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

Guidance for Industry and Food and Drug Administration Staff

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**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

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

Guidance for Industry and Food and Drug Administration Staff

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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 States¹ 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

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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

<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).

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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.

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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/device-regulation-and-guidance/guidance-documents/ucm373461.htm)” (<http://www.fda.gov/medicaldevices/device-regulation-and-guidance/guidance-documents/ucm373461.htm>) and FDA’s workshop on “[Streamlining Good Manufacturing Process for Hearing Aids](http://www.fda.gov/medicaldevices/news-events/workshops-conferences/ucm480336.htm)” (<http://www.fda.gov/medicaldevices/news-events/workshops-conferences/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>.

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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).)

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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.