

labels × 7.25 hours = 174 hours). In addition, 12 respondents will each spend 1 hour reading the guidance document, for a total of 12 hours. Thus, we estimate the total hour burden of the proposed collection of information to be 186 hours (174 hours + 12 hours = 186 hours).

The guidance also refers to previously approved collections of information found in our regulations. The collections of information in §§ 101.3, 101.4, 101.5, 101.9, 101.22, and 101.105 have been approved under OMB control number 0910–0381. Allergen labeling of these beers under section 403(w)(1) of the FD&C Act, which was added by the Food Allergen Labeling and Consumer Protection Act of 2004, has been approved under OMB control number 0910–0792.

Dated: August 6, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015–19741 Filed 8–11–15; 8:45 am]

**BILLING CODE 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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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-N-0882]

#### Generic Drug User Fees; Stakeholder Meetings on Generic Drug User Fee Amendments of 2012 Reauthorization; Request for Notification of Stakeholder Intent To Participate; Extension of Closing Date

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; request for notification of intent to participate; extension of closing date.

**SUMMARY:** The Food and Drug Administration (FDA) is extending the closing date for the document that appeared in the **Federal Register** of June 3, 2015. In that document, FDA requested that public stakeholders, including patient and consumer advocacy groups, health care professionals, and scientific and academic experts, notify FDA of their intent to participate in periodic consultation meetings on the reauthorization of the Generic Drug User Fee Amendments of 2012 (GDUFA). The statutory authority for GDUFA expires at the end of September 2017. At that time, new legislation will be required for FDA to continue collecting user fees for the generic drug program. The Federal Food, Drug, and Cosmetic Act (the FD&C Act) requires that FDA consult with a range of stakeholders in developing recommendations for the next GDUFA program. The FD&C Act also requires that FDA hold continued discussions with patient and consumer advocacy groups at least monthly during FDA's negotiations with the regulated industry. The purpose of the request for notification is to ensure continuity and progress in these monthly discussions

by establishing consistent stakeholder representation.

**DATES:** FDA is extending the closing date in the notice published June 3, 2015 (80 FR 31602). Submit notification of intent to participate by April 30, 2016.

**ADDRESSES:** Submit notification of intent to participate in monthly stakeholder meetings by email to [GenericDrugPolicy@fda.hhs.gov](mailto:GenericDrugPolicy@fda.hhs.gov).

**FOR FURTHER INFORMATION CONTACT:** Connie Wisner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1718, Silver Spring, MD 20993-0002, 240-402-7946, [Connie.Wisner@fda.hhs.gov](mailto:Connie.Wisner@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Introduction

FDA is requesting that public stakeholders, including patient and consumer advocacy groups, health care professionals, and scientific and academic experts, notify the Agency of their intent to participate in periodic consultation meetings on the reauthorization of GDUFA. GDUFA authorizes FDA to collect fees from drug companies that submit marketing applications for certain generic human drug applications, certain drug master files, and certain facilities. GDUFA requires that generic drug manufacturers pay user fees to finance critical and measurable generic drug program enhancements. The statutory authority for GDUFA expires at the end of September 2017. Without new legislation, FDA will no longer be able to collect user fees for future fiscal years to fund the human generic drug review process. Section 744C(d) (21 U.S.C. 379j-43(d)) of the FD&C Act requires that FDA consult with a range of stakeholders in developing recommendations for the next GDUFA program, including representatives from patient and consumer groups, health care professionals, and scientific and academic experts. FDA initiated this process on June 15, 2015, by holding a public meeting at which stakeholders and other members of the public were given an opportunity to present their views on reauthorization (April 21, 2015, 80 FR 22204). The FD&C Act further requires that FDA continue meeting with these stakeholders at least once every month during negotiations with the regulated industry to continue discussions of stakeholder views on the reauthorization.

FDA is issuing this **Federal Register** notice to request that stakeholder representatives from patient and consumer groups, health care

professional associations, as well as scientific and academic experts notify FDA of their intent to participate in periodic consultation meetings on GDUFA reauthorization. FDA believes that consistent stakeholder representation at these meetings will be important to ensuring progress in these discussions. If you wish to participate in this part of the reauthorization process, please designate one or more representatives from your organization who will commit to attending these meetings and preparing for the discussions as needed. Stakeholders who identify themselves through this notice will be included in all stakeholder discussions while FDA negotiates with the regulated industry. Stakeholders who decide to participate in these monthly meetings at a later time may still participate in remaining monthly meetings by notifying FDA (see **ADDRESSES**). These stakeholder discussions will satisfy the requirement in section 744C(d)(3) of the FD&C Act.

##### II. Notification of Intent To Participate in Periodic Consultation Meetings

If you intend to participate in continued periodic stakeholder consultation meetings regarding GDUFA reauthorization, please provide notification by email to [GenericDrugPolicy@fda.hhs.gov](mailto:GenericDrugPolicy@fda.hhs.gov) by April 30, 2016. Your email should contain complete contact information, including name, title, affiliation, address, email address, phone number, and notice of any special accommodations required because of disability. Stakeholders will receive confirmation and additional information about the first meeting once FDA receives their notification.

Dated: August 6, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2015-N-0001]

#### Pediatric Advisory Committee; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration