Dated: July 26, 2019.

Lowell J. Schiller,

Principal 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 2020

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the fiscal year (FY) 2020 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 (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 2020 rates for the small business establishment fee ($5,599), the non-small business establishment fee ($18,288), and the re-inspection fee ($16,798) for outsourcing facilities; provides information on how the fees for FY 2020 were determined; and describes the payment procedures outsourcing facilities should follow. These fee rates are effective October 1, 2019, and will remain in effect through September 30, 2020.

FOR FURTHER INFORMATION CONTACT:

For more information on human drug compounding and outsourcing facility fees: Visit FDA's website at: *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/default.htm.*

For questions relating to this notice: Melissa Hurley, Office of Financial Management, Food and Drug Administration, 4041 Powder Mill Rd., Rm. 61075, Beltsville, MD 20705–4304, 240–402–4585.

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 website at: *https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM391102.pdf.*

II. Fees for FY 2020

A. Methodology for Calculating FY 2020 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 2020. The 3-year average is 3.1175 percent.

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

Fiscal year	2016	2017	2018	3-year average
Total PC&B	$2,414,728,159	$2,581,551,000	$2,690,678,000	
Total FTE	16,381	17,022	17,023	
PC&B per FTE	$147,408	$151,660	$158,061	
Percent change from previous year	2.2474%	2.8845%	4.2206%	3.1175%

Section 744K(c)(2)(A)(ii) of the FD&C Act specifies that this 3.1175 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	2016	2017	2018	3-year average
Total PC&B	$2,414,728,159	$2,581,551,000	$2,690,678,000	.....
Total Costs	$4,666,236,000	$5,104,580,000	$5,370,935,000	.....
PC&B Percent	51.7490%	50.5732%	50.0970%	50.8064%

The payroll adjustment is 3.1175 percent multiplied by 50.8064 percent, or 1.5839 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 2020 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 website: *https://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	2016	2017	2018	3-year average
Annual CPI	240.007	245.120	251.107	.....
Annual Percent Change	1.2615%	2.1304%	2.4425%	1.9448%

Section 744K(c)(2)(A)(iii) of the FD&C Act specifies that this 1.9448 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 2016 to 2018 is 49.1936 percent (100 percent − 50.8064 percent = 49.1936 percent). Therefore, the non-pay adjustment is 1.9448 percent times 49.1936 percent, or 0.9567 percent.

The PC&B component (1.5839 percent) is added to the non-PC&B component (0.9567 percent), for a total inflation adjustment of 2.5406 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 1.025406.

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 2020 (2.5406 percent) is compounded by adding one to it, and then multiplying it by one plus the inflation adjustment factor for FY 2019 (9.2148 percent), as published in the **Federal Register** of August 1, 2018 (83 FR 37500 at 37502). The result of this multiplication of the inflation factors for the 5 years since FY 2015 (1.025406 × 1.092148) becomes the inflation adjustment for FY 2020. For FY 2020, the inflation adjustment is 11.9895 percent (rounded). We then add one, making the FY 2020 inflation adjustment factor 1.119895.

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 2020, FDA must estimate: (1) The number of outsourcing facilities that will pay the reduced fee for small businesses for FY 2020 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 2020 were to pay the inflation-adjusted fee amount of $16,798).

With respect to (1), FDA estimates that 14 entities will qualify for small business exceptions and will pay the reduced fee for FY 2020. With respect to (2), to estimate the total number of entities that will register as outsourcing facilities for FY 2020, FDA used data submitted by outsourcing facilities through the voluntary registration process, which began in December 2013. Accordingly, FDA estimates that 85 outsourcing facilities, including 14 small businesses, will be registered with FDA in FY 2020.

If the projected 85 outsourcing facilities paid the full inflation-adjusted fee of $16,798, this would result in total revenue of $1,427,830 in FY 2020 ($16,798 × 85). However, 14 of the entities that are expected to register as outsourcing facilities for FY 2020 are projected to qualify for the small business exception and to pay one-third of the full fee ($5,599 × 14), totaling $78,386 instead of paying the full fee ($16,798 × 14), which would total $235,172. This would leave a potential shortfall of $156,786 ($235,172 − $78,386).

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 2018 ($2,012), to what would have been the small business adjustment factor for FY

2018 ($1,262) 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 2018, this was $1,223,068 ($16,093 × 76). The actual FY 2018 revenue from the 76 total registrants (*i.e.,* 68 registrants paying FY 2018 non-small business establishment fee and eight small business registrants) paying establishment fees is $1,137,236. $1,137,236 is calculated as follows: (FY 2018 Non-Small Business Establishment Fee adjusted for inflation only) × (total number of registrants in FY 2018 paying Non-Small Business Establishment Fee) + (FY 2018 Small Business Establishment Fee) × (total number of small business registrants in FY 2018 paying Small Business Establishment Fee). $16,093 × 68 + $5,364 × 8 = $1,137,236. This left a shortfall of $85,832 from the estimated total target collection amount ($1,223,068 − $1,137,236). $85,832 divided by the total number of registrants in FY 2018 paying Standard Establishment Fee (68) equals $1,262.

The difference between the small business adjustment factor used in FY 2018 and the small business adjustment factor that would have been used had FDA estimated perfectly; is $749 ($2,012 − $1,262). The $749 (rounded to the nearest dollar) is then multiplied by the number of actual registrants who paid the standard fee for FY 2018 (68), which provides us a total excess collection of $50,963 in FY 2018.

Therefore, to calculate the small business adjustment factor for FY 2020, FDA subtracts $50,963 from the projected shortfall of $156,786 for FY 2020 to arrive at the numerator for the small business adjustment amount, which equals $105,823. This number divided by 71 (the number of expected non-small businesses for FY 2020) is the small business adjustment amount for FY 2020, which is $1,490 (rounded to the nearest dollar).

B. FY 2020 Rates for Small Business Establishment Fee, Non-Small Business Establishment Fee, and Re-Inspection Fee

1. Establishment Fee for Qualified Small Businesses [1]

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 2020 is 1.119895. See section II.A.1 for the methodology used to calculate the FY 2020 inflation adjustment factor. Therefore, the establishment fee for a qualified small business for FY 2020 is one third of $16,798, which equals $5,599 (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 2020 is 1.119895. The small business adjustment amount for FY 2020 is $1,490. See section II.A.2 for the methodology used to calculate the small business adjustment factor for FY 2020. Therefore, the establishment fee for a non-small business for FY 2020 is $15,000 multiplied by 1.119895 plus $1,490, which equals $18,288 (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 2020 re-inspection fee is equal to $15,000, multiplied by the inflation adjustment factor for that fiscal year. The inflation adjustment factor for FY 2020 is 1.119895. Therefore, the re-inspection fee for FY 2020 is $15,000 multiplied by 1.119895, which equals $16,798 (rounded to the nearest dollar). There is no reduction in this fee for small businesses.

C. Summary of FY 2020 Fee Rates

TABLE 4—OUTSOURCING FACILITY FEES

Qualified Small Business Establishment Fee	$5,599
Non-Small Business Establishment Fee	18,288
Re-inspection Fee	16,798

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 2019 and wish to maintain their status as an outsourcing facility in FY 2020 must register during the annual registration period that lasts from October 1, 2019, to December 31, 2019. Failure to register and complete payment by December 31, 2019, will result in a loss of status as an outsourcing facility on January 1, 2020. Entities should submit their registration information no later than December 10, 2019, 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

[1] To qualify for a small business reduction of the FY 2020 establishment fee, entities had to submit their exception requests by April 30, 2019. See section 744K(c)(4)(B) of the FD&C Act. The time for requesting a small business exception for FY 2020 has now passed. An entity that wishes to request a small business exception for FY 2021 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 website at *https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm391102.pdf*.

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: U.S. Dept of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No. 75060099, Routing No. 021030004, SWIFT: FRNYUS33. If needed, FDA's tax identification number is 53–0196965.

Dated: July 25, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–1203]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Information To Accompany Humanitarian Device Exemption Applications and Annual Distribution Number Reporting Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by August 30, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0661. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Information To Accompany Humanitarian Device Exemption Applications and Annual Distribution Number Reporting Requirements

OMB Control Number 0910–0661—Extension

Under section 520(m) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360j(m)), as amended by section 3052 of the 21st Century Cures Act (Cures Act) (Pub. L. 114–255), FDA is authorized to exempt a humanitarian use device (HUD) from the effectiveness requirements in sections 514 and 515 of the FD&C Act (21 U.S.C. 360d and 360e) provided that the device: (1) Is designed to treat or diagnose a disease or condition that affects not more than 8,000 individuals in the United States; (2) would not be available to a person with such a disease or condition unless the exemption is granted and there is no comparable device, other than another HUD approved under this exemption, available to treat or diagnose the disease or condition; and (3) the device will not expose patients to an unreasonable or significant risk of illness or injury and the probable benefit to health from using the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment.

HUDs approved under a humanitarian device exemption (HDE) cannot be sold for an amount that exceeds the costs of research and development, fabrication, and distribution of the device (*i.e.,* for profit), except in narrow circumstances. Under section 520(m)(6)(A)(i) of the FD&C Act, a HUD approved under an HDE is eligible to be sold for profit if the device meets the following criteria: The device is intended for the treatment or diagnosis of a disease or condition that occurs in pediatric patients or in a pediatric subpopulation, and such device is labeled for use in pediatric patients or in a pediatric subpopulation in which the disease or condition occurs; or the device is intended for the treatment or diagnosis of a disease or condition that does not occur in pediatric patients, or that occurs in pediatric patients in such numbers that the development of the device for such patients is impossible, highly impracticable, or unsafe.

Section 520(m)(6)(A)(ii) of the FD&C Act, provides that the Secretary of Health and Human Services will determine the annual distribution number (ADN) for devices that meet the eligibility criteria to be permitted to be sold for profit. The Cures Act amended the FD&C Act definition of the ADN as the number of devices reasonably needed to treat, diagnose, or cure a population of 8,000 individuals in the United States.

Section 520(m)(6)(A)(iii) of the FD&C Act provides that an HDE holder immediately notify the Agency if the number of such devices distributed during any calendar year exceeds the ADN. Section 520(m)(6)(C) of the FD&C Act provides that an HDE holder may petition to modify the ADN if additional information arises.