FY 2018 that qualify for fees after the December 2017 billing.

Dated: July 26, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2017–N–0007]**

### Outsourcing Facility Fee Rates for Fiscal Year 2018

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the fiscal year (FY) 2018 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 2018 rates for the small business establishment fee ($5,364), the non-small business establishment fee ($17,364), and the re-inspection fee ($16,093) for outsourcing facilities; provides information on how the fees for FY 2018 were determined; and describes the payment procedures outsourcing facilities should follow. These fee rates are effective October 1, 2017, and will remain in effect through September 30, 2018.

**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/GuidanceCompliance RegulatoryInformation/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 20993–0002, 301–796–7111.

**SUPPLEMENTARY INFORMATION:**

## I. Background

The Drug Quality and Security Act (DQSA) contains important provisions relating to the oversight of compounding 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: *https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM391102.pdf.*

## II. Fees for FY 2018

### *A. Methodology for Calculating FY 2018 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 3 of the 4 previous fiscal years. The payroll component of the annual inflation adjustment is calculated by taking the average change in FDA's per-full time equivalent (FTE) personnel compensation and benefits (PC&B) in the first 3 of the 4 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 3 of the 4 fiscal years preceding FY 2018. The 3-year average is 2.2354 percent.

TABLE 1—FDA PC&BS EACH YEAR AND PERCENT CHANGE

| Fiscal year | 2014 | 2015 | 2016 | 3-Year average |
|---|---|---|---|---|
| Total PC&B | $2,054,937,000 | $2,232,304,000 | $2,414,728,159 | ..... |
| Total FTE | 14,555 | 15,484 | 16,381 | ..... |
| PC&B per FTE | $141,184 | $144,168 | $147,408 | ..... |
| Percent change from previous year | 2.3451% | 2.1136% | 2.2474% | 2.2354% |

Section 744K(c)(2)(A)(ii) of the FD&C Act specifies that this 2.2354 percent should be multiplied by the proportion of PC&B to total costs of an average FDA FTE for the same 3 fiscal years.

TABLE 2—FDA PC&BS AS A PERCENT OF FDA TOTAL COSTS OF AN AVERAGE FTE

| Fiscal year | 2014 | 2015 | 2016 | 3-Year average |
|---|---|---|---|---|
| Total PC&B | $2,054,937,000 | $2,232,304,000 | $2,414,728,159 | ..... |
| Total Costs | $4,298,476,000 | $4,510,565,000 | $4,666,236,000 | ..... |
| PC&B Percent | 47.8062% | 49.4906% | 51.7490% | 49.6819% |

The payroll adjustment is 2.2354 percent multiplied by 49.6819 percent, or 1.1106 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 2018 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 | 2014 | 2015 | 2016 | 3-Year average |
|---|---|---|---|---|
| Annual CPI | 236.736 | 237.017 | 240.007 | ..... |
| Annual Percent Change | 1.6222% | 0.1187% | 1.2615% | 1.0008% |

Section 744K(c)(2)(A)(iii) of the FD&C Act specifies that this 1.0008 percent should be multiplied by the proportion of all non-PC&B costs to total costs of an average FTE for the same 3 fiscal years. The proportion of all non-PC&B costs to total costs of an average FDA FTE for FYs 2014 to 2016 is 50.3181 percent (100 percent − 49.6819 percent = 50.3181 percent). Therefore, the non-pay adjustment is 1.0008 percent times 50.3181 percent, or 0.5036 percent.

The PC&B component (1.1106 percent) is added to the non-PC&B component (0.5036 percent), for a total inflation adjustment of 1.6142 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 1.016142.

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 2018 (1.6142 percent) is compounded by adding one to it, and then multiplying it by one plus the inflation adjustment factor for FY 2017 (5.5792 percent), as published in the **Federal Register** of August 1, 2016 (81 FR 50528 at 50529). The result of this multiplication of the inflation factors for the 3 years since FY 2015 (1.016142 × 1.055792) becomes the inflation adjustment for FY 2018. For FY 2018, the inflation adjustment is 7.2835 percent (rounded). We then add one, making the FY 2018 inflation adjustment factor 1.072835.

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 2018, FDA must estimate: (1) The number of outsourcing facilities that will pay the reduced fee for small businesses for FY 2018 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 2018 were to pay the inflation-adjusted fee amount of $16,093).

With respect to (1), FDA estimates that 12 entities will qualify for small business exceptions and will pay the reduced fee for FY 2018. With respect to (2), to estimate the total number of entities that will register as outsourcing facilities for FY 2018, FDA used data submitted by outsourcing facilities through the voluntary registration process, which began in December 2013. Accordingly, FDA estimates that 76 outsourcing facilities, including 12 small businesses, will be registered with FDA in FY 2018.

If the projected 76 outsourcing facilities paid the full inflation-adjusted fee of $16,093, this would result in total revenue of $1,223,068 in FY 2018 ($16,093 × 76). However, 12 of the entities that are expected to register as outsourcing facilities for FY 2018 are projected to qualify for the small business exception and to pay one-third of the full fee ($5,364 × 12), totaling $64,368 instead of paying the full fee ($16,093 × 12), which would total $193,116. This would leave a potential shortfall of $128,748 ($193,116 − $64,368).

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 2016 ($1,771), to what would have been the small business adjustment factor for FY

2016 ($1,007) 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 × [inflation adjustment factor] × [number of registrants]). For the most recent complete fiscal year, FY 2016, this was $1,061,480 ($15,610 × 68). The actual FY 2016 revenue from the 68 total registrants (*i.e.,* 62 registrants paying FY 2016 non-small business establishment fee and six small business registrants) paying establishment fees is $999,038. $999,038 is calculated as follows: [FY 2016 Non-Small Business Establishment Fee adjusted for inflation only] × [total number of registrants in FY 2016 paying Non-Small Business Establishment Fee] + [FY 2016 Small Business Establishment Fee] × [total number of small business registrants in FY 2016 paying Small Business Establishment Fee]. $15,610 × 62 + $5,203 × 6 = $999,038. This left a shortfall of $62,442 from the estimated total target collection amount ($1,061,480 − $999,038). $62,442 divided by the total number of registrants in FY 2016 paying Standard Establishment Fee (62) equals $1,007.

The difference between the small business adjustment factor used in FY 2016 and the small business adjustment factor that would have been used had FDA estimated perfectly, is $764 ($1,771 − $1,007). The $764 is then multiplied by the number of actual registrants who paid the standard fee for FY 2016 (62), which provides us a total excess collection of $47,385 in FY 2016.[1]

Therefore, to calculate the small business adjustment factor for FY 2018, FDA subtracts $47,385 from the projected shortfall of $128,748 for FY 2018 to arrive at the numerator for the small business adjustment amount, which equals $81,363. This number divided by 64 (the number of expected non-small businesses for FY 2018) is the small business adjustment amount for FY 2018, which is $1,271.

*B. FY 2018 Rates for Small Business Establishment Fee, Non-Small Business Establishment Fee, and Re-Inspection Fee*

1. Establishment Fee for Qualified Small Businesses [2]

The amount of the establishment fee for a qualified small business 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 2018 is 1.072835. See section II.A.1 for the methodology used to calculate the FY 2018 inflation adjustment factor. Therefore, the establishment fee for a qualified small business for FY 2018 is one third of $16,093, which equals $5,364 (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 2018 is 1.072835. The small business adjustment amount for FY 2018 is $1,271. See section II.A.2 for the methodology used to calculate the small business adjustment factor for FY 2018. Therefore, the establishment fee for a non-small business for FY 2018 is $15,000 multiplied by 1.072835 plus $1,271, which equals $17,364 (rounded to the nearest dollar).

3. Re-Inspection Fee

Section 744K(c)(1)(B) of the FD&C Act provides that the amount of the FY 2018 re-inspection fee is equal to $15,000, multiplied by the inflation adjustment factor for that fiscal year. The inflation adjustment factor for FY 2018 is 1.072835. Therefore, the re-inspection fee for FY 2018 is $15,000 multiplied by 1.072835, which equals $16,093 (rounded to the nearest dollar). There is no reduction in this fee for small businesses.

*C. Summary of FY 2018 Fee Rates*

TABLE 4—OUTSOURCING FACILITY FEES

| | |
|---|---|
| Qualified Small Business Establishment Fee | $5,364 |
| Non-Small Business Establishment Fee | 17,364 |
| Re-inspection Fee | 16,093 |

## 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 2017 and wish to maintain their status as an outsourcing facility in FY 2018 must register during the annual registration period that lasts from October 1, 2017, to December 31, 2017. Failure to register and complete payment by December 31, 2017, will result in a loss of status as an outsourcing facility on January 1, 2018. Entities should submit their registration information no later than December 10, 2017, 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.

[1] The small business adjustment credit in place for FY 2017 fee setting is not relevant to setting fees for FY 2018 due to having more complete collection information.

[2] To qualify for a small business reduction of the FY 2018 establishment fee, entities had to submit their exception requests by April 30, 2017. See section 744K(c)(4)(B) of the FD&C Act. Although the time for requesting a small business exception for FY 2018 has now passed, an entity that wishes to request a small business exception for FY 2019 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 *https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm391102.pdf*.

*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.* (**Note:** Only full payments are accepted. No partial payments can be made online.) Once you search for your invoice, click ''Pay Now'' to be redirected to *Pay.gov.* 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 made using 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. When paying by wire transfer, the invoice number must be included. Without the invoice number the payment may not be applied. Regarding re-inspection fees, if the payment amount is not applied, the invoice amount will be referred to collections. The originating financial institution may charge a wire transfer fee. If the financial institution charges a wire transfer fee, it is required that the outsourcing facility add that amount to the payment to ensure that the invoice is paid in full. 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. If needed, FDA's tax identification number is 53–0196965.

Dated: July 25, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### Over-the-Counter Monograph User Fees: Stakeholder Meeting

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

**ACTION:** Notice of public meeting.

**SUMMARY:** The Food and Drug Administration (FDA) will hold a webinar for stakeholders on August 23, 2017, to provide stakeholders with a status update on the process of FDA and industry discussions on an Over-the-Counter (OTC) Monograph user fee program that began in July 2016. FDA will also provide an overview of proposed performance goals and procedures related to a potential new OTC monograph user fee program. This webinar is intended to be a followup to the June 10, 2016, public meeting and the September 6, 2016, stakeholder webinar on a potential new OTC monograph user fee program.

**DATES:** FDA will hold a webinar for stakeholders on Wednesday, August 23, 2017, from 12:30 p.m. to 2 p.m. EDT.

**FOR FURTHER INFORMATION CONTACT:** Mary Vienna, Office of Executive Programs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20903–0002, 301–796–4150, email: *OTCMonographUserFeeProgram@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:**

## I. Introduction

On June 10, 2016, FDA held a public meeting on a potential new user fee program for nonprescription (over-the-counter or OTC) monograph drugs. In the announcement of the public meeting in the **Federal Register** (May 11, 2016, 81 FR 29275), FDA invited public comment as the Agency considers a user-fee program for OTC monograph drugs. A user-fee program would provide funding to supplement congressional non-user-fee appropriations, and would support timely and efficient FDA review of the efficacy and safety of ingredients included in or proposed for inclusion in a monograph. Interested persons were given until July 11, 2016, to submit comments. A stakeholder webinar was held on September 6, 2016, which provided stakeholders with a status update on the process of FDA and industry discussions that began in July 2016. In the notice of public meeting (August 8, 2016, 81 FR 52444), FDA invited public comments and interested parties were given until October 6, 2016, to submit comments.

FDA will hold a webinar for stakeholders on August 23, 2017, to provide stakeholders with a status update on the process of FDA and industry discussions on an OTC Monograph user fee program that began in July 2016. FDA will also provide an overview of proposed performance goals and procedures related to a potential new OTC monograph user fee program. This webinar is intended to be a followup to the June 10, 2016, public meeting and the September 6, 2016, stakeholder webinar on a potential new OTC monograph user fee program.

## II. Background

Meeting minutes from FDA and industry discussions on a new OTC monograph user fee program can be found at: *https://www.fda.gov/ForIndustry/UserFees/OTCMonographUserFee/default.htm.* The proposed OTC Monograph User Fee Program Performance Goals and Procedures—Fiscal Years 2018–2022 document can also be found at that same Web site.

Additional background information on OTC monograph drugs (such as how OTC drugs can be marketed, and the differences between marketing through approved applications and marketing under the monographs), factors FDA considers important in developing a user-fee program, and the questions for which FDA asked the public to consider and provide input, can be found in the **Federal Register** notice from the June 10, 2016, public meeting (*https://www.federalregister.gov/articles/2016/05/11/2016-11098/over-the-counter-monograph-user-fees-public-meeting-request-for-comments*). The meeting transcript, meeting recording, and presentations from the June 10, 2016, public meeting, which can serve as further background information, can be found at: *https://www.fda.gov/ForIndustry/UserFees/OTCMonographUserFee/default.htm.* A summary of the September 6, 2016, stakeholders' webinar, can also be found at: *https://www.fda.gov/ForIndustry/UserFees/OTCMonographUserFee/default.htm.*

## III. Stakeholder Meeting Participation

FDA is seeking participation at the webinar by stakeholders, including scientific and academic experts, health care professionals, representatives of patient and consumer advocacy groups, and representatives of the OTC monograph industry. Participating in the webinar is free. The webinar format