Archived Webcast and Transcripts: Please be advised that FDA will post the webcast along with complete transcripts on the internet at *https://www.fda.gov/TobaccoProducts/NewsEvents/default.htm* as soon as they are available.

Dated: September 20, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–20904 Filed 9–25–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–4317]

Compounding and Repackaging of Radiopharmaceuticals by Outsourcing Facilities; Guidance for Industry; 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 a final guidance for industry entitled ''Compounding and Repackaging of Radiopharmaceuticals by Outsourcing Facilities.'' Specifically, this guidance sets forth FDA's policy regarding compounding and repackaging of radiopharmaceuticals for human use by entities that are registered with FDA as outsourcing facilities. This guidance describes how FDA generally intends to apply section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to radiopharmaceuticals compounded by outsourcing facilities, and it describes the conditions under which FDA generally does not intend to take action for violations of certain provisions of the FD&C Act when an outsourcing facility repackages radiopharmaceuticals.

DATES: The announcement of the guidance is published in the **Federal Register** on September 26, 2018.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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–4317 for ''Compounding and Repackaging of Radiopharmaceuticals by Outsourcing Facilities.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff 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 *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. 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: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Sara Rothman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Silver Spring, MD, 301–796–3110.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Compounding and Repackaging of Radiopharmaceuticals by Outsourcing Facilities; Guidance for Industry.'' In 2013, the Drug Quality and Security Act created a new section, 503B, of the FD&C Act (21 U.S.C. 353b), which describes a new category of compounders called *outsourcing facilities.* Section 503B of the FD&C Act describes the conditions that must be satisfied for human drug products compounded by or under the direct supervision of a licensed pharmacist in

an outsourcing facility to qualify for exemptions from the following three sections of the FD&C Act:

- Section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning labeling with adequate directions for use);
- section 505 (21 U.S.C. 355) (concerning drug approval requirements); and
- section 582 (21 U.S.C. 360eee–1) (concerning drug supply chain security requirements).

In contrast to section 503A (21 U.S.C. 353a), section 503B of the FD&C Act does not exclude radiopharmaceuticals. Therefore, FDA's overall policies regarding section 503B apply to the compounding of radiopharmaceutical drug products. However, we have developed specific policies that apply only to the compounding of radiopharmaceuticals by outsourcing facilities using bulk drug substances and to the compounding of radiopharmaceuticals by outsourcing facilities that are essentially copies of approved drugs when such compounding is limited to *minor deviations,* as that term is defined in the guidance. FDA is also issuing this guidance in part to describe the conditions under which the Agency does not generally intend to take action for violations of sections 505 and 502(f)(1) of the FD&C Act when an outsourcing facility repackages radiopharmaceuticals for human use.

Elsewhere in this issue of the **Federal Register**, FDA has announced the availability of a separate guidance document concerning compounding and repackaging of radiopharmaceuticals by State-licensed nuclear pharmacies, Federal facilities, and other facilities that are not registered as outsourcing facilities, entitled ''Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies, Federal Facilities, and Certain Other Entities.''

In the **Federal Register** of December 29, 2016 (81 FR 96005), FDA issued a notice announcing the availability of the draft version of this guidance. The comment period on the draft guidance ended on February 27, 2017. FDA received approximately three comments on the draft guidance. In response to received comments or on its own initiative, FDA made certain changes to the guidance to clarify particular points. For example, the reference to the syringe as an example of primary packaging was deleted in response to a comment stating that a syringe containing a radiopharmaceutical should not be described as ''primary packaging'' for labeling purposes because of the unique risks associated with radioactive drug products. In addition, FDA made revisions to align language used in this guidance with language used in the guidance entitled ''Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies, Federal Facilities, and Certain Other Entities.''

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance represents the current thinking of FDA on ''Compounding and Repackaging of Radiopharmaceuticals by Outsourcing Facilities.'' 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. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This guidance contains collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520). Under the PRA, Federal Agencies must obtain approval from OMB for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3 and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party.

Specifically, the guidance references registration, adverse event reporting, product reporting, and current good manufacturing practices (CGMP) requirements for outsourcing facilities. The collections of information for outsourcing facility registration have been approved under OMB control number 0910–0777 (79 FR 69859, November 24, 2014). The collections of information for adverse event reporting by outsourcing facilities have been approved under OMB control number 0910–0800 (80 FR 60917, October 8, 2015). The collections of information for electronic drug product reporting by outsourcing facilities have been approved under OMB control number 0910–0827 (82 FR 129, January 3, 2017).

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: September 20, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–2268]

Insanitary Conditions at Compounding Facilities; Revised Draft Guidance for Industry; 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 a revised draft guidance for industry entitled, ''Insanitary Conditions at Compounding Facilities.'' Drug products compounded under insanitary conditions could become contaminated and cause serious adverse events, including death, in patients. FDA is issuing this revised draft guidance to help compounding facilities identify insanitary conditions so that they can implement appropriate corrective actions. This revised draft guidance is also intended to help state regulatory agencies understand some examples of what FDA considers to be insanitary conditions that could cause a drug to become contaminated or rendered injurious to health. This guidance revises the draft guidance entitled ''Insanitary Conditions at Compounding Facilities'' that was published on August 4, 2016.

DATES: Submit either electronic or written comments on the draft guidance by November 26, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins works on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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,