4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0453]

Draft Guidance for Industry and Food and Drug Administration Staff; 510(k) Device Modifications: Deciding When to Submit a 510(k) for a Change to an Existing Device; Availability; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until November 28, 2011, the comment period for the notice entitled "Draft Guidance for Industry and Food and Drug Administration Staff; 510(k) Device Modifications: Deciding When to Submit a 510(k) for a Change to an Existing Device; Availability," that appeared in the Federal Register of July 27, 2011 (76 FR 44935). In that document, FDA announced the availability of a draft guidance for industry and FDA staff and requested comments. The Agency is taking this action to allow interested persons additional time to submit comments.

DATES: Submit either electronic or written comments by November 28, 2011.

ADDRESSES: Submit electronic comments on the draft guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

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or

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I. Background

In the Federal Register of July 27, 2011 (76 FR 44935), FDA published a notice with a 90-day comment period to request comments on the draft guidance for industry and FDA staff entitled "510(k) Device Modifications: Deciding When to Submit a 510(k) for a Change to an Existing Device." Comments on the draft guidance will assist FDA in the development of a final guidance for industry and FDA staff.

FDA is reopening the comment period for the notice until November 28, 2011. The Agency believes that this will allow adequate time for interested persons to submit comments without significantly delaying action by the Agency.

II. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all Center for Devices and Radiological Health (CDRH) guidance documents is available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm. Guidance documents are also available at http://www.regulations.gov or from the Center for Biologics Evaluation and Research at http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm. To receive "510(k) Device Modifications: Deciding When to Submit a 510(k) for a Change to an Existing Device" from CDRH, you may either send an email request to dsmica@fda.hhs.gov to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1793 to identify the guidance you are requesting.

Dated: November 1, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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