 18 years of age and older, while posing barriers to access for consumers that would benefit from the use of a hearing aid. On the basis of these viewpoints, and in light of the fact that the majority of consumers today are opting to waive the requirement for a medical examination, FDA intends to reexamine and propose to modify the corresponding "conditions for sale" regulation (21 CFR 801.421). Notice of such a proposal would be provided in the Federal Register. However, for the same reasons prompting FDA to reassess the hearing aid regulations, and until such publication of a final rule or order, FDA does not intend to enforce compliance with the specified "conditions of sale" for certain hearing aids as described in this guidance.

This policy is also informed by the continued enforcement of existing labeling requirements for hearing aids including the required notice for prospective hearing aid users (21 CFR 801.420(c)(3)) which states, in part:

> *The User Instructional Brochure shall contain the following notice:*
> *IMPORTANT NOTICE FOR PROSPECTIVE HEARING AID USERS*

[10] 81 FR 786, Docket No. FDA-2013-D-1295, https://www.regulations.gov/document?D=FDA-2013-D-1295-0048.
[11] 81 FR 784 and 81 FR 28083, Docket No. FDA-2015-N-4602, https://www.regulations.gov/searchResults?rpp=25&po=0&s=FDA-2015-N-4602&fp=true&ns=true.

Contains Nonbinding Recommendations

Good health practice requires that a person with a hearing loss have a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing aid. Licensed physicians who specialize in diseases of the ear are often referred to as otolaryngologists, otologists or otorhinolaryngologists. The purpose of the medical evaluation is to assure that all medically treatable conditions that may affect hearing are identified and treated before the hearing aid is purchased.

Additionally, a warning statement is also required as provided in 21 CFR 801.420(c)(2), which states the following:

Warning statement. The User Instructional Brochure shall contain the following warning statement:

Warning to Hearing Aid Dispensers

A hearing aid dispenser should advise a prospective hearing aid user to consult promptly with a licensed physician (preferably an ear specialist) before dispensing a hearing aid if the hearing aid dispenser determines 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:

(i) Visible congenital or traumatic deformity of the ear.

(ii) History of active drainage from the ear within the previous 90 days.

(iii) History of sudden or rapidly progressive hearing loss within the previous 90 days.

(iv) Acute or chronic dizziness.

(v) Unilateral hearing loss of sudden or recent onset within the previous 90 days.

(vi) Audiometric air-bone gap equal to or greater than 15 decibels at 500 hertz (Hz), 1,000 Hz, and 2,000 Hz.

(vii) Visible evidence of significant cerumen accumulation or a foreign body in the ear canal.

(viii) Pain or discomfort in the ear.

Special care should be exercised in selecting and fitting a hearing aid whose maximum sound pressure level exceeds 132 decibels because there may be risk of impairing the remaining hearing of the hearing aid user. (This provision is required only for those hearing aids with a maximum sound pressure capability greater than 132 decibels (dB).)

Finally, under 21 CFR 801.421(b) and (c), hearing aid dispensers are required to provide prospective users an opportunity to review and to make available the User Instructional Brochure, containing the above labeling requirements, before the sale of a hearing aid.

Due to the specific needs and health concerns associated with children with hearing loss, we believe that the medical evaluation requirement should continue to be enforced for all prospective hearing aid users younger than 18 years of age. As such, this guidance does not apply to users under 18 years of age.

Excerpts of Cited Federal Rules

Title 21: Food and Drugs
PART 801—LABELING
Subpart H—Special Requirements for Specific Devices

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§801.420 Hearing aid devices; professional and patient labeling.

(a) *Definitions for the purposes of this section and §801.421.* (1) *Hearing aid* means any wearable instrument or device designed for, offered for the purpose of, or represented as aiding persons with or compensating for, impaired hearing.

(2) *Ear specialist* means any licensed physician who specializes in diseases of the ear and is medically trained to identify the symptoms of deafness in the context of the total health of the patient, and is qualified by special training to diagnose and treat hearing loss. Such physicians are also known as otolaryngologists, otologists, and otorhinolaryngologists.

(3) *Dispenser* means any person, partnership, corporation, or association engaged in the sale, lease, or rental of hearing aids to any member of the consuming public or any employee, agent, sales person, and/or representative of such a person, partnership, corporation, or association.

(4) *Audiologist* means any person qualified by training and experience to specialize in the evaluation and rehabilitation of individuals whose communication disorders center in whole or in part in the hearing function. In some states audiologists must satisfy specific requirements for licensure.

(5) *Sale* or *purchase* includes any lease or rental of a hearing aid to a member of the consuming public who is a user or prospective user of a hearing aid.

(6) *Used hearing aid* means any hearing aid that has been worn for any period of time by a user. However, a hearing aid shall not be considered "used" merely because it has been worn by a prospective user as a part of a bona fide hearing aid evaluation conducted to determine whether to select that particular hearing aid for that prospective user, if such evaluation has been conducted in the presence of the dispenser or a hearing aid health professional selected by the dispenser to assist the buyer in making such a determination.

(b) *Label requirements for hearing aids.* Hearing aids shall be clearly and permanently marked with:

(1) The name of the manufacturer or distributor, the model name or number, the serial number, and the year of manufacture.

(2) A " + " symbol to indicate the positive connection for battery insertion, unless it is physically impossible to insert the battery in the reversed position.

(c) *Labeling requirements for hearing aids*—(1) *General.* All labeling information required by this paragraph shall be included in a User Instructional Brochure that shall be developed by the manufacturer or distributor, shall accompany the hearing aid, and shall be provided to the prospective user by the dispenser of the hearing aid in accordance with §801.421 (c). The User Instructional Brochure accompanying each hearing aid shall contain the following information and instructions for use, to the extent applicable to the particular requirements and characteristics of the hearing aid:

(i) An illustration(s) of the hearing aid, indicating operating controls, user adjustments, and battery compartment.

(ii) Information on the function of all controls intended for user adjustment.

(iii) A description of any accessory that may accompany the hearing aid, e.g., accessories for use with a television or telephone.

(iv) Specific instructions for:

(*a*) Use of the hearing aid.

(*b*) Maintenance and care of the hearing aid, including the procedure to follow in washing the earmold, when replacing tubing on those hearing aids that use tubing, and in storing the hearing aid when it will not be used for an extended period of time.

(*c*) Replacing or recharging the batteries, including a generic designation of replacement batteries.

(v) Information on how and where to obtain repair service, including at least one specific address where the user can go, or send the hearing aid to, to obtain such repair service.

(vi) A description of commonly occurring avoidable conditions that could adversely affect or damage the hearing aid, such as dropping, immersing, or exposing the hearing aid to excessive heat.

(vii) Identification of any known side effects associated with the use of a hearing aid that may warrant consultation with a physician, e.g., skin irritation and accelerated accumulation of cerumen (ear wax).

(viii) A statement that a hearing aid will not restore normal hearing and will not prevent or improve a hearing impairment resulting from organic conditions.

(ix) A statement that in most cases infrequent use of a hearing aid does not permit a user to attain full benefit from it.

(x) A statement that the use of a hearing aid is only part of hearing habilitation and may need to be supplemented by auditory training and instruction in lipreading.

(xi) The warning statement required by paragraph (c)(2) of this section.

(xii) The notice for prospective hearing aid users required by paragraph (c)(3) of this section.

(xiii) The technical data required by paragraph (c)(4) of this section, unless such data is provided in separate labeling accompanying the device.

(2) *Warning statement.* The User Instructional Brochure shall contain the following warning statement:

WARNING TO HEARING AID DISPENSERS

A hearing aid dispenser should advise a prospective hearing aid user to consult promptly with a licensed physician (preferably an ear specialist) before dispensing a hearing aid if the hearing aid dispenser determines 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:

(i) Visible congenital or traumatic deformity of the ear.

(ii) History of active drainage from the ear within the previous 90 days.

(iii) History of sudden or rapidly progressive hearing loss within the previous 90 days.

(iv) Acute or chronic dizziness.

(v) Unilateral hearing loss of sudden or recent onset within the previous 90 days.

(vi) Audiometric air-bone gap equal to or greater than 15 decibels at 500 hertz (Hz), 1,000 Hz, and 2,000 Hz.

(vii) Visible evidence of significant cerumen accumulation or a foreign body in the ear canal.

(viii) Pain or discomfort in the ear.

Special care should be exercised in selecting and fitting a hearing aid whose maximum sound pressure level exceeds 132 decibels because there may be risk of impairing the remaining hearing of the hearing aid user. (This provision is required only for those hearing aids with a maximum sound pressure capability greater than 132 decibels (dB).)

(3) *Notice for prospective hearing aid users.* The User Instructional Brochure shall contain the following notice:

IMPORTANT NOTICE FOR PROSPECTIVE HEARING AID USERS

Good health practice requires that a person with a hearing loss have a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing aid. Licensed physicians who specialize in diseases of the ear are often referred to as otolaryngologists, otologists or otorhinolaryngologists. The purpose of medical evaluation is to assure that all medically treatable conditions that may affect hearing are identified and treated before the hearing aid is purchased.

Following the medical evaluation, the physician will give you a written statement that states that your hearing loss has been medically evaluated and that you may be considered a candidate for a hearing aid. The physician will refer you to an audiologist or a hearing aid dispenser, as appropriate, for a hearing aid evaluation.

The audiologist or hearing aid dispenser will conduct a hearing aid evaluation to assess your ability to hear with and without a hearing aid. The hearing aid evaluation will enable the audiologist or dispenser to select and fit a hearing aid to your individual needs.

If you have reservations about your ability to adapt to amplification, you should inquire about the availability of a trial-rental or purchase-option program. Many hearing aid dispensers now offer programs that permit you to wear a hearing aid for a period of time for a nominal fee after which you may decide if you want to purchase the hearing aid.

Federal law restricts the sale of hearing aids to those individuals who have obtained a medical evaluation from a licensed physician. Federal law permits a fully informed adult to sign a waiver statement declining the medical evaluation for religious or personal beliefs that preclude consultation with a physician. The exercise of such a waiver is not in your best health interest and its use is strongly discouraged.

CHILDREN WITH HEARING LOSS

In addition to seeing a physician for a medical evaluation, a child with a hearing loss should be directed to an audiologist for evaluation and rehabilitation since hearing loss may cause problems in language development and the educational and social growth of a child. An audiologist is qualified by training and experience to assist in the evaluation and rehabilitation of a child with a hearing loss.

(4) *Technical data.* Technical data useful in selecting, fitting, and checking the performance of a hearing aid shall be provided in the User Instructional Brochure or in separate labeling that accompanies the device. The determination of technical data values for the hearing aid labeling shall be conducted in accordance with the test procedures of the American National Standard "Specification of Hearing Aid Characteristics," ANSI S3.22-2003 (Revision of ANSI S3.22-1996) (Includes April 2007 Erratum). The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Standards Secretariat of the Acoustical Society of America, 120 Wall St., New York, NY 10005-3993, or are available for inspection at the Regulations Staff, CDRH (HFZ-215), FDA, 1350 Piccard Dr., rm. 150, Rockville, MD 20850, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.* As a minimum, the User Instructional Brochure or such other labeling shall include the appropriate values or information for the following technical data elements as these elements are defined or used in such standard:

(i) Saturation output curve (SSPL 90 curve).

(ii) Frequency response curve.

(iii) Average saturation output (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) Battery current drain.

(x) Induction coil sensitivity (telephone coil aids only).

(xi) Input-output curve (ACG aids only).

(xii) Attack and release times (ACG aids only).

(5) *Statement if hearing aid is used or rebuilt.* If a hearing aid has been used or rebuilt, this fact shall be declared on the container in which the hearing aid is packaged and on a tag that is physically attached to such hearing aid. Such fact may also be stated in the User Instructional Brochure.

(6) *Statements in User Instructional Brochure other than those required.* A User Instructional Brochure may contain statements or illustrations in addition to those required by paragraph (c) of this section if the additional statements:

(i) Are not false or misleading in any particular, e.g., diminishing the impact of the required statements; and

(ii) Are not prohibited by this chapter or by regulations of the Federal Trade Commission.

[42 FR 9294, Feb. 15, 1977, as amended at 47 FR 9398, Mar. 5, 1982; 50 FR 30154, July 24, 1985; 54 FR 52396, Dec. 21, 1989; 64 FR 59620, Nov. 3, 1999; 69 FR 18803, Apr. 9, 2004; 73 FR 31360, June 2, 2008]

Need assistance?

Title 21: Food and Drugs
PART 801—LABELING
Subpart H—Special Requirements for Specific Devices

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§801.421 Hearing aid devices; conditions for sale.

(a) *Medical evaluation requirements*—(1) *General.* Except as provided in paragraph (a)(2) of this section, a hearing aid dispenser shall not sell a hearing aid unless the prospective user has presented to the hearing aid dispenser a written statement signed by a licensed physician that states that the patient's hearing loss has been medically evaluated and the patient may be considered a candidate for a hearing aid. The medical evaluation must have taken place within the preceding 6 months.

(2) *Waiver to the medical evaluation requirements.* If the prospective hearing aid user is 18 years of age or older, the hearing aid dispenser may afford the prospective user an opportunity to waive the medical evaluation requirement of paragraph (a)(1) of this section provided that the hearing aid dispenser:

(i) Informs the prospective user that the exercise of the waiver is not in the user's best health interest;

(ii) Does not in any way actively encourage the prospective user to waive such a medical evaluation; and

(iii) 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.

(b) *Opportunity to review User Instructional Brochure.* Before signing any statement under paragraph (a)(2)(iii) of this section and before the sale of a hearing aid to a prospective user, the hearing aid dispenser shall:

(1) Provide the prospective user a copy of the User Instructional Brochure for a hearing aid that has been, or may be selected for the prospective user;

(2) Review the content of the User Instructional Brochure with the prospective user orally, or in the predominate method of communication used during the sale;

(3) Afford the prospective user an opportunity to read the User Instructional Brochure.

(c) *Availability of User Instructional Brochure.* (1) Upon request by an individual who is considering purchase of a hearing aid, a dispenser shall, with respect to any hearing aid that he dispenses, provide a copy of the User Instructional Brochure for the hearing aid or the name and address of the manufacturer or distributor from whom a User Instructional Brochure for the hearing aid may be obtained.

(2) In addition to assuring that a User Instructional Brochure accompanies each hearing aid, a manufacturer or distributor shall with respect to any hearing aid that he manufactures or distributes:

(i) Provide sufficient copies of the User Instructional Brochure to sellers for distribution to users and prospective users;

(ii) Provide a copy of the User Instructional Brochure to any hearing aid professional, user, or prospective user who requests a copy in writing.

(d) *Recordkeeping.* The dispenser shall retain for 3 years after the dispensing of a hearing aid a copy of any written statement from a physician required under paragraph (a)(1) of this section or any written statement waiving medical evaluation required under paragraph (a)(2)(iii) of this section.

(e) *Exemption for group auditory trainers.* Group auditory trainers, defined as a group amplification system purchased by a qualified school or institution for the purpose of communicating with and educating individuals with hearing impairments, are exempt from the requirements of this section.

[42 FR 9296, Feb. 15, 1977]

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e-CFR data is current as of January 20, 2017

Title 21: Food and Drugs
PART 874—EAR, NOSE, AND THROAT DEVICES
Subpart D—Prosthetic Devices

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§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.

[51 FR 40389, Nov. 6, 1986, as amended at 65 FR 2316, Jan. 14, 2000]

Title 21: Food and Drugs
PART 874—EAR, NOSE, AND THROAT DEVICES
Subpart D—Prosthetic Devices

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§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 electro magnetic 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.

[76 FR 34846, June 15, 2011]
