



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-1295]

Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products;
Draft Guidance for Industry and Food and Drug Administration Staff; Reopening of the
Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA or Agency) is reopening the comment period for the draft guidance entitled "Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products." A notice of availability requesting comments on the draft guidance document appeared in the **Federal Register** of November 7, 2013. The Agency is reopening the comment period to receive updated comments and any new information.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by **[INSERT DATE 120 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

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-2013-D-1295 for "Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products" draft guidance. 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 dockets, 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 draft guidance document is available for download from the Internet. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the draft guidance. Submit written requests for a single hard copy of the draft guidance document entitled "Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products" 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: Eric Mann, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 2438, Silver Spring, MD 20993-0002, 301-796-6460.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 7, 2013 (78 FR 66940), FDA published a notice of availability with a 90-day comment period to request comments on the draft guidance entitled "Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products."

Since issuance of the November 7, 2013, draft guidance entitled "Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products," FDA has become aware of other efforts by the President's Council of Advisors on Science and Technology (PCAST) and Institute of Medicine (IOM) regarding hearing aids and personal sound amplification products (PSAP). In order to allow FDA and other interested parties to consider the PCAST recommendations and information presented and discussed during the recent public IOM meetings on this issue, FDA is reopening the comment period. This will further allow FDA to ensure consistent interpretation, consistent application of relevant regulatory requirements, and adequate protection of the public health.

FDA is reopening the comment period for 120 days. The Agency believes that a 120-day extension allows adequate time for interested parties to submit comments without significantly delaying finalizing the draft guidance on these important issues.

II. Other Issues for Consideration

FDA is soliciting comments on the availability, accessibility, and use of hearing aids and PSAPs for consumers with hearing impairment. Further, FDA requests interested parties to comment on the key issues and recommendations identified in the PCAST reporting, including: (1) The degree to which current FDA regulatory requirements may be acting as a barrier to hearing aid accessibility, affordability, and use of hearing aids; (2) the appropriateness of creating a "basic" category of hearing aids for consumers with "bilateral, gradual onset, mild-to-moderate age-related hearing loss" with appropriate labeling for over-the-counter sale; and (3) whether the benefits of expanded, over-the-counter access to hearing aids in this age-related hearing loss population outweigh the risks of forgoing the condition for sale (that the consumer may waive) that requires a medical evaluation to rule out treatable, potentially progressive causes

of hearing loss.

III. Electronic Access

Persons interested in obtaining a copy of the draft 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 "Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1832 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft 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 801 have been approved under OMB control number 0910-0485, and the collections of information in 21 CFR part 807 subpart E have been approved under OMB control number 0910-0120.

Dated: December 31, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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