4164-01-P

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; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the comment period for the document entitled "Streamlining Regulations for Good Manufacturing Practices for Hearing Aids; Public Workshop" that appeared in the Federal Register of January 7, 2016. In the document, FDA requested comments on the appropriate level of good manufacturing practices (GMPs) regulation to ensure the safety and effectiveness of air-conduction hearing aid devices. The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the document published January 7, 2016 (81 FR 784). Submit either electronic or written comments by June 30, 2016.

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-2015-N-4602 for "Streamlining Regulations for Good Manufacturing Practices for Hearing Aids; Public Workshop; Request for Comments." 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.

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: In the Federal Register of January 7, 2016 (81 FR 784), FDA published a document with a 30-day comment period to request comments on the appropriate level of GMPs regulation to ensure the safety and effectiveness of air-conduction hearing aid devices; the current regulations for air-conduction hearing aids that may hinder innovation, reduce competition, and lead to increased cost and reduced use of these devices by Americans with age-related hearing loss; and the potential exemption of hearing aids from the Quality System Regulation (QSReg,) 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. Comments on the "Streamlining Regulations for Good Manufacturing Practices for Hearing Aids" will inform the Agency on an alternative model for quality verification.

The Agency has received requests for a 30-day extension of the comment period for the document. Each request conveyed concern that the current 30-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the document on "Streamlining Regulations for Good Manufacturing Practices for Hearing Aids."

FDA has considered the requests and is extending the comment period for the document on "Streamlining Regulations for Good Manufacturing Practices for Hearing Aids" for 30 days,

until June 30, 2016. The Agency believes that a 30-day extension allows adequate time for interested persons to submit comments without significantly delaying regulation on these important issues.

Dated: May 3, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-10798 Filed: 5/6/2016 8:45 am; Publication Date: 5/9/2016]