regulators around the world is expected, as they will join their counterparts from Europe, Japan, the United States, Canada, and Switzerland as ICH Regulatory Members. The reforms build on a 25-year track record of successful delivery of harmonized guidelines for global pharmaceutical development, and their regulation. Additionally, the reforms strengthen ICH as the leading platform for global pharmaceutical regulatory harmonization, and brings together in a transparent manner all key regulatory authorities and industry stakeholders.

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for medical product development among regulatory Agencies. ICH was organized to provide an opportunity for harmonization initiatives to be developed with input from both regulatory and industry representatives. Members of the ICH Management Committee include the European Union; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labor, and Welfare; the Japanese Pharmaceutical Manufacturers Association; FDA; the Pharmaceutical Research and Manufacturers of America; Health Canada; Swissmedic; the World Health Organization; and International Federation of Pharmaceutical Manufacturers and Associations (as Observers). The ICH process has achieved significant harmonization of the technical requirements for the approval of pharmaceuticals for human use in the ICH regions over the past two decades. The current ICH process and structure can be found at the following Web site: *http://www.ich.org.* (FDA has verified the Web site addresses as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.)

II. Webcast Attendance and Participation

A. Registration

If you wish to attend this meeting, visit *http://ichpublicconsult2016.eventbrite.com.* Please register by May 4, 2016. If you are unable to attend the meeting in person, you can register to view a live Webcast on the meeting. You will be asked to indicate in your registration if you plan to attend in person or via the Webcast. Your registration must also contain your complete contact information, including name, title, affiliation, address, email address, and phone number. Registrations may be limited, so early registration is recommended. Registration is free and will be on a first-come, first-served basis. However, the number of participants from each organization may be limited based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the meeting will be based on space availability. If you need special accommodations because of a disability, please contact Amanda Roache (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the Webcast.

B. Requests for Oral Presentations

Interested persons may present data, information, or views orally or in writing on issues pending at the public Webcast. Public oral presentations will be scheduled between approximately 11:30 a.m. and 12 p.m. Time allotted for oral presentations may be limited to 5 minutes. Those desiring to make oral presentations should notify Amanda Roache (see **FOR FURTHER INFORMATION CONTACT**) by April 29, 2016, and submit a brief statement of the general nature of the evidence or arguments they wish to present; the names and addresses, telephone number, fax, and email of proposed participants; and an indication of the approximate time requested to make their presentation. The agenda for the public Webcast will be made available on the Internet at *http://www.fda.gov/Drugs/NewsEvents/ucm488618.htm.*

Dated: April 13, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–08880 Filed 4–15–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–2065]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the guidance entitled ''Radiation Biodosimetry Medical Countermeasure Devices.'' FDA has developed this guidance to provide industry and Agency staff with recommendations for the types of information that should be submitted to support marketing authorization for radiation biodosimetry medical countermeasure devices.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential,

if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2014–D–2065 for ''Radiation Biodosimetry Medical Countermeasure Devices.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper 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.

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 guidance document entitled ''Radiation Biodosimetry Medical Countermeasure 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.

FOR FURTHER INFORMATION CONTACT: Jennifer Dickey, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5648, Silver Spring, MD 20993–0002, 301–796–5028.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance provides recommendations for the types of information that should be submitted to support marketing authorization (*e.g.,* the clearance or approval) for radiation biodosimetry medical countermeasure devices (referred to as ''biodosimetry devices'' or ''biodosimeters'' throughout this document).

This guidance applies to premarket submissions for medical device systems intended to measure biological responses to unintended (non-therapeutic) radiation absorption. Biodosimetry 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. Biodosimetry technologies may be used at various stages during triage, including both early mass casualty triage and subsequent clinical evaluation. Such exposures could be the result of intentional harm or as a 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) (Pub. L. 100–578) certified clinical laboratories. FDA considered both high-throughput and single-use devices in developing this guidance document.

This guidance only applies to validation of diagnostic biodosimetry devices intended to be used to assess radiation absorption that occurs as a result of non-therapeutic or accidental exposures (*e.g.,* a deliberate attack, such as use of an improvised nuclear device, or a natural disaster), and does not apply to medical devices intended to be used to measure doses delivered as a result of radiation therapy nor to devices that measure effects from long-term radiation 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 guidance document.

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

In the **Federal Register** of December 30, 2014 (79 FR 78448), the Agency announced the issuance of the draft guidance entitled ''Radiation Biodosimetry Devices; Draft Guidance for Industry and Food and Drug Administration Staff.'' In the **Federal Register** of May 28, 2015 (80 FR 30466), FDA reopened and extended the comment period on the draft guidance. The Agency has considered the comments, as appropriate.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Radiation Biodosimetry Medical Countermeasure Devices.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the 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 Medical Countermeasure 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 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; 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; and the collections of information in the guidance document entitled ''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff'' have been approved under OMB control number 0910–0756.

Dated: April 12, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–08899 Filed 4–15–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–0269]

Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability of a draft guidance for industry entitled ''Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act.'' This guidance sets forth FDA's policy concerning certain prescription requirements for compounding human drug products for identified individual patients under section 503A of the Federal Food, Drug, and Cosmetic Act (the FD&C Act). It addresses compounding after the receipt of a prescription for an identified individual patient, compounding before the receipt of a prescription for an identified individual patient (anticipatory compounding), and compounding for office use.

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 on this draft guidance before it begins work to finalize the guidance, submit either electronic or written comments on this draft guidance by July 18, 2016. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by May 18, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–D–0269 for ''Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov*. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm*.

Docket: For access to the docket to read background documents or the electronic and written/paper 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