4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0689]

Draft Guidance for Industry and Food and Drug Administration Staff; De Novo Classification Process (Evaluation of Automatic Class III Designation); Availability; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to January 3, 2012, the comment period for the notice entitled "Draft Guidance for Industry and Food and Drug Administration Staff; De Novo Classification Process (Evaluation of Automatic Class III Designation); Availability," that appeared in the Federal Register of October 3, 2011 (76 FR 61103). In that document, FDA announced the availability of a draft guidance for industry and FDA staff and requested comments.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 due to a discrepancy in the comment period in the notice as compared to the comment period listed in the guidance document.

DATES: Submit either electronic or written comments by January 3, 2012.

ADDRESSES: Submit electronic comments on the draft guidance to http://www.regulations.gov.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. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

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or

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I. Background

In the Federal Register of October 3, 2011 (76 FR 61103), FDA published a notice with a 60-day comment period to request comments on the draft guidance for industry and FDA staff entitled "De Novo Classification Process (Evaluation of Automatic Class III Designation)." Comments on the draft guidance will assist FDA in the development of a final guidance for industry and FDA staff on the de novo classification process.

The Agency received a comment that the 60-day comment period in the notice was inconsistent with the 90-day comment period in the draft guidance document. FDA is extending

the comment period for the notice until January 3, 2012. The Agency believes that this extension allows adequate time for interested persons to submit comments without significantly delaying action by the Agency.

II. Request for 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 "De Novo Classification Process (Evaluation of Automatic Class III Designation)" 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 paper copy. Please use the document number 1769 to identify the guidance you are requesting.

Dated: November 1, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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