4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-D-0238]

Facility Definition Under Section 503B of the Federal Food, Drug, and Cosmetic Act; 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 "Facility Definition Under Section 503B of the Federal Food, Drug, and Cosmetic Act." Section 503B defines an outsourcing facility, in part, as "a facility at one geographic location or address." FDA has received questions from outsourcing facilities and other stakeholders about the meaning of this term, such as whether multiple suites used for compounding human drugs at a single street address constitute one or multiple facilities, or whether a single location where human drugs are compounded can be subdivided into separate operations compounding under different standards. FDA is issuing this guidance to provide the Agency's current thinking on these questions and related issues regarding how to ensure that the compounding of drugs in an outsourcing facility occurs only in accordance with section 503B.

DATES: The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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-0238 for "Facility Definition Under Section 503B 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 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 this 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, Rm. 5197, Silver Spring, MD 301-796-3110.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Facility Definition Under Section 503B of the Federal Food, Drug, and Cosmetic Act." Section 503B (21 U.S.C. 353b), added to the Federal Food, Drug, and Cosmetic Act (FD&C Act) by the Drug Quality and Security Act in 2013, created a new category of compounders called outsourcing facilities. Section 503B 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 three sections of the FD&C Act:

- section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning labeling requirements);
- 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 Act requirements).

Section 503B(d)(4) of the FD&C Act defines an outsourcing facility as a facility at one geographic location or address that: (1) is engaged in the compounding of sterile drugs; (2) has elected to register as an outsourcing facility; and (3) complies with all of the requirements of this section. In addition, an outsourcing facility is not required to be a licensed pharmacy, and it may or may not obtain prescriptions for identified individual patients. Because drugs compounded by outsourcing facilities are not exempt from section 501(a)(2)(B) of the FD&C Act (21 U.S.C. 351(a)(2)(B)), outsourcing facilities are subject to current good manufacturing practice requirements.

FDA has received questions from outsourcing facilities and other stakeholders about the meaning of the term "facility at one geographic location or address," such as whether multiple suites used for compounding human drugs at a single street address constitute one or multiple facilities, or whether a single location where human drugs are compounded can be subdivided into separate operations compounding under different standards. FDA is issuing this guidance to provide its current thinking on these questions and related issues regarding how to ensure that the compounding of drugs in an outsourcing facility occurs only in accordance with section 503B.

In the *Federal Register* of April 18, 2016 (81 FR 22611), FDA issued a notice announcing the availability of the draft version of this guidance. The comment period on the draft guidance ended on July 18, 2016. FDA received 19 comments on the draft guidance. In response to received comments, FDA made certain changes. In particular, FDA revised the

guidance to provide for a compounder seeking to operate under section 503A of the FD&C Act (21 U.S.C. 353a) to be located next to an outsourcing facility provided that there is complete segregation between the outsourcing facility and the 503A compounder.

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 "Facility Definition Under Section 503B of the Federal Food, Drug, and Cosmetic Act." 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. 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: May 7, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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