prompt you through the entry of information about your establishment and your devices. If you have any problems with this process, email: *reglist@cdrh.fda.gov* or call 301–796–7400 for assistance. (*Note:* This email address and this telephone number are for assistance with establishment registration only; they are not to be used for questions related to other aspects of medical device user fees.) Problems with the eBER system should be directed to *https://www.accessdata.fda.gov/scripts/email/cber/bldregcontact.cfm* or call 240–402–8360.

D. Enter Your DFUF Order PIN and PCN

After completing your annual or initial registration and device listing, you will be prompted to enter your DFUF order PIN and PCN, when applicable. This process does not apply to establishments engaged only in the manufacture, preparation, propagation, compounding, or processing of licensed biologic devices. CBER will send invoices for payment of the establishment registration fee to such establishments.

IX. Small Business Fee Reductions and Fee Waivers

To qualify for reduced fees for small businesses or a small business fee waiver, please see the requirements for qualification provided in Section V. How To Qualify as a Small Business for Purposes of Medical Device Fees. The applicant should submit a Small Business Certification Request and the supporting materials showing you qualify as a small business at least 60 days before you send your submission to FDA. FDA will review your information and determine whether you qualify as a small business eligible for the reduced fee and/or fee waiver. If you make a submission before FDA finds that you qualify as a small business, you must pay the standard (full) fee for that submission.

If you need assistance, please contact the Division of Industry and Consumer Education at 800–638–2041 or 301–796–7100 or email at *DICE@fda.hhs.gov.*

A. Premarket Approval Fee Reduction or Waiver

A small business applicant may request to pay a reduced rate for premarket approval fees. An applicant may also request a fee waiver for their first premarket application or premarket report (see 21 U.S.C. 379j(d)).

B. Premarket Notification Submission Fee Reduction

A small business applicant may request to pay a reduced rate for a premarket notification submission.

C. Annual Establishment Registration Fee

There is no small business waiver for the annual establishment registration fee; all establishments pay the same fee.

X. Refunds

To qualify for consideration for a refund, a person shall submit to FDA a written request for a refund not later than 180 days after such fee is due. FDA has discretion to refund a fee or a portion of the fee. A determination by FDA concerning a refund shall not be reviewable. For more information on qualifying and submitting a refund, see 21 U.S.C. 379j(a)(2)(D).

Dated: July 21, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–15919 Filed 7–27–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–2895]

Outsourcing Facility Fee Rates for Fiscal Year 2024

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the fiscal year (FY) 2024 rates for the establishment and reinspection 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 reinspection fee for each reinspection of an outsourcing facility. This document establishes the FY 2024 rates for the small business establishment fee ($6,196), the non-small business establishment fee ($20,036), and the reinspection fee ($18,588) for outsourcing facilities; provides information on how the fees for FY 2024 were determined; and describes the payment procedures outsourcing facilities should follow.

DATES: These fee rates are effective October 1, 2023, and will remain in effect through September 30, 2024.

ADDRESSES: Office of Financial Management, Food and Drug Administration, 4041 Powder Mill Rd., Rm. 61075, Beltsville, MD 20705–4304.

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/guidance-compliance-regulatory-information/human-drug-compounding.*

For questions relating to this notice: Olufunmilayo Ariyo, Office of Financial Management, Food and Drug Administration, 4041 Powder Mill Rd., Beltsville, MD 20705–4304, 240–402–4989; or the User Fee Support Staff at *OO-OFBAP-OFM-UFFS-Government@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Under section 503B of the FD&C Act (21 U.S.C. 353b), a human drug compounder can register with FDA as an ''outsourcing facility.'' Outsourcing facilities, as defined in section 503B(d)(4), are facilities that meet all 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 or abbreviated new drug applications; 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 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).

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, 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 guidance can be accessed on FDA's website at: *https://www.fda.gov/media/136683/download.*

II. Fees for FY 2024

A. Methodology for Calculating FY 2024 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 2024. The 3-year average is 3.9280 percent.

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

	FY 2020	FY 2021	FY 2022	3-Year average
Total PC&B	$2,875,592,000	$3,039,513,000	$3,165,477,000	
Total FTE	$17,535	$18,501	$18,474	
PC&B per FTE	$163,992	$164,289	$171,348	
Percent Change From Previous Year	7.3063%	0.1811%	4.2967%	3.9280%

Section 744K(c)(2)(A)(ii) of the FD&C Act specifies that this 3.9280 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

	FY 2020	FY 2021	FY 2022	3-Year average
Total PC&B	$2,875,592,000	$3,039,513,000	$3,165,477,000	
Total Costs	$6,039,320,747	$6,105,480,000	$6,251,981,000	
PC&B Percent	47.6145%	49.7834%	50.6316%	49.3432%

The payroll adjustment is 3.9280 percent multiplied by 49.3432 percent, or 1.9382 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 2024 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. city average, All items—CUUR0000SA0'' and then selecting ''Retrieve Data.''

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

	FY 2020	FY 2021	FY 2022	3-Year average
Annual CPI	258.81	270.97	292.66	
Annual Percent Change	1.2337%	4.6980%	8.0027%	4.6448%

Section 744K(c)(2)(A)(iii) of the FD&C Act specifies that this 4.6448 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 2019 to 2021 is 50.6568 percent (100 percent minus 49.3432 percent equals 50.6568 percent). Therefore, the non-pay adjustment is 4.6448 percent times 50.6568 percent, or 2.3529 percent.

The PC&B component (1.9382 percent) is added to the non-PC&B component (2.3529 percent), for a total inflation adjustment of 4.2911 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 1.042911.

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 2024 (4.2911 percent) is compounded by adding one to it, and then multiplying it by one plus the inflation adjustment factor for FY 2023 (18.8227 percent), as published in the

Federal Register on July 28, 2022 (87 FR 45335). The result of this multiplication of the inflation factors for the 8 years since FY 2015 (1.042922 × 1.239215) becomes the inflation adjustment for FY 2024. For FY 2024, the inflation adjustment is 12.39215 percent (rounded). We then add one, making the FY 2024 inflation adjustment factor 1.1239215.

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 2024, FDA must estimate: (1) the number of outsourcing facilities that will pay the reduced fee for small businesses for FY 2024 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 2024 were to pay the inflation-adjusted fee amount of $18,588).

With respect to (1), FDA estimates that 10 entities will qualify for small business exceptions and will pay the reduced fee for FY 2024. With respect to (2), to estimate the total number of entities that will register as outsourcing facilities for FY 2024, FDA used data submitted by outsourcing facilities through the voluntary registration process, which began in December 2013. Accordingly, FDA estimates that 79 outsourcing facilities, including 10 small businesses, will be registered with FDA in FY 2024.

If the projected 79 outsourcing facilities paid the full inflation-adjusted fee of $18,588, this would result in total revenue of $1,468,452 in FY 2024 ($18,588 × 79). However, 10 of the entities that are expected to register as outsourcing facilities for FY 2024 are projected to qualify for the small business exception and to pay one-third of the full fee ($6,196 × 10), totaling $61,960 instead of paying the full fee ($18,588 × 10), which would total $185,880. This would leave a potential shortfall of $123,920 ($185,880 minus $61,960).

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 2022 ($2,056), to what would have been the small business adjustment factor for FY 2022 ($1,731) 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 2022, this was $1,485,120 ($17,472 × 85). The actual FY 2022 revenue from the 85 total registrants (*i.e.,* 74 registrants paying FY 2022 non-small business establishment fee and 11 small business registrants) paying establishment fees is $1,356,992. $1,356,992 is calculated as follows: (FY 2022 Non-Small Business Establishment Fee adjusted for inflation only) × (total number of registrants in FY 2022 paying Non-Small Business Establishment Fee) + (FY 2022 Small Business Establishment Fee) × (total number of small business registrants in FY 2022 paying Small Business Establishment Fee). $17,472 × 74 + $5,824 × 11 = $1,356,992. This left a shortfall of $128,128 from the estimated total target collection amount ($1,485,120 minus $1,356,992). This amount ($128,128) divided by the total number of registrants in FY 2022 paying Standard Establishment Fee (74) equals $1,731.

The difference between the small business adjustment factor used in FY 2022 and the small business adjustment factor that would have been used had FDA estimated perfectly is $325 ($2,056 minus $1,731). The $325 (rounded to the nearest dollar) is then multiplied by the number of actual registrants who paid the standard fee for FY 2022 (74), which provides us a total excess collection of $24,050 in FY 2022.

Therefore, to calculate the small business adjustment factor for FY 2024, FDA subtracts $24,050 from the projected shortfall of $123,920 for FY 2024 to arrive at the numerator for the small business adjustment amount, which equals $99,870. This number divided by 69 (the number of expected non-small businesses for FY 2024) is the small business adjustment amount for FY 2024, which is $1,447 (rounded to the nearest dollar).

B. FY 2024 Rates for Small Business Establishment Fee, Non-Small Business Establishment Fee, and Reinspection 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 3 (see section 744K(c)(4)(A) and (c)(1)(A) of the FD&C Act). The inflation adjustment factor for FY 2024 is 1.239215. See section II.A.1 of this document for the methodology used to calculate the FY 2024 inflation adjustment factor. Therefore, the establishment fee for a qualified small business for FY 2024 is one third of $18,588, which equals $6,196 (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 2024 is 1.239215. The small business adjustment amount for FY 2024 is $1,447. See section II.A.2 of this document for the methodology used

[1] To qualify for a small business reduction of the FY 2024 establishment fee, entities had to submit their exception requests by April 30, 2023. See section 744K(c)(4)(B) of the FD&C Act. The time for requesting a small business exception for FY 2024 has now passed. An entity that wishes to request a small business exception for FY 2025 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/media/136683/download.*

to calculate the small business adjustment factor for FY 2024. Therefore, the establishment fee for a non-small business for FY 2024 is $15,000 multiplied by 1.239215 plus $1,447, which equals $20,036 (rounded to the nearest dollar).

3. Reinspection Fee

Section 744K(c)(1)(B) of the FD&C Act provides that the amount of the FY 2024 reinspection fee is equal to $15,000, multiplied by the inflation adjustment factor for that fiscal year. The inflation adjustment factor for FY 2024 is 1.239215. Therefore, the reinspection fee for FY 2024 is $15,000 multiplied by 1.239215, which equals $18,588 (rounded to the nearest dollar). There is no reduction in this fee for small businesses.

C. Summary of FY 2024 Fee Rates

TABLE 4—OUTSOURCING FACILITY FEES

Qualified Small Business Establishment Fee	$6,196.00
Non-Small Business Establishment Fee	20,036.00
Reinspection Fee	18,588.00

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. 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 2023 and wish to maintain their status as an outsourcing facility in FY 2024 must register during the annual registration period that lasts from October 1, 2023, to December 31, 2023. Failure to register and complete payment by December 31, 2023, will result in a loss of status as an outsourcing facility on January 1, 2024. Entities should submit their registration information no later than December 10, 2023, 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 after the conclusion of the reinspection, via email to the email address indicated in the registration file or via regular mail if email is not an option. Payments must be made within 30 days of the invoice date.

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 a check, bank draft, or postal money order is submitted, make it payable to the order of the Food and Drug Administration and include the user fee ID number to ensure that the payment is applied to the correct fee(s). Payments can be mailed to: Food and Drug Administration, P.O. Box 979107, St. Louis, MO 63197–9000. If a check, bank draft, or money order is to be sent by a courier that requests a street address, the courier should deliver your payment to: U.S. Bank, Attention: Government Lockbox 979107, 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. This telephone number is only for questions about courier delivery.) Please make sure that the FDA post office box number (P.O. Box 979107) is written on the check, bank draft, or postal money order.

3. For payments made by wire transfer, the invoice number must be included. Without the invoice number the payment may not be applied. Regarding reinspection 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 24, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–15909 Filed 7–27–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–2850]

Prescription Drug User Fee Rates for Fiscal Year 2024

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the rates for prescription drug user fees for fiscal year (FY) 2024. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Prescription Drug User Fee Amendments of 2022 (PDUFA VII), authorizes FDA to collect application fees for certain applications for the review of human drug and biological products and prescription drug program fees for certain approved products. This notice establishes the fee rates for FY 2024.

DATES: These fees apply to the period from October 1, 2023, through September 30, 2024.

FOR FURTHER INFORMATION CONTACT: Olufunmilayo Ariyo, Office of Financial Management, Food and Drug Administration, 4041 Powder Mill Rd., 6th Floor, Beltsville, MD 20705, 240–402–4989; and the User Fee Support Staff at *OO-OFBAP-OFM-UFSS-Government@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Sections 735 and 736 of the FD&C Act (21 U.S.C. 379g and 379h, respectively)