4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-1399]

Guidance for Entities Considering Whether to Register as Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final guidance entitled "Guidance for Entities Considering Whether to Register as Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act." This guidance is intended to inform entities that are considering registering as outsourcing facilities under section 503B of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as added by the Drug Quality and Security Act (DQSA), of the regulatory implications of registration as an outsourcing facility.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: 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.

Submit electronic comments on the guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Sara Rothman, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-3110.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry entitled "Guidance for Entities Considering Whether to Register as Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act." On November 27, 2013, President Obama signed the DQSA (Pub. L. 113-54) into law. The DQSA added a new section 503B to the FD&C Act that created a category of entities called "outsourcing facilities." Section 503B(d)(4) of the FD&C Act (21 U.S.C. 353b(d)(4)) defines an outsourcing facility, in part, as a facility that complies with all of the requirements of section 503B, including registering with FDA as an outsourcing facility and paying associated fees. If the conditions outlined in section 503B(a) of the FD&C Act are satisfied, a drug compounded by or under the direct supervision of a licensed pharmacist in an outsourcing facility is exempt from certain sections of the FD&C Act, including section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use) and 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)). Drugs compounded in outsourcing facilities are not exempt from the requirements of section 501(a)(2)(B) of the FD&C Act (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice for drugs).

FDA has received questions about whether entities engaged in various types of activities (e.g., a facility that is compounding only non-sterile drugs or only repackaging biological products) should register as an outsourcing facility. Because entities that register as outsourcing facilities must pay a registration fee and FDA has determined that fees paid pursuant to sections 503B and 744K of the FD&C Act will not be refunded, FDA is issuing this guidance to answer some of these questions and to provide potential registrants additional information about the regulatory impact of registering as an outsourcing facility.

In the Federal Register of February 19, 2015 (80 FR 8871), FDA issued a notice announcing the availability of the draft version of this guidance. The comment period on the draft guidance ended on May 20, 2015. FDA received eleven comments on the draft guidance. Some of the comments raised issues that were not directly pertinent to the topics addressed in this guidance. FDA intends to consider those comments as they relate to issues being addressed in other policy documents being developed by the Agency.

In response to received comments or on its own initiative, FDA made the following changes as it finalized this guidance: (1) Removed the reference to a separate guidance document that explains how outsourcing facilities should report the products they compound to FDA because that guidance is not directly related to the issue of entities considering whether to register as outsourcing facilities; (2) noted that FDA has issued separate guidance documents addressing some of the conditions of section 503B and that it intends to publish additional guidance addressing other conditions; (3) added a reference to FDA's draft guidance regarding compounding animal drug products from bulk drug substances, which addresses outsourcing facilities engaging in this activity; and (4) made grammatical and other minor editorial changes for clarity.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on registering as an outsourcing facility under section 503B of the FD&C Act. It does not create 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.

II. Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments 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.

III. Electronic Access

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

Dated: August 6, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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