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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-4602]

Streamlining Regulations for Good Manufacturing Practices for
Hearing Aids; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public workshop entitled ``Streamlining Regulations for Good Manufacturing Practices (GMPs) for Hearing Aids.'' The topic to be discussed is the appropriate level of good manufacturing practices (GMPs) regulation to ensure the safety and effectiveness of air-conduction hearing aid devices.

DATES: The public workshop will be held on April 21, 2016, from 8:30 a.m. to 5 p.m. Submit either electronic or written comments on the public workshop by May 19, 2016.

ADDRESSES: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to <http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.
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-2015-N-4602 for ``Streamlining Regulations for Good Manufacturing Practices (GMPs) for 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 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.

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FOR FURTHER INFORMATION CONTACT: Srinivas Nandkumar, Food and Drug Administration, Center for Devices and Radiological Health, Bldg. 66, Rm. 2436, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-6480, FAX: 301-847-8126, Srinivas.nandkumar@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Over 35 million people in the United States have some degree of hearing loss. However, it is estimated that only 20 percent of individuals who could benefit from hearing aids are using them. There are several well-recognized reasons or ``barriers'' causing underuse of hearing aids, including the high cost of these devices, the stigma associated with hearing aid use, and the fact that hearing aids do not restore hearing to normal the way that eyeglasses can correct visual problems. On October 26, 2015, the President's Council on Science and Technology (PCAST) issued a report in recognition of the substantial national public health problem of barriers to accessibility and affordability of hearing aids for Americans with ``normal, age-related, progressive, mild-to-moderate hearing loss'' and the underuse of these devices in the older American population. The report includes a number of recommendations regarding possible modifications to Federal Regulation of hearing aids by FDA and the Federal Trade Commission, which PCAST believes could ``enhance the pace of innovation and level of competition, leading to rapid decrease in cost and improvement in capability, convenience, and use of assistive hearing devices'' (https://www.whitehouse.gov/sites/default/files/microsites/ostp/PCAST/pcast_hearing_tech_letterreport_final2.pdf).

Among these recommendations, PCAST recommended FDA exempt hearing aids indicated for bilateral, gradual onset, mild-to-moderate age-related hearing loss from the Quality System Regulation (QSR) in its present form and ``substitute compliance with standards for product quality and recordkeeping appropriate for the consumer electronics industry, developed by an appropriate third-party organization and approved by FDA.''

II. Topics for Discussion at the Public Workshop

In response to PCAST's recommendations outlined in this document, the workshop will discuss the current GMPs that are required under the QSR and gather suggestions for an alternative model for quality verification. Invited speakers will discuss how the current regulations may be unsuitable for air-conduction hearing aids and may hinder innovation, reduce competition, and lead to increased cost and reduced use of these devices by Americans with age-related hearing loss. Additionally, the potential exemption of hearing aids from the QSR, through use of alternative standards developed in collaboration with key stakeholders and standards development organizations, and recognized by FDA and recordkeeping to ensure product quality, will be discussed.

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by 4 p.m. on April 13, 2016. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permits, onsite registration on the day of the public workshop will be provided beginning at 7:30 a.m.

If you need special accommodations due to a disability, please contact Susan Monahan, Center for Devices and Radiological Health, Office of Communication and Education, 301-796-5661, susan.monahan@fda.hhs.gov no later than April 7, 2016.

To register for the public workshop, please visit FDA's Medical Devices News & Events--Workshops & Conferences calendar at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>. (Select this meeting/public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, email, and telephone number. Those without Internet access should contact Susan Monahan (contact for special accommodations) to register. Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

Streaming Webcast of the Public Workshop: This public workshop will

also be Webcast. The Webcast link will be available on the workshop Web page after April 14, 2016. Please visit FDA's Medical Devices News & Events--Workshops & Conferences calendar at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>. (Select this public workshop from the posted events list.) If you have never attended a Connect Pro event before, test your connection at https://collaboration.fda.gov/common/help/en/support/meeting_test.htm. To get a quick overview of the Connect Pro program, visit http://www.adobe.com/go/connectpro_overview. FDA has verified the Web site addresses in this document, as of the date this document publishes in the Federal Register, but Web sites are subject to change over time.

Requests for Oral Presentations: This public workshop includes a public comment session and topic-focused sessions. During online registration, you may indicate if you wish to present during a public comment session or participate in a specific session, and which topics you wish to address. FDA has included general topics in this document. FDA will do its best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the focused sessions. Following the close of registration, FDA will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by April 15, 2016. All requests to make oral presentations must be received by the close of registration on April 13, 2016, 4 p.m. If selected for presentation, any presentation materials must be emailed to Srinivas Nandkumar (see FOR FURTHER INFORMATION CONTACT) no later than April 19, 2016. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

FDA is holding this public workshop to obtain information on the appropriate level of good manufacturing practices for hearing aids. In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the public workshop topics. The deadline for submitting comments related to this public workshop is May 19, 2016.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (see ADDRESSES). A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on the Agency's Web site at <http://www.fda.gov>. A link to the transcripts will also be available approximately 45 days after the public workshop on the Internet at <http://www.fda.gov/MedicalDevices/>

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[NewsEvents/WorkshopsConferences/default.htm](http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm). (Select this meeting/public workshop from the posted events list.)

Dated: December 31, 2015.
Leslie Kux,
Associate Commissioner for Policy.
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