10.115). The draft guidance, when finalized, will represent the Agency's current thinking on this topic. 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.

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 514 and 21 CFR 511.1 have been approved under OMB control numbers 0910–0032 and 0910–0117 respectively.

IV. 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.*

V. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm* or *http://www.regulations.gov.*

Dated: July 28, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–18134 Filed 7–31–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0967]

Intent To Exempt Certain Class II and Class I Reserved Medical Devices From Premarket Notification Requirements; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Intent to Exempt Certain Class II and Class I Reserved Medical Devices from Premarket Notification Requirements.'' This draft guidance describes FDA's intent to exempt certain Class II medical devices and certain Class I medical devices, subject to the reserved criteria, from premarket notification requirements. FDA believes devices identified in this guidance document are sufficiently well understood and do not present risks that require premarket notification review to assure their safety and effectiveness. This draft guidance is not final nor is it in effect at this time.

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 September 30, 2014.

ADDRESSES: An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Intent to Exempt Certain Class II and Class I Reserved Medical Devices from Premarket Notification Requirements'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

Submit electronic comments on the draft 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. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Abiy Desta, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1682, Silver Spring, MD 20993–0002, 301–796–0293.

SUPPLEMENTARY INFORMATION:

I. Background

In the commitment letter (section 1.G of the Performance Goals and Procedures) that was drafted as part of the reauthorization process for the Medical Device User Fee Amendments of 2012 (Pub. L. 112–144), FDA committed to identifying low-risk medical devices to exempt from premarket notification. This draft guidance describes FDA's intent to exempt certain Class II medical devices and certain Class I medical devices that are subject to the reserved criteria of section 510(*l*) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(*l*)) from premarket submission requirements. FDA believes devices identified in this guidance document are sufficiently well understood and do not present risks that require 510(k) review.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on identifying low risk medical devices to exempt from premarket notification. 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 statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov.* To receive ''Intent to Exempt Certain Class II and Class I Reserved Medical Devices from Premarket Notification Requirements,'' you may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1300046 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995

(44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120.

V. 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.*

Dated: July 29, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–18198 Filed 7–31–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0007]

Outsourcing Facility Fee Rates for Fiscal Year 2015

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the rates for fiscal year (FY) 2015 for the establishment and reinspection fees related to human drug compounding outsourcing facilities (outsourcing facilities) that elect to register under the Federal Food, Drug, and Cosmetic Act (the FD&C Act). The FD&C Act authorizes FDA to assess and collect an annual establishment fee from outsourcing facilities that have elected to register, as well as a reinspection fee for each reinspection of an outsourcing facility. This document establishes the FY 2015 rates for the small business establishment fee ($5,103), the non-small business establishment fee ($16,442) and the reinspection fee ($15,308) for outsourcing facilities, provides information on how the fees for FY 2015 were determined, and describes the payment procedures outsourcing facilities should follow.

FOR FURTHER INFORMATION CONTACT:

For information on pharmacy compounding and pharmacy compounding user fees: Visit FDA's Web site at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/default.htm*.

For questions relating to this notice: Rachel Richter, Office of Financial Management Food and Drug Administration, 8455 Colesville Rd., COLE–14216, Silver Spring, MD 20933–0002, 301–796–7111.

SUPPLEMENTARY INFORMATION:

I. Background

On November 27, 2013, President Obama signed the Drug Quality and Security Act (DQSA), legislation that contains important provisions relating to the oversight of compounding of human drugs. Title I of this law, the Compounding Quality Act, creates a new section 503B in the FD&C Act (21 U.S.C. 353b). Under section 503B, a human drug compounder can become an ''outsourcing facility.''

Outsourcing facilities, as defined in section 503B(d)(4) of the FD&C Act, are facilities that meet all of the conditions described in section 503B(a), including registering with FDA as an outsourcing facility and paying an annual establishment fee. 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)). 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).

Section 744K of the FD&C Act (21 U.S.C. 379j–62) authorizes FDA to assess and collect the following fees associated with outsourcing facilities that elect to register under section 503B of the FD&C Act: (1) An annual establishment fee from each outsourcing facility; and (2) a reinspection fee from each outsourcing facility subject to a reinspection (see section 744K(a)(1) of the FD&C Act). Under statutorily defined conditions, a qualified applicant may pay a reduced small business establishment fee (see section 744K(c)(4) of the FD&C Act).

On April 1, 2014, FDA announced in the **Federal Register** of April 1, 2014 (79 FR 18297) the availability of a draft guidance for industry entitled ''Fees for Human Drug Compounding Outsourcing Facilities Under Sections 503B and 744K of the FD&C Act.'' The draft guidance provides additional information on the annual fees for registered outsourcing facilities and adjustments required by law, reinspection fees, 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. This draft guidance can be accessed on FDA's Web site at *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM391102.pdf*.

II. Fees for FY 2015 [1]

A. FY 2015 Rates for Small Business Establishment Fee, Non-Small Business Establishment Fee, and Reinspection Fee

1. Establishment Fee for Qualified Small Businesses [2]

The amount of the establishment fee for a qualified small business fee is equal to $15,000 multiplied by the inflation adjustment factor for that fiscal year, divided by three (see section 744K(c)(4)(A) and (c)(1)(A)). The inflation adjustment factor for FY 2015 is 1.020558. See section II.B.1, below, for the methodology used to calculate the FY 2015 inflation adjustment factor. Therefore, the establishment fee for a qualified small business for FY 2015 is one third of $15,308, which equals $5,103 (rounded to the nearest dollar).

2. Establishment Fee for Non-Small Businesses

Under section 744K(c)(1)(A) of the FD&C Act, the amount of the establishment fee for a non-small business fee is equal to $15,000 multiplied by the inflation adjustment factor for that fiscal year, plus the small business adjustment factor for that fiscal year. The inflation adjustment factor for FY 2015 is 1.020558. (See section II.B.1). The small business adjustment amount for FY 2015 is $1,134. See section II.B.2, for the methodology used

[1] FY 2015 runs from October 1, 2014 through September 30, 2015.

[2] To qualify for a small business reduction of the FY 2015 establishment fee, entities had to submit their exception requests by April 30, 2014. See section 744K(c)(4)(B) of the FD&C Act. Although the time for requesting a small business exception for FY 2015 has now passed, an entity that wishes to request a small business exception for FY 2016 should consult section 744K(c)(4) of the FD&C Act and section III.D of FDA's draft guidance for industry entitled ''Fees for Human Drug Compounding Outsourcing Facilities Under Sections 503B and 744K of the FD&C Act,'' which can be accessed on FDA's Web site at *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM391102.pdf*.