4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter I

[Docket No. FDA-2013-N-1524]

Bulk Drug Substances That May Be Used to Compound Drug Products in Accordance With Section 503B of the Federal Food, Drug, and Cosmetic Act, Concerning Outsourcing Facilities; Request for Nominations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; request for nominations.

SUMMARY: The Food and Drug Administration (FDA or Agency) is preparing to develop a list of bulk drug substances (bulk drugs) that may be used to compound drug products in accordance with section 503B of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), concerning outsourcing facilities. To identify candidates for this bulk drugs list, interested groups and individuals may nominate specific bulk drug substances, and FDA is describing the information that should be provided to the Agency in support of each nomination.

DATES: Submit either electronic or written nominations for the bulk drug substances list by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit nominations, identified by Docket No. FDA-2013-N-1524, by any of the following methods.

Electronic Submissions

Submit electronic nominations in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Written Submissions

Submit written nominations in the following ways:

- Mail/Hand delivery/Courier (for paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA-2013-N-1524 for this request for nominations. All nominations received may be posted without change to http://www.regulations.gov, including any personal information provided. For additional information on submitting nominations, see the "Request for Nominations" heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or nominations 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.

FOR FURTHER INFORMATION CONTACT: Marissa Chaet Brykman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, suite 5100, Silver Spring, MD 20993-0002, 301-796-3110.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Quality and Security Act (DQSA) adds a new section 503B to the FD&C Act (21 U.S.C. 353b) that creates a new category of "outsourcing facilities."[1] Outsourcing facilities, as defined in section 503B of the FD&C Act, are facilities that meet certain conditions described in section 503B, including registering with FDA as an outsourcing facility. If these conditions are satisfied, a drug compounded by or under the direct supervision of a licensed pharmacist in an outsourcing facility is exempt from two sections of the FD&C Act: (1) Section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use) and (2) section 505 (21 U.S.C. 355) (concerning the approval of human drug products under new drug applications (NDAs) or abbreviated new drug applications (ANDAs)); but not section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice for drugs).

One of the conditions in section 503B of the FD&C Act that must be satisfied to qualify for the exemptions is that an outsourcing facility does not compound using a bulk drug substance unless: (1) The bulk drug substance appears on a list established by the Secretary identifying bulk drug substances for which there is a clinical need, or the drug compounded from such bulk drug substance 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; (2) "if an applicable monograph exists under the United States Pharmacopeia, the National Formulary, or another compendium or pharmacopeia recognized by the Secretary for purposes of this paragraph, the bulk drug [substance complies] with the monograph;" (3) the bulk drug substance is

[1] The DQSA also removes from section 503A of the FD&C Act the provisions that had been held unconstitutional by the U.S. Supreme Court in 2002. See Thompson v. Western States Med. Ctr., 535 U.S. 357 (2002).

manufactured by an establishment that is registered under section 510 of the FD&C Act (21 U.S.C. 360); and (4) the bulk drug substance is accompanied by a valid certificate of analysis (see section 503B(a)(2) of the FD&C Act).

Section 503B of the FD&C Act refers to the definition of "bulk drug substance" in FDA regulations at 21 CFR 207.3(a)(4): "any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug, but the term does not include intermediates used in the synthesis of such substances" (see section 503B(a)(2)).

II. Request for Nominations

To identify candidates for this list, FDA is seeking public input in the form of specific bulk drug nominations. All interested groups and individuals may nominate specific bulk drug substances for inclusion on the list.

Nominations should include the following information about the bulk drug substance being nominated and the product(s) that will be compounded using such substance, and any other relevant information available. If the information requested is unknown or unavailable, that fact should be noted accordingly.

Bulk Drug Substance

- Ingredient name;
- Chemical name;
- Common name(s);
- Chemical grade or description of the strength, quality, and purity of the ingredient;
- Information about how the ingredient is supplied (e.g., powder, liquid);

- Information about recognition of the substance in foreign pharmacopeias and the status of its registration(s) in other countries, including whether information has been submitted to USP for consideration of monograph development;
- A bibliography of available safety and efficacy data,[2] including any relevant peer-reviewed medical literature; and
- An explanation of why there is a clinical need to compound from the bulk drug substance.

Compounded Product

- Information about the dosage form(s) into which the drug substance will be compounded (including formulations);
- Information about the strength(s) of the compounded product(s);
- Information about the anticipated route(s) of administration of the compounded product(s);
- Information about the past and proposed use(s) of the compounded product(s), including the rationale for its use or why the compounded product(s), as opposed to an FDA-approved product, is necessary; and
- Available stability data for the compounded product(s).

FDA cannot guarantee that all drugs nominated during the nomination period will be considered for inclusion on the next published bulk drugs list. Nominations received during the nomination period that are supported by the most complete and relevant information will likely be evaluated first. Nominations that are not evaluated during this first phase will receive consideration for list amendments, because the development of this list will be an ongoing

[2] FDA recognizes that the available safety and efficacy data supporting consideration of a bulk drug substance for inclusion on the list may not be of the same type, amount, or quality as is required to support an NDA.

process. Individuals and organizations also will be able to petition FDA to make additional list amendments after the list is published.

Interested persons may submit either electronic nominations to http://www.regulations.gov or written nominations to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of nominations. Identify nominations with the docket number found in brackets in the heading of this document. Received nominations may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

Dated: November 27, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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