



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2020-D-1380]

### Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification

Products; Draft Guidance for Industry and Food and Drug Administration Staff;

### Availability

**AGENCY:** Food and Drug Administration, Health and Human Services (HHS).

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled “Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products.” The FDA Reauthorization Act of 2017 (FDARA) directed FDA to update and finalize the draft guidance entitled “Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products,” issued on November 7, 2013. Therefore, FDA is issuing this updated draft guidance, which supersedes the November 7, 2013, draft guidance. This updated draft guidance is intended to describe hearing aids, personal sound amplification products (PSAPs), their respective intended uses, and the regulatory requirements that apply to these products. This draft guidance is not final nor is it in effect at this time.

**DATES:** Submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance at any time as follows:

#### *Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://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 <https://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): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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-2020-D-1380 for "Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- 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 <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. 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:

<https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

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 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 Policy, 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:** Shu-Chen Peng, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1224, Silver Spring, MD 20993-0002, 301-796-6481.

**SUPPLEMENTARY INFORMATION:**

I. Background

The FDA Reauthorization Act of 2017 (FDARA) (Pub. L. 115-52) directs FDA to establish a category of over-the-counter (OTC) hearing aids through rulemaking, and mandates that FDA establish various requirements for this category of devices. FDA has issued a proposed rule to establish the OTC category of hearing aids and to implement the requirements of FDARA (“Proposed Rule”) as published elsewhere in this edition of the *Federal Register*. In the proposed rule, FDA has also proposed multiple related changes to the overall regulatory framework for hearing aids to harmonize existing regulations with the proposed OTC category while continuing to provide a reasonable assurance of safety and effectiveness.

FDARA also directed FDA to update and finalize the draft guidance entitled “Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products,” issued on November 7, 2013. To fulfill this requirement of FDARA, FDA is issuing this updated draft guidance, which supersedes the November 7, 2013, draft guidance. This updated draft guidance reflects the current regulatory framework for hearing aids and summarizes the new regulatory framework for hearing aids in the proposed rule. After the proposed rule is finalized, this guidance will be updated accordingly so that it only reflects the final regulatory framework for hearing aids.

This guidance identifies current applicable legal requirements under the Federal Food, Drug, and Cosmetic Act for hearing aids and for PSAPs. This guidance is intended to describe hearing aids, PSAPs, their respective intended uses, and the regulatory requirements that apply to both types of products.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on "Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products." 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.

## II. 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 <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products>. This guidance is also available at <https://www.regulations.gov> and at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>. 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](mailto:CDRH-Guidance@fda.hhs.gov) to receive an electronic copy of the document. Please use the document number 1832 and complete title to identify the guidance you are requesting.

## III. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521) is

not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulations have been approved by OMB as listed in the following table:

| 21 CFR Part(s)    | Topic                                                                                                                                 | OMB Control No. |
|-------------------|---------------------------------------------------------------------------------------------------------------------------------------|-----------------|
| 800, 801, and 809 | Medical Device Labeling Regulations                                                                                                   | 0910-0485       |
| 803               | Medical Devices; Medical Device Reporting; Manufacturer reporting, importer reporting, user facility reporting, distributor reporting | 0910-0437       |
| 807, subpart E    | Premarket notification                                                                                                                | 0910-0120       |
| 814               | Premarket Approval Application                                                                                                        | 0910-0231       |
| 1000 through 1050 | Electronic Products                                                                                                                   | 0910-0025       |

This draft guidance also refers to proposed collections of information described in FDA’s proposed rule on “Medical Devices; Ear, Nose, and Throat Devices; Establishing Over-the-Counter Hearing Aids.” The proposed collections of information in the proposed rule are subject to review by OMB under the PRA (44 U.S.C. 3501-3521). As required by the PRA, FDA has published an analysis of the information collection provisions of the proposed rule as published elsewhere in this edition of the *Federal Register* and has submitted it for OMB approval.

Dated: October 12, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

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