



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-D-3466]

Immediately in Effect Guidance Document: Conditions for Sale for Air-Conduction Hearing Aids; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the guidance entitled "Immediately in Effect Guidance Document: Conditions for Sale for Air-Conduction Hearing Aids." FDA is issuing this guidance to communicate to 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 or recordkeeping requirements prior to the dispensing of certain hearing aid devices to individuals 18 years of age and older.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to

<http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2016-D-3466 for "Immediately in Effect Guidance Document: Conditions for Sale for Air-Conduction Hearing Aids." Received comments will be placed in the docket and, except for those submitted as

"Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public docket, see 80 FR 56469, September 18, 2015, or access the information at:

<http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the

prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

An electronic copy of the guidance document is available for download from the Internet. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled "Immediately in Effect Guidance Document: Conditions for Sale for Air-Conduction Hearing Aids" to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Srinivas Nandkumar, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 2436, Silver Spring, MD 20993-0002, 301-796-6480.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is issuing this guidance to communicate to 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 (§ 801.421(a) (21 CFR 801.421(a)) or recordkeeping (§ 801.421(d)) requirements prior to the dispensing of certain hearing aid devices to individuals 18 years of age and older.

This guidance applies to the subset of hearing aids that are regulated as class I air-conduction hearing aids under § 874.3300(b)(1) (21 CFR 874.3300(b)(1)) and class II wireless

air-conduction hearing aids under § 874.3305, where 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,” as defined in § 801.420(a)(1). This guidance does not apply to class II bone-conduction hearing aids as identified in § 874.3300(b)(2). 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 is being implemented without prior public comment because the Agency has determined that prior public participation is not feasible or appropriate (see section 701(h)(1)(C)(i) of the FD&C Act (21 U.S.C. 371(h)(1)(C)(i)) and § 10.115.(g)(2) (21 CFR 10.115(g)(2))). FDA believes that immediate implementation of the guidance is needed to assist in addressing a significant public health issue. Further, 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.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (§ 10.115). The guidance represents the current thinking of FDA on conditions for sale for air-conduction hearing aids. 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.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and

Radiological Health guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov>. Persons unable to download an electronic copy of "Immediately in Effect Guidance Document: Conditions for Sale for Air-Conduction Hearing Aids" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 16041 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910-0120; and the collections of information in 21 CFR part 801 have been approved under OMB control number 0910-0485.

Dated: December 1, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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