(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*.

to calculate the small business adjustment factor for FY 2015. Therefore, the establishment fee for a non-small business for FY 2015 is $15,000 multiplied by 1.020558, plus $1,134, which equals $16,442.

3. Reinspection Fee

Section 744K(c)(1)(B) of the FD&C Act provides that the amount of the FY 2015 reinspection fee is equal to $15,000, multiplied by the inflation adjustment factor for that fiscal year. The inflation adjustment factor for FY 2015 is 1.020558. See section II.B.1. Therefore, the reinspection fee for FY 2015 is $15,000 multiplied by 1.020558, which equals $15,308. There is no reduction in this fee for small businesses.

B. Methodology for Calculating FY 2015 Adjustment Factors

1. Inflation Adjustment Factor

Section 744K(c)(2) of the FD&C Act specifies the annual inflation adjustment for outsourcing facility fees. The inflation adjustment has two components: One based on FDA's payroll costs and one based on FDA's non-pay costs for the first 3 years of the 4 previous FYs. The payroll component of the annual inflation adjustment is calculated by taking the average change in the FDA's per-full time equivalent (FTE) personnel compensation and benefits (PC&B) in the first 3 years of the 4 previous FYs (see section 744K(c)(2)(A)(ii) of the FD&C Act). FDA's total annual spending on PC&B is divided by the total number of FTEs per FY to determine the average PC&B per FTE. The data on total PC&B paid and numbers of FTEs paid, from which the average cost per FTE can be derived, are published in FDA's Justification of Estimates for Appropriations Committees.

Table 1 summarizes the actual cost and FTE data for the specified FYs, and provides the percent change from the previous FY and the average percent change over the first 3 of the 4 FYs preceding FY 2015. The 3-year average is 1.8829 percent.

TABLE 1—FDA PC&B'S EACH YEAR AND PERCENT CHANGE

Fiscal year	2011	20112	2013	3-Year average
Total PC&B	$1,761,655,000	$1,824,703,000	$1,927,703,000	.....
Total FTE	13,331	13,382	13,974	.....
PC&B per FTE	$132,147	$136,355	$137,949	.....
Percent change from previous year	1.2954%	3.1843%	1.1690%	1.8829%

Section 744K(c)(2)(A)(ii) of the FD&C Act specifies that this 1.8829 percent should be multiplied by the proportion of PC&B to total costs of an average FTE of FDA for the same 3 FYs.

TABLE 2—FDA PC&B'S AS A PERCENT OF FDA TOTAL COSTS OF AN AVERAGE FTE

Fiscal year	2011	20112	2013	3-Year average
Total PC&B	$1,761,655,000	$1,824,703,000	$1,927,703,000	.....
Total Costs	$3,333,407,000	$3,550,496,000	$4,151,343,000	.....
PC&B Percent	52.8485%	51.3929%	46.4356%	50.2257%

The payroll adjustment is 1.8829 percent multiplied by 50.2257 percent, or 0.9457 percent.

Section 744K(c)(2)(A)(iii) of the FD&C Act specifies that the portion of the inflation adjustment for non-payroll costs for FY 2015 is equal to the average annual percent change in the Consumer Price Index (CPI) for urban consumers (U.S. City Average; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the preceding 4 years of available data, multiplied by the proportion of all costs other than PC&B costs to total costs of an average FTE of the FDA for the first 3 years of the preceding 4 fiscal years.

Table 2 provides the summary data for the percent change in the specified CPI for U.S. cities. These data are published by the Bureau of Labor Statistics and can be found on its Web site at *http://data.bls.gov/cgi-bin/surveymost?cu* by checking the box marked ''U.S. All items, 1982–84 = 100 – CUUR0000SA0'' and then clicking on the ''Retrieve Data'' button.

TABLE 3—ANNUAL AND 3-YEAR AVERAGE PERCENT CHANGE IN U.S. CITY AVERAGE CPI

Year	2011	2012	2013	3-Year average
Annual CPI	224.939	229.594	232.957	.....
Annual percent change	3.1565%	2.0694%	1.4648%	2.2302%

Section 744K(c)(2)(A)(iii) of the FD&C Act specifies that this 2.2302 percent should be multiplied by the proportion of all costs other than PC&B costs to total costs of an average FTE of the FDA for the same 3 FYs. The proportion of all costs other than PC&B costs to total costs of an average FTE of FDA for FYs 2011–2013 is 49.7743 percent (100 percent minus 50.2257 percent equals 49.7743 percent). Therefore, the non-pay adjustment is 2.2302 percent times 49.7743 percent, or 1.1101 percent.

To complete the inflation adjustment, the payroll component (0.9457 percent) is added to the non-pay component (1.1101 percent), for a total inflation adjustment of 2.0558 percent (rounded), and then one is added, making 1.020558.

2. Small Business Adjustment Factor

Section 744K(c)(3) of the FD&C Act specifies that in addition to the inflation

adjustment factor, the establishment fee for non-small businesses is to be further adjusted for a small business adjustment factor. Section 744K(c)(3)(B) provides that the small business adjustment factor is the adjustment to the establishment fee for non-small businesses that is necessary to achieve total fees equaling the total fees that FDA would have collected if no entity qualified for the small business exception in section 744K(c)(4) of the FD&C Act.

Therefore, to calculate the small business adjustment to the establishment fee for non-small businesses for FY 2015, FDA must estimate: (1) The number of outsourcing facilities that will pay the reduced fee for small businesses for FY 2015; and (2) the total fee revenue it would have collected if no entity had qualified for the small business exception (i.e., if each outsourcing facility that registers for FY 2015 were to pay the inflation-adjusted fee amount of $15,308). With respect to (1), FDA estimates that 5 entities will qualify for small business exceptions for FY 2015. Accordingly, FDA estimates that 5 entities will pay the reduced fee for small businesses for FY 2015. With respect to (2), to estimate the total number of outsourcing facilities that will register for FY 2015, FDA used data submitted to date by outsourcing facilities through the voluntary registration process, which began in December 2013. Accordingly, FDA estimates that 50 outsourcing facilities, including 5 small businesses, will register with the Agency in FY 2015.

If the projected 50 outsourcing facilities paid the full inflation-adjusted fee of $15,308, this would result in total revenue of $765,400 in FY 2015 ($15,308 times 50). However, because 5 of the outsourcing facilities expected to register for FY 2015 are estimated to qualify for the small business exception and will pay one-third of the full fee ($5,103 × 5), totaling $25,515 instead of paying the full fee ($15,308 × 5), which totals $76,540, this would leave a shortfall of $51,025 ($76,540 − $25,515). Dividing $51,025 by 45 (the number of estimated non-small businesses) yields $1,134 (rounded to the nearest dollar). Therefore, the FY 2015 small business adjustment to the establishment fee for non-small businesses is $1,134.

C. Summary of FY 2015 Fee Rates

TABLE 4—OUTSOURCING FACILITY FEES

Qualified Small Business Establishment Fee	$5,103
Non-Small Business Establishment Fee	16,442
Reinspection Fee	15,308

III. Fee Payment Options and Procedures

A. Establishment Fee

Once an entity submits registration information and FDA has reviewed the information and determined that it is complete, the entity will incur the annual establishment fee. FDA will send an invoice to the entity via email, to the email address indicated in the registration file, or via regular mail if email is not an option. The invoice will contain information regarding the obligation incurred, the amount owed, and payment procedures. A facility will not be deemed registered as an outsourcing facility until it has paid the annual establishment fee under section 744K of the FD&C Act. Accordingly, it is important that facilities seeking to operate as registered outsourcing facilities pay all fees immediately upon receiving an invoice. If an entity does not pay the full invoiced amount within fifteen calendar days after FDA issues the invoice, FDA will consider the submission of registration information to have been withdrawn and adjust the invoice to reflect that no fee is due.

Outsourcing facilities that registered in FY 2014 and wish to maintain their status as an outsourcing facility in FY 2015 must register during the annual registration period that lasts from October 1, 2014 to December 31, 2014. Failure to register and complete payment by December 31, 2014, will result in a loss of status as an outsourcing facility on January 1, 2015. Entities should submit their registration information no later than December 10, 2014 to allow enough time for review of the registration information, invoicing, and payment of fees before the end of the registration period.

B. Reinspection Fee

FDA will issue invoices for each reinspection via email, to the email address indicated in the registration file, or via regular mail if email is not an option.

C. Fee Payment Procedures

Entities may remit payments via check or wire transfer.

1. If paying with a paper check: Checks must be in U.S. currency from a U.S. bank and made payable to the Food and Drug Administration. Payments can be mailed to: Food and Drug Administration, P.O. Box 956733, St. Louis, MO 63195–6733. If a check is sent by a courier that requests a street address, the courier can deliver the check to: U.S. Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (**Note:** This U.S. Bank address is for courier delivery only; do not send mail to this address.)

2. If paying with a wire transfer: Use the following account information when sending a wire transfer: New York Federal Reserve Bank, U.S. Dept of Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No. 75060099, Routing No. 021030004, SWIFT: FRNYUS33, Beneficiary: FDA, 8455 Colesville Road, Silver Spring, MD 20993. The originating financial institution may charge a wire transfer fee. An outsourcing facility should ask its financial institution about the fee and add it to the payment to ensure that the order is fully paid. The tax identification number of FDA is 53–0196965.

Dated: July 25, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–18111 Filed 7–31–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0007]

Prescription Drug User Fee Rates for Fiscal Year 2015

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the rates for prescription drug user fees for fiscal year (FY) 2015. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Prescription Drug User Fee Amendments of 2012 (PDUFA V), authorizes FDA to collect user fees for certain applications for the review of human drug and biological products, on establishments where the products are made, and on such products. This notice establishes the fee rates for FY 2015.

FOR FURTHER INFORMATION CONTACT: Robert J. Marcarelli, Office of Financial Management, Food and Drug