



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0007]

Outsourcing Facility Fee Rates for Fiscal Year 2017

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the fiscal year (FY) 2017 rates for the establishment and re-inspection fees related to entities that compound human drugs and elect to register as outsourcing facilities 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, as well as a re-inspection fee for each re-inspection of an outsourcing facility. This document establishes the FY 2017 rates for the small business establishment fee (\$5,279), the non-small business establishment fee (\$16,852), and the re-inspection fee (\$15,837) for outsourcing facilities; provides information on how the fees for FY 2017 were determined; and describes the payment procedures outsourcing facilities should follow. These fee rates are effective October 1, 2016, and will remain in effect through September 30, 2017.

FOR FURTHER INFORMATION CONTACT: For more information on human drug compounding and outsourcing facility fees, visit FDA's Web site at:

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/default.htm>.

For questions relating to this notice: Monica R. Vega, Office of Financial Management, Food and Drug Administration, 8455 Colesville Rd., COLE-14202J, Silver Spring, MD 20993-0002, 301-796-2127.

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, created a new section 503B in the FD&C Act (21 U.S.C. 353b). Under section 503B of the FD&C Act, 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 the conditions of section 503B are met, a drug compounded by or under the direct supervision of a licensed pharmacist in an outsourcing facility is exempt from three 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; (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); and (3) section 582 (21 U.S.C. 360eee-1) concerning drug supply chain security requirements. 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 requirements 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: (1) An annual establishment fee from each outsourcing facility and (2) a re-inspection fee from each outsourcing facility subject to a re-inspection (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).

FDA announced in the Federal Register of November 24, 2014 (79 FR 69856), 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 provides additional information on the annual fees for outsourcing facilities and adjustments required by law, re-inspection 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 guidance can be accessed on FDA’s Web site at:

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM391102.pdf>.

II. Fees for FY 2017

A. Methodology for Calculating FY 2017 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-payroll costs for the first three of the four previous fiscal years. 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 three of the four previous fiscal years (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 fiscal year to determine the average PC&B per FTE.

Table 1 summarizes the actual cost and FTE data for the specified fiscal years, and provides the percent change from the previous fiscal year and the average percent change over the first three of the four fiscal years preceding FY 2017. The 3-year average is 1.8759 percent.

Table 1.--FDA PC&Bs Each Year and Percent Change

Fiscal Year	2013	2014	2015	3-Year Average
Total PC&B	\$1,927,703,000	\$2,054,937,000	\$2,232,304,000	
Total FTE	13,974	14,555	15,484	
PC&B per FTE	\$137,949	\$141,184	\$144,168	
Percent change from previous year	1.1690%	2.3451%	2.1136%	1.8759%

Section 744K(c)(2)(A)(ii) of the FD&C Act specifies that this 1.8759 percent should be multiplied by the proportion of PC&B to total costs of an average FDA FTE for the same three fiscal years.

Table 2.--FDA PC&Bs as a Percent of FDA Total Costs of an Average FTE

Fiscal Year	2013	2014	2015	3-Year Average
Total PC&B	\$1,927,703,000	\$2,054,937,000	\$2,232,304,000	
Total Costs	\$4,151,343,000	\$4,298,476,000	\$4,510,565,000	
PC&B Percent	46.4356%	47.8062%	49.4906%	47.9108%

The payroll adjustment is 1.8759 percent multiplied by 47.9108 percent, or 0.8988 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 2017 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 non-PC&B costs to total costs of an average FDA FTE for the same period.

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: <http://data.bls.gov/cgi-bin/surveymost?cu>. The data can be viewed by checking the box marked “U.S. All items, 1982-84=100 - CUUR0000SA0” and then selecting “Retrieve Data”.

Table 3.--Annual and 3-Year Average Percent Change in U.S. City Average CPI

Year	2013	2014	2015	3-Year Average
Annual CPI	232.957	236.736	237.017	
Annual Percent Change	1.4648%	1.6222%	0.1187%	1.0686%

Section 744K(c)(2)(A)(iii) of the FD&C Act specifies that this 1.0686 percent should be multiplied by the proportion of all non-PC&B costs to total costs of an average FTE for the same three fiscal years. The proportion of all non-PC&B costs to total costs of an average FDA FTE for FYs 2013 to 2015 is 52.0892 percent (100 percent – 47.9108 percent = 52.0892 percent). Therefore, the non-pay adjustment is 1.0686 percent times 52.0892 percent, or 0.5566 percent.

The PC&B component (0.8988 percent) is added to the non-PC&B component (0.5566 percent), for a total inflation adjustment of 1.4554 percent (rounded). Section 744K(c)(2)(A)(i) of the FD&C Act specifies that one is added to that figure, making the inflation adjustment 1.014554.

Section 744K(c)(2)(B) of the FD&C Act provides for this inflation adjustment to be compounded after FY 2015. This factor for FY 2017 (1.4554 percent) is compounded by adding one to it, and then multiplying it by one plus the inflation adjustment factor for FY 2016 (4.0646 percent), as published in the Federal Register of August 3, 2015 (80 FR 46007). The result of this multiplication of the inflation factors for the 2 years since FY 2015 (1.014554×1.040646) becomes the inflation adjustment for FY 2017. For FY 2017, the inflation adjustment is 5.5792 percent (rounded). We then add one, making the FY 2017 inflation adjustment factor 1.055792.

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) of the FD&C Act 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 amount that FDA would have collected if no entity qualified for the small business exception in section 744K(c)(4) of the FD&C Act. Additionally, section 744K(c)(5)(A) states that in establishing the small business adjustment factor for a fiscal year, FDA shall provide for the crediting of fees from the previous year to the next year if FDA overestimated the amount of the small business adjustment factor for such previous fiscal year.

Therefore, to calculate the small business adjustment to the establishment fee for non-small businesses for FY 2017, FDA must estimate: (1) The number of outsourcing facilities that will pay the reduced fee for small businesses for FY 2017 and (2) the total fee revenue it would have collected if no entity had qualified for the small business exception (i.e., if each entity that registers as an outsourcing facility for FY 2017 were to pay the inflation-adjusted fee amount of \$15,837).

With respect to (1), FDA estimates that seven entities will qualify for small business exceptions and will pay the reduced fee for FY 2017. With respect to (2), to estimate the total number of entities that will register as outsourcing facilities for FY 2017, FDA used data submitted by outsourcing facilities through the voluntary registration process, which began in December 2013. Accordingly, FDA estimates that 72 outsourcing facilities, including seven small businesses, will be registered with FDA in FY 2017.

If the projected 72 outsourcing facilities paid the full inflation-adjusted fee of \$15,837, this would result in total revenue of \$1,140,264 in FY 2017 ($\$15,837 \times 72$). However, seven of the entities that are expected to register as outsourcing facilities for FY 2017 are projected to qualify for the small business exception and to pay one-third of the full fee ($\$5,279 \times 7$), totaling \$36,953 instead of paying the full fee ($\$15,837 \times 7$), which would total \$110,859. This would leave a potential shortfall of \$73,906 ($\$110,859 - \$36,953$).

Additionally, section 744K(c)(5)(A) of the FD&C Act states that in establishing the small business adjustment factor for a fiscal year, FDA shall provide for the crediting of fees from the previous year to the next year if FDA overestimated the amount of the small business adjustment factor for such previous fiscal year. FDA has determined that it is appropriate to credit excess fees collected from the last completed fiscal year, due to the inability to conclusively determine the amount of excess fees from the fiscal year that is in progress at the time this calculation is made. This crediting is done by comparing the small business adjustment factor for the last completed fiscal year, FY 2015 (\$1,134), to what would have been the small business adjustment factor for FY 2015 (\$324) if FDA had estimated perfectly.

The calculation for what the small business adjustment would have been if FDA had estimated perfectly begins by determining the total target collections ($15,000 \times [\text{inflation adjustment factor}] \times [\text{number of registrants}]$). For the most recent complete fiscal year, FY 2015, this was \$995,020 ($\$15,308 \times 65$). The actual FY 2015 revenue from the 65 total registrants (i.e., 63 registrants paying FY 2015 non-small business establishment fee and two small business registrants) paying establishment fees is \$974,610. \$974,610 is calculated as follows: $[\text{FY 2015 Non-Small Business Establishment Fee}] \times [\text{total number of registrants in FY 2015 paying Non-Small Business Establishment Fee}] + [\text{FY 2015 Small Business Establishment Fee}] \times [\text{total$

number of small business registrants in FY 2015 paying Small Business Establishment Fee].
 $\$15,308 \times 63 + \$5,103 \times 2 = \$974,610$. This left a shortfall of \$20,410 from the estimated total target collection amount ($\$995,020 - \$974,610$). \$20,410 divided by the total number of registrants in FY 2015 paying Standard Establishment Fee (63) equals \$324.

The difference between the small business adjustment factor used in FY 2015 and the small business adjustment factor that would have been used had FDA estimated perfectly, is \$810 ($\$1,134 - \324). The \$810 is then multiplied by the number of actual registrants who paid the standard fee for FY 2015 (63), which provides us a total excess collection of \$51,025 (rounded down to the nearest \$5) in FY 2015.

When calculating the small business adjustment factor for FY 2016, FDA estimated the excess collection for FY 2015 because that fiscal year was not complete.¹ FDA estimated that the excess collection would be \$43,094 and credited that amount to the fee calculation for FY 2016. The difference between the estimated excess collection applied as a credit to FY 2016 revenue (\$43,094) and the actual excess collection of \$51,025 results in a small business adjustment credit for FY 2017 of \$7,931 ($\$51,025 - \$43,094$).

Therefore, to calculate the small business adjustment factor for FY 2017, FDA subtracts \$7,931 from the projected shortfall of \$73,906 for FY 2017 to arrive at the numerator for the small business adjustment amount, which equals \$65,975. This number divided by 65 (the number of expected non-small businesses for FY 2017) is the small business adjustment amount for FY 2017, which is \$1,015.

¹ FDA intends to eliminate this adjustment step from the calculation going forward by crediting fees from the most recent completed fiscal year.

B. FY 2017 Rates for Small Business Establishment Fee, Non-Small Business Establishment Fee, and Re-Inspection Fee

1. Establishment Fee for Qualified Small Businesses²

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) of the FD&C Act). The inflation adjustment factor for FY 2017 is 1.055792. See section II.A.1 for the methodology used to calculate the FY 2017 inflation adjustment factor. Therefore, the establishment fee for a qualified small business for FY 2017 is one third of \$15,837, which equals \$5,279 (rounded to the nearest dollar).

2. Establishment Fee for Non-Small Businesses

Under section 744K(c) of the FD&C Act, the amount of the establishment fee for a non-small business 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, and plus or minus an adjustment factor to account for over- or under-collections due to the small business adjustment factor in the prior year. The inflation adjustment factor for FY 2017 is 1.055792. The small business adjustment amount for FY 2017 is \$1,015. See section II.A.2 for the methodology used to calculate the small business adjustment factor for FY 2017. Therefore, the establishment fee for a non-small business for FY 2017 is \$15,000 multiplied by 1.055792 plus \$1,015, which equals \$16,852 (rounded to the nearest dollar).

² To qualify for a small business reduction of the FY 2017 establishment fee, entities had to submit their exception requests by April 30, 2016. See section 744K(c)(4)(B) of the FD&C Act. Although the time for requesting a small business exception for FY 2017 has now passed, an entity that wishes to request a small business exception for FY 2018 should consult section 744K(c)(4) of the FD&C Act and section III.D of FDA's 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>.

3. Re-Inspection Fee

Section 744K(c)(1)(B) of the FD&C Act provides that the amount of the FY 2017 re-inspection fee is equal to \$15,000, multiplied by the inflation adjustment factor for that fiscal year. The inflation adjustment factor for FY 2017 is 1.055792. Therefore, the re-inspection fee for FY 2017 is \$15,000 multiplied by 1.055792, which equals \$15,837 (rounded to the nearest dollar). There is no reduction in this fee for small businesses.

C. Summary of FY 2017 Fee Rates

Table 4.--Outsourcing Facility Fees

Qualified Small Business Establishment Fee	\$5,279
Non-Small Business Establishment Fee	\$16,852
Re-inspection Fee	\$15,837

III. Fee Payment Options and Procedures

A. Establishment Fee

Once an entity submits registration information and FDA has determined that the information 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 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 outsourcing facilities pay all fees immediately upon receiving an invoice. If an entity does not pay the full invoiced amount within 15 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 2016 and wish to maintain their status as an outsourcing facility in FY 2017 must register during the annual registration period that lasts from October 1, 2016, to December 31, 2016. Failure to register and complete payment by December 31, 2016, will result in a loss of status as an outsourcing facility on January 1, 2017. Entities should submit their registration information no later than December 10, 2016, to allow enough time for review of the registration information, invoicing, and payment of fees before the end of the registration period.

B. Re-Inspection Fee

FDA will issue invoices for each re-inspection after the conclusion of the re-inspection, via email to the email address indicated in the registration file or via regular mail if email is not an option. Invoices must be paid within 30 days.

C. Fee Payment Procedures

1. The preferred payment method is online using electronic check (Automated Clearing House (ACH) also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). Secure electronic payments can be submitted using the User Fees Payment Portal at <https://userfees.fda.gov/pay>. Once you search for your invoice, click “Pay Now” to be redirected to Pay.gov. Note that electronic payment options are based on the balance due. Payment by credit card is available for balances less than \$25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be drawn on U.S bank accounts as well as U.S. credit cards.
2. 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 979033, St. Louis, MO 63197-9000. 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 979033, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This U.S. Bank address is for courier delivery only. If you have any questions concerning courier delivery contact the U.S. Bank at 314-418-4013).

3. 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 Rd., 14th Floor, Silver Spring, MD 20993-0002. 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 27, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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