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Radiation Biodosimetry Devices; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled "Radiation Biodosimetry Devices." This draft guidance provides recommendations to assist industry in designing studies to establish the analytical and clinical performance characteristics of radiation biodosimetry medical countermeasure devices. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].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 Submit written requests for a single hard copy of the draft guidance document entitled "Radiation Biodosimetry Devices" to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological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Submit electronic comments on the draft guidance to http://www.regulations.gov.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

This draft guidance provides recommendations to assist industry in designing studies to establish the analytical and clinical performance characteristics of radiation biodosimetry medical countermeasure devices.

Radiation biodosimetry countermeasure devices are devices used for the purpose of reconstructing the ionizing radiation dose received by individuals or populations using physiological, chemical or biological markers of exposure found in humans. Radiation biodosimetry technologies may be used at various stages during triage and treatment after the exposure of a population to ionizing radiation as a result of intentional harm or as an unintended consequence of a disaster. Devices may be designed to give quantitative outputs or qualitative information around a clinical decision making cut-point. Likewise, devices may be designed for use in field triage settings, at patient bedsides, or in Clinical Laboratory Improvement Amendments of 1988 (CLIA) (Public Law 100-578) certified clinical laboratories. FDA

considered both high-throughput and single-use devices in developing this draft guidance document.

This draft guidance only applies to validation of biodosimetry devices intended to be used to assess exposure in non-therapeutic or accidental scenarios (e.g. a deliberate attack, such as use of an improvised nuclear device, or a natural disaster). This draft guidance neither applies to devices that assess deliberate radiation dosing that may occur in the course of medical treatment nor to devices that measure effects from long term exposure. In addition, dosimeters, which are devices that detect radiation exposure on a physical substrate rather than through a biological response and are worn by people who might be exposed to radiation during the course of their normal work (such as film badges), are not addressed in this guidance document. Finally, biological assays that might be used to detect the presence of ingested radioisotopes in sputum or urine are not considered in this draft guidance document.

This draft guidance document does not provide specific study designs; it describes design principles for studies that may be used to establish the safety and effectiveness of radiation biodosimetry devices.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on evaluating the performance characteristics of radiation biodosimetry devices. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. 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.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 58 have been approved under OMB control number 0910-0119; the collections of information in 21 CFR parts 801 and 809 have been approved under OMB control number 0910-0485; the collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910-0078; the collections of information in 21 CFR part 814 have been approved under OMB control number 0910-0231; the collections of information in the guidance document entitled "Informed Consent For In Vitro Diagnostic Device Studies Using Leftover Human Specimens That Are Not Individually Identifiable" have been approved under OMB control number 0910-0582; and the collections of information in the guidance document entitled "Guidance for Industry and FDA

Staff: Administrative Procedures for CLIA Categorization" have been approved under OMB control number 0910-0607.

V. 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: December 22, 2014.

Leslie Kux,

Associate Commissioner for Policy.

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