4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-2065]

Radiation Biodosimetry Devices; Draft Guidance for Industry and Food and Drug Administration Staff; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period for an additional 30 days, for the notice of availability entitled "Radiation Biodosimetry Devices; Draft Guidance for Industry and Food and Drug Administration Staff; Availability", published in the Federal Register of December 30, 2014. In that document, FDA announced the availability of a draft guidance for industry and FDA staff and requested comments.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 in response to a request for an extension to allow interested persons additional time to submit comments.

DATES: FDA is reopening and extending the comment period on the draft guidance. Submit either electronic or written comments by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: An electronic copy of the guidance document is available for download from the Internet. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance

document entitled "Radiation Biodosimetry Devices" to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

Submit electronic comments on the draft guidance to http://www.regulations.gov.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: Jennifer Dickey, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5262, Silver Spring, MD 20993-0002, 301-796-5028.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of December 30, 2014 (79 FR 78448), FDA published a notice with a 90-day comment period to request comments on the draft guidance for industry and FDA staff entitled "Radiation Biodosimetry Devices".

The Agency received a request for an extension of the comment period for the draft guidance (Docket No. FDA-2014-D-2065-0005). The request conveyed concern that the current 90-day comment period does not allow sufficient time to respond. FDA has considered the request and is reopening and extending the comment period for the draft guidance for 30 days. The Agency believes that a 30-day extension allows adequate time for interested persons to submit comments without significantly delaying further FDA action on this guidance document.

II. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm. Guidance documents are also available at http://www.regulations.gov. Persons unable to download an electronic copy of "Radiation Biodosimetry Devices" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1400045 to identify the guidance you are requesting.

III. Comments

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. 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: May 21, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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