Dated: January 12, 2018.

Martique Jones,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2018–00832 Filed 1–18–18; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–1267]

Compounded Drug Products That Are Essentially Copies of Approved Drug Products 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 guidance for industry entitled ''Compounded Drug Products That Are Essentially Copies of Approved Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act.'' For a drug product compounded by an outsourcing facility to qualify for the exemptions under section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act), it must not be essentially a copy of one or more approved drug products and must meet other conditions in section 503B. This guidance sets forth FDA's policies concerning the ''essentially a copy'' provision of section 503B of the FD&C Act.

DATES: The announcement of the guidance is published in the **Federal Register** on January 19, 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–1267 for ''Compounded Drug Products That Are Essentially Copies of Approved Drug Products 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 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, Rm. 5197, Silver Spring, MD 20993, 301–796–3110.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Compounded Drug Products That Are Essentially Copies of Approved Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act.'' In 2013, the Drug Quality and Security Act, created 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 of drugs with adequate directions for use);

• Section 505 (21 U.S.C. 355) (concerning the approval of drugs under new drug applications or abbreviated new drug applications); and

• Section 582 (21 U.S.C. 360eee–1) (concerning drug supply chain security requirements).

One of the conditions that must be met for a compounded drug product to qualify for the exemptions under section 503B of the FD&C Act is that the drug is not essentially a copy of one or more approved drugs (section 503B(a)(5)).

Section 503B(d)(2) defines essentially a copy of an approved drug as:

• A drug that is identical or nearly identical to an approved drug, or a marketed drug not subject to section 503(b) and not subject to approval in an application submitted under section 505, unless, in the case of an approved drug, the drug appears on the drug shortage list in effect under section 506E at the time of compounding, distribution, and dispensing (section 503B(d)(2)(A)) or

• a drug, a component of which is a bulk drug substance that is a component of an approved drug or a marketed drug that is not subject to section 503(b) and not subject to approval in an application submitted under section 505, unless there is a change that produces for an individual patient a clinical difference, as determined by the prescribing practitioner, between the compounded drug and the comparable approved drug (section 503B(d)(2)(B)).

This guidance sets forth FDA's policies concerning the ''essentially a copy'' provision of section 503B of the FD&C Act.

In the **Federal Register** of July 11, 2016 (81 FR 44879), FDA issued a notice announcing the availability of the draft version of this guidance. The comment period on the draft guidance ended on October 11, 2016. FDA received 29 comments on the draft guidance. In response to received comments or on its own initiative, FDA made several changes. For example, in response to requests in comments for direction on records retention, FDA added a recommendation that compounders maintain the records described in the guidance for at least 3 years. In addition, to address questions raised in comments, FDA clarified that the Agency does not intend to take action against an outsourcing facility for failing to compound in accordance with section 503B(a)(5) if it fills orders for a compounded drug that is essentially a copy of an approved drug that has been discontinued and is no longer marketed.

FDA received comments from hospital organizations regarding the potential implications of proposed policies for the preparation of compounded drugs used in in-patient settings. The final guidance notes that FDA is considering the applicability of the policies described in this guidance to hospitals and health systems. We recognize that this issue is of interest to many stakeholders and will publicly convey our further thinking on the applicability of these policies to hospitals and health systems with an opportunity for comment.

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 ''Compounded Drug Products That Are Essentially Copies of Approved Drug Products 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. Paperwork Reduction Act of 1995

This guidance contains collections of information that are subject to review by OMB under the PRA (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. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, in the **Federal Register** of July 11, 2016, we gave interested persons 60 days to comment on the information collection provisions in the draft guidance.

The information collection provisions in this guidance have been submitted to OMB for review as required by section 3507(d) of the PRA. These provisions are not in effect until they display a currently valid OMB control number. FDA will publish a notice in the **Federal Register** announcing OMB's decision regarding the information collection provisions in this guidance.

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: January 16, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–00914 Filed 1–18–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1525]

Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application; 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 final guidance for industry entitled ''Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application.'' This final guidance describes the conditions under which FDA does not intend to take action against a State-licensed pharmacy, a Federal facility, or an outsourcing facility that mixes, dilutes, or repackages certain biological products outside the scope of an approved biologics license application (BLA). It also describes the conditions under which FDA does not intend to take action when a State-licensed pharmacy, a Federal facility, an outsourcing facility, or a physician prepares prescription sets of allergenic extracts for subcutaneous immunotherapy.

DATES: The announcement of the guidance is published in the **Federal Register** on January 19, 2018.

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

Electronic Submissions

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