Column A—What information is requested?	Column B—Put data specific to the nominated substance
What is the chemical grade of the substance?	Provide the chemical grade.
What is the strength, quality, stability, and purity of the ingredient?	Provide the strength, quality, stability, and purity information and attach a certificate of analysis.
How is the ingredient supplied?	Describe how the ingredient is supplied (e.g., powder, liquid).
Is the substance recognized in foreign pharmacopeias or registered in other countries?	List the foreign pharmacopeias or other countries in which it is registered.
Has information been submitted about the substance to the USP for consideration of drug monograph development?	Put yes, no, or unknown. If yes, state the status of the monograph, if known.
What dosage form(s) will be compounded using the bulk drug substance?	State the dosage form(s).
What strength(s) will be compounded from the nominated substance?	List the strength(s) of the drug product(s) that will be compounded from the nominated substance, or a range of strengths, if known.
What are the anticipated route(s) of administration of the compounded drug product(s)?	List the route(s) of administration of the compounded drug product(s).
Are there safety and efficacy data on compounded drugs using the nominated substance?	Provide a bibliography of safety and efficacy data for the drug compounded using the nominated substance, if available, including any relevant peer-reviewed medical literature.
Has the bulk drug substance been used previously to compound drug product(s)?	Describe past uses of the bulk drug substance in compounding.
What is the proposed use for the drug product(s) to be compounded with the nominated substance?	Provide information on the proposed use of the compounded drug product.
What is the reason for use of a compounded drug product rather than an FDA-approved product?	Provide a rationale for the use of a compounded drug product.
Is there any other relevant information?	Provide any other information you would like FDA to consider in evaluating the nomination.

In addition to nominating new substances or renominating substances previously nominated without sufficient supporting information, individuals and organizations will be able to comment via the docket established by this notice on substances nominated for the 503A bulks list that have not yet been addressed in a Notice of Proposed Rulemaking (NPRM). Comments may be submitted regarding nominations submitted to both this docket and Docket No. FDA–2013–N–1525. Comments may provide any relevant information about particular bulk drug substances, including that in support of, or in opposition to, the placement of a nominated bulk drug substance on the 503A bulks list. However, comments submitted should not address the 503A bulks list generally or other matters related to the Agency's regulation of compounding. Comments about nominated substances that have been addressed by the Agency in an NPRM should be submitted to the docket for the proposed rulemaking in which the substance is addressed.

Please do not submit comments that have already been submitted to other dockets. Such submissions are duplicative and not helpful to the Agency. If comments on particular documents or issues are submitted to this docket rather than the docket specifically opened for the particular document or issue, the comment might not be considered as the specific documents are being finalized and issues considered. FDA will not respond to questions submitted to this docket.

Information in the docket will be publicly available. Therefore, we remind nominators and commenters not to submit personal or confidential information.

Dated: October 21, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–27271 Filed 10–26–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–3539]

Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B 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 entitled ''Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act.'' The draft guidance describes FDA's interim regulatory policy regarding outsourcing facilities that compound human drug products using bulk drug substances while FDA develops the list of bulk drug substances that can be used in compounding under the Federal Food, Drug, and Cosmetic Act (the FD&C Act). When final, the guidance will reflect the Agency's current thinking on the issues addressed by the guidance.

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 on the final version of the guidance, submit either electronic or written comments on the draft guidance by December 28, 2015.

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–2015–D–3539 for ''Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act; Draft Guidance for Industry; Availability.'' 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.

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 20993–0002, 301–796–3110.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled ''Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act.'' A new section 503B (21 U.S.C. 353b), added to the FD&C Act by the Drug Quality and Security Act (Pub. L. 113–54) in 2013, describes the conditions that must be satisfied for human drug products compounded by an outsourcing facility to be exempt from the following three sections of the FD&C Act: Section 505 (21 U.S.C. 355) (concerning the approval of drugs under new drug applications or abbreviated new drug applications); section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use); 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 drug product compounded by an outsourcing facility to qualify for these exemptions is that the outsourcing facility does not compound drug products using a bulk drug substance unless: (1) It appears on a list established by the Secretary identifying bulk drug substances for which there is a clinical need (see section 503B(a)(2)(A)(i) of the FD&C Act) or (2) the drug product compounded from such bulk drug substances appears on the drug shortage list in effect under section 506E of the FD&C Act (21 U.S.C. 356e) at the time of compounding, distribution, and dispensing (see section 503B(a)(2)(A)(ii) of the FD&C Act).

This guidance describes the conditions under which FDA does not intend to take action against an outsourcing facility for compounding a drug product from a bulk drug substance that does not appear on a list of bulk drug substances that may be used in compounding and is not used to compound a drug product that appears on the FDA drug shortage list at the time of compounding, distribution, and dispensing, while FDA develops the list of bulk drug substances that can be used in compounding under section 503B(a)(2)(A)(i) of the FD&C Act.

Elsewhere in this issue of the **Federal Register**, the Agency is making available for public comment a draft guidance entitled ''Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act,'' which describes the conditions under which FDA does not intend to take action against a licensed pharmacist at a State-licensed pharmacy or a Federal facility for compounding a drug product from a bulk drug substance that cannot otherwise be used in compounding under section 503A of the FD&C Act while FDA develops the list of bulk drug substances that can be used in compounding under section 503A(b)(1)(A)(i)(III).

II. Electronic Access

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

Dated: October 21, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–27268 Filed 10–26–15; 8:45 am]

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