4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-1205]

Accessible Medical Device Labeling in a Standard Content and Format Public Workshop; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending the comment period for the notice that appeared in the Federal Register of January 7, 2013 (78 FR 951). In the notice, FDA requested comments on the public workshop entitled "Accessible Standardized Medical Device Labeling." The agency is taking this action in response to a request for an extension to allow interested persons additional time to submit comments.

DATES: Submit either electronic or written comments by May 17, 2013.

ADDRESSES: You may submit comments, identified by Docket No. FDA-2012-N-1205, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- Mail/Hand delivery/Courier (for paper or CD-ROM submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and Docket No. FDA-2012-N-1205. All comments received may be posted without change to http://www.regulations.gov, including any personal information provided. For additional information on submitting comments, see the "Request for Comments" heading of the SUPPLEMENTARY INFORMATION section.

Docket: For access to the docket to read background documents or 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:

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SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of January 7, 2013 (78 FR 951), FDA published a notice of public workshop with a 90-day comment period to request comments on all aspects of the public workshop, including topics outlined in section II of that document (78 FR 951 at 952).

The agency has received a request for an extension of the comment period until May 30, 2013. The request conveyed concern that the current comment period does not allow sufficient time to develop a meaningful or thoughtful response that allows for consideration of presentations by FDA and other stakeholders at the public workshop on April 29 and 30, 2013.

FDA has considered the request and is extending the comment period for the notice of public workshop until May 17, 2013. The agency believes that the extension allows adequate time for interested persons to submit comments without significantly delaying consideration of these important issues.

II. Request for Comments

Regardless of attendance at the public workshop, interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. In addition, when responding to specific questions as outlined in section II of the notice of public workshop (78 FR 951 at 952), please identify the question you are addressing. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

Dated: March 20, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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