4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-0329]

Fees for Human Drug Compounding Outsourcing Facilities Under the FD&C 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 for industry entitled "Fees for Human Drug Compounding Outsourcing Facilities Under Sections 503B and 744K of the FD&C Act." The guidance is intended for entities that compound human drugs and elect to register as outsourcing facilities under the Federal Food, Drug, and Cosmetic Act (FD&C Act), as added by the Drug Quality and Security Act (DQSA). Entities that elect to register as outsourcing facilities must pay certain fees to be considered outsourcing facilities. This guidance describes the annual establishment fee, the reinspection fee, annual adjustments to fees required by law, how to submit payment, the effect of failure to pay fees, and how to qualify as a small business to obtain a reduction of the annual establishment fee.

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, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, 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: Jonathan Gil, Food and Drug Administration, 10001 New Hampshire Ave., Silver Spring, MD 20903, 301-796-7900.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry entitled "Fees for Human Drug Compounding Outsourcing Facilities Under Sections 503B and 744K of the FD&C Act." On November 27, 2013, President Obama signed the DQSA (Public Law 113-54) into law. The DQSA added a new section 503B to the FD&C Act (21 U.S.C. 353B) that created a category of entities called "outsourcing facilities." Section 503B(d)(4) of the FD&C Act 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). This guidance describes in detail the fee types and amounts an entity must pay to satisfy the fee requirements of

sections 503B and 744K of the FD&C Act to be deemed an outsourcing facility and maintain its status as an outsourcing facility, the adjustments to the fees required by law, how to qualify as a small business to obtain a reduction of the annual establishment fee, how and when to submit payment to FDA, the effect of failure to pay fees, and fee-related dispute resolution.

On April 1, 2014 (79 FR 18297), FDA announced the availability of the draft version of this guidance. The public comment period closed on June 2, 2014. One comment was received from the public, and FDA carefully considered that comment as it finalized the guidance. Some of the issues raised relate to matters that FDA intends to address in other policy documents and were not directly pertinent to the topics addressed in this guidance. During finalization of the guidance, FDA made both clarifying changes and minor editorial changes to the guidance and accompanying form. For example, FDA clarified that it intends to issue an invoice for reinspection fees within 14 calendar days of the close of the reinspection, and that the reinspection fee must be paid within 30 calendar days of the date of the invoice.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA's current thinking on fees associated with human drug compounding outsourcing facilities. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons can 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 can 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. Paperwork Reduction Act of 1995

This guidance contains collections of information that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information have been approved under OMB control number 0910-0776.

IV. Electronic Access

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

Dated: November 18, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014-27692 Filed 11/21/2014 at 8:45 am; Publication Date: 11/24/2014]