with the letters ''AG'', on the upper right-hand corner of your completed Animal Generic Drug User Fee Cover Sheet. Also write FDA's post office box number (P.O. Box 979033) and PIN on the enclosed check, bank draft, or money order. Mail the payment and a copy of the completed Animal Generic Drug User Fee Cover Sheet to: Food and Drug Administration, P.O. Box 979033, St. Louis, MO 63197–9000. *Note:* In no case should the payment for the fee be submitted to FDA with the application or JINAD file submission.

When paying by wire transfer, the invoice number or PIN needs to be included. Without the invoice number or PIN, the payment may not be applied, and the invoice amount would 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 to add that amount to the payment to ensure that the invoice is paid in full. Use the following account information when sending a payment by wire transfer: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Account Name: Food and Drug Administration, Account Number: 75060099, U.S. Department of the Treasury routing/transit number: 021030004, SWIFT Number: FRNYUS33.

To send a check by a courier such as FedEx, the courier must deliver the check and printed copy of the cover sheet to U.S. Bank: U.S. Bank, Attn: Government Lockbox 979033, 3180 Rider Trail S, Earth City, MO 63045. (*Note:* This address is for courier delivery only. If you have any questions concerning courier delivery, contact U.S. Bank at 855–259–3064. This telephone number is only for questions about courier delivery.)

It is important that the fee arrives at the bank at least a day or two before the abbreviated application or JINAD submission arrives at FDA's CVM. FDA records the official abbreviated application or JINAD submission receipt date as the later of the following: the date the application or submission was received by CVM, or the date U.S. Bank notifies FDA that your payment in the full amount has been received, or when the U.S. Department of the Treasury notifies FDA of payment. U.S. Bank and the U.S. Department of the Treasury are required to notify FDA within 1 working day, using the PIN described previously.

The tax identification number of FDA is 53–0196965.

B. Application and JINAD File Submission Cover Sheet Procedures

Step One: Create a user account and password. Log onto the AGDUFA website at *https://www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/ucm137049.htm* and, under Application Submission Information, click on ''Create AGDUFA User Fee Cover Sheet'' and follow the directions. For security reasons, each firm submitting an application and/or a JINAD file submission will be assigned an organization identification number, and each user will also be required to set up a user account and password the first time you use this site. Online instructions will walk you through this process.

Step Two: Create an Animal Generic Drug User Fee Cover Sheet, transmit it to FDA, and print a copy. After logging into your account with your username and password, complete the steps required to create an Animal Generic Drug User Fee Cover Sheet. One cover sheet is needed for each abbreviated application for a generic new animal drug or JINAD file submission. Once you are satisfied that the data on the cover sheet is accurate and you have finalized the cover sheet, you will be able to transmit it electronically to FDA and you will be able to print a copy of your cover sheet showing your unique PIN.

Step Three: Send the payment for your application or JINAD file submission as described in section IX.A.

Step Four: Submit your application or JINAD file submission.

C. Product and Sponsor Fees

By December 31, 2024, FDA will issue invoices and payment instructions for product and sponsor fees for FY 2025 using this fee schedule. Payment will be due by January 31, 2025. FDA will issue invoices in November 2025 for any products and sponsors subject to fees for FY 2025 that qualify for fees after the December 2024 billing.

Dated: July 26, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–16885 Filed 7–30–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3005]

Outsourcing Facility Fee Rates for Fiscal Year 2025

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the fiscal year (FY) 2025 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 2025 rates for the small business establishment fee ($6,488), the non-small business establishment fee ($21,534), and the reinspection fee ($19,465) for outsourcing facilities; provides information on how the fees for FY 2025 were determined; and describes the payment procedures outsourcing facilities should follow.

DATES: These fee rates are effective October 1, 2024, and will remain in effect through September 30, 2025.

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, 10903 New Hampshire Ave., Silver Spring, MD 20903, 240–402–4989; or the User Fee Support Staff at *OO-OFBAP-OFM-UFSS-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 2025

A. Methodology for Calculating FY 2025 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 2025. The 3-year average is 3.8539 percent.

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

	FY 2021	FY 2022	FY 2023	3-Year average
Total PC&B	$3,039,513,000	$3,165,477,000	$3,436,513,000	
Total FTE	$18,501	$18,474	$18,729	
PC&B per FTE	$164,289	$171,348	$183,486	
Percent Change From Previous Year	0.1811%	4.2967%	7.0838%	3.8539%

Section 744K(c)(2)(A)(ii) of the FD&C Act specifies that this 3.8539 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 2021	FY 2022	FY 2023	3-Year average
Total PC&B (proportion of costs)	$3,039,513,000	$3,165,477,000	$3,436,513,000	
Total Costs	$6,105,480,000	$6,251,981,000	$6,654,058,000	
PC&B percent	49.7834%	50.6316%	51.6454%	50.6868%

The payroll adjustment is 3.8539 percent multiplied by 50.6868 percent, or 1.9534 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 2025 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 3 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

	2021	2022	2023	3-Year average
Annual CPI	270.970	292.655	304.702	
Annual Percent Change	4.6980%	8.0027%	4.1165%	5.6057%

Section 744K(c)(2)(A)(iii) of the FD&C Act specifies that this 5.6057 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 2021 to 2023 is 49.3132 percent (100 percent minus 50.6868 percent equals 49.3132 percent). Therefore, the non-pay adjustment is 5.6057 percent times 49.3132 percent, or 2.7644 percent.

The PC&B component (1.9534 percent) is added to the non-PC&B component (2.7644 percent), for a total inflation adjustment of 4.7178 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 1.047178.

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 2025 (4.7178 percent) is compounded by adding one to it, and then multiplying it by one plus the inflation adjustment factor for FY 2024 (23.9215 percent), as published in the **Federal Register** on July 28, 2023 (88 FR 48878). The result of this multiplication of the inflation factors for the 10 years since FY 2015 (1.047178×1.239215) becomes the inflation adjustment for FY 2025. For FY 2025, the inflation adjustment is 29.7679 percent (rounded). We then add one, making the FY 2025 inflation adjustment factor 1.297679.

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 2025, FDA must estimate: (1) the number of outsourcing facilities that will pay the reduced fee for small businesses for FY 2025 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 2025 were to pay the inflation-adjusted fee amount of $19,465).

With respect to (1), FDA estimates that 11 entities will qualify for small business exceptions and will pay the reduced fee for FY 2025. With respect to (2), to estimate the total number of entities that will register as outsourcing facilities for FY 2025, FDA used data submitted by outsourcing facilities through the voluntary registration process, which began in December 2013. Accordingly, FDA estimates that 80 outsourcing facilities, including 11 small businesses, will be registered with FDA in FY 2025.

If the projected 80 outsourcing facilities paid the full inflation-adjusted fee of $19,465, this would result in total revenue of $1,557,200 in FY 2025 ($\$19,465 \times 80$). However, 11 of the entities that are expected to register as outsourcing facilities for FY 2025 are projected to qualify for the small business exception and to pay one-third of the full fee ($\$6,488 \times 11$), totaling $71,368 instead of paying the full fee ($\$19,465 \times 11$), which would total $214,115. This would leave a potential shortfall of $142,747 ($214,115 minus $71,368).

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 2023 ($1,747), to what would have been the small business adjustment factor for FY 2023 ($2,011) 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 ($15{,}000 \times$ [inflation adjustment factor] $\times$ [number of registrants]). For the most recent complete fiscal year, FY 2023, this was $1,354,548 ($\$17{,}823 \times 76$). The actual FY 2023 revenue from the 76 total registrants (*i.e.,* 65 registrants paying FY 2023 non-small business establishment fee and 11 small business registrants) paying establishment fees is $1,223,846. $1,223,846 is calculated as follows: (FY 2023 Non-Small Business Establishment Fee adjusted for inflation only) $\times$ (total number of registrants in FY 2023 paying Non-Small Business Establishment Fee) + (FY 2023 Small Business Establishment Fee) $\times$ (total number of small business registrants in FY 2023 paying Small Business Establishment Fee). $\$17{,}823 \times 65 + \$5{,}824 \times 11 = \$1{,}223{,}846$. This left a shortfall of $130,702 from the estimated total target collection amount ($1,354,548 minus $1,223,846). This amount ($130,702) divided by the total number of registrants in FY 2023 paying Standard Establishment Fee (65) equals $2,011.

The difference between the small business adjustment factor used in FY 2023 and the small business adjustment factor that would have been used had FDA estimated perfectly is $-\$263$ ($1,747 minus $2,011). The $-\$263$ (rounded to the nearest dollar) is then multiplied by the number of actual registrants who paid the standard fee for FY 2023 (65), which provides us a total collection deficit of $-\$17{,}124$ in FY 2023. No credit will be applied in FY 2025.

Therefore, to calculate the small business adjustment factor for FY 2025, FDA divides the projected shortfall of $142,747 for FY 2025 by 69 (the number of expected non-small businesses for FY 2025), which is $2,069 (rounded to the nearest dollar).

B. FY 2025 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 2025 is 1.297679. See section II.A.1 of this document for the methodology used to calculate the FY 2025 inflation adjustment factor. Therefore, the establishment fee for a qualified small business for FY 2025 is one third of $19,465, which equals $6,488 (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 2025 is 1.297609. The small business adjustment amount for FY 2025 is $2,069. See section II.A.2 of this document for the methodology used to calculate the small business adjustment factor for FY 2025. Therefore, the establishment fee for a non-small business for FY 2025 is $15,000 multiplied by 1.297679 plus $2,069, which equals $21,534 (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 2025 reinspection fee is equal to $15,000, multiplied by the inflation adjustment factor for that fiscal year. The inflation adjustment factor for FY 2025 is 1.297679. Therefore, the reinspection fee for FY 2025 is $15,000 multiplied by 1.297679, which equals $19,465 (rounded to the nearest dollar). There is no reduction in this fee for small businesses.

C. Summary of FY 2025 Fee Rates

TABLE 4—OUTSOURCING FACILITY FEES

Qualified Small Business Establishment Fee	$6,488
Non-Small Business Establishment Fee	21,534
Reinspection Fee	19,465

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 2024 and wish to maintain their status as an outsourcing facility in FY 2025 must register during the annual registration period that lasts from October 1, 2024, to December 31, 2024. Failure to register and complete payment by December 31, 2024, will result in a loss of status as an outsourcing facility on January 1, 2025. Entities should submit their registration information no later than December 10, 2024, 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 979033, 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 979033, 3180 Rider Trail S, Earth City, MO 63045. (*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 800–495–4981. This telephone number is only for questions about courier delivery). Please make sure that the FDA post office box number (P.O. Box 979033) 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.

[1] To qualify for a small business reduction of the FY 2025 establishment fee, entities had to submit their exception requests by April 30, 2024. *See* section 744K(c)(4)(B) of the FD&C Act. The time for requesting a small business exception for FY 2025 has now passed. An entity that wishes to request a small business exception for FY 2026 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.*

Dated: July 26, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–16876 Filed 7–30–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–0007]

Prescription Drug User Fee Rates for Fiscal Year 2025

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) 2025. 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 2025.

DATES: These fees apply to the period from October 1, 2024, through September 30, 2025.

FOR FURTHER INFORMATION CONTACT: Olufunmilayo Ariyo, Office of Financial Management, Food and Drug Administration, 10903 New Hampshire Ave, Silver Spring, MD 20903, 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) establish two different kinds of user fees. Fees are assessed as follows: (1) application fees are assessed on certain types of applications for the review of human drug and biological products and (2) prescription drug program fees are assessed on certain approved products (section 736(a) of the FD&C Act). The statute also includes conditions under which such fees may be waived or reduced (section 736(d) of the FD&C Act), or under which fee exceptions, refunds, or exemptions apply (sections 736(a)(1)(C) through (H), 736(a)(2)(B) through (C), and 736(k) of the FD&C Act).

For FY 2023 through FY 2027, the base revenue amounts for the total revenues from all PDUFA fees are established by PDUFA VII. The base revenue amount for FY 2025 is $1,358,764,346. The FY 2025 base revenue amount is adjusted for inflation, strategic hiring and retention, and for the resource capacity needs for the process for the review of human drug applications (the capacity planning adjustment (CPA)). This amount is further adjusted to include the additional dollar amount as specified in the statute (see section 736(b)(1)(G) of the FD&C Act) to provide for additional full-time equivalent (FTE) positions to support PDUFA VII initiatives. If applicable, an operating reserve adjustment is added to provide sufficient operating reserves of carryover user fees. The amount from the preceding adjustments is then adjusted to provide for additional direct costs to fund PDUFA VII initiatives. Fee amounts are to be established each year so that revenues from application fees provide 20 percent of the total revenue, and prescription drug program fees provide 80 percent of the total revenue (see section 736(b)(2) of the FD&C Act).

This document provides fee rates for FY 2025 for an application requiring covered clinical data [1] ($4,310,002), for an application not requiring covered clinical data ($2,155,001), and for the prescription drug program fee ($403,889). These fees are effective on October 1, 2024, and will remain in effect through September 30, 2025. For applications that are submitted on or after October 1, 2024, the new fee schedule must be used.

II. Fee Revenue Amount for FY 2025

The base revenue amount for FY 2025 is $1,358,764,346 (see section 736(b)(1)(A) and (b)(3) of the FD&C Act). This amount is prior to any adjustments made for inflation, the strategic hiring and retention adjustment, CPA, additional dollar amount, operating reserve adjustment (if applicable), and additional direct costs (see section 736(b)(1) of the FD&C Act).

A. FY 2025 Statutory Fee Revenue Adjustments for Inflation

PDUFA VII specifies that the $1,358,764,346 is to be adjusted for inflation increases for FY 2025 using two separate adjustments: one for personnel compensation and benefits (PC&B) and one for non-PC&B costs (see section 736(c)(1) of the FD&C Act).

The component of the inflation adjustment for payroll costs is the average annual percent change in the cost of all PC&B paid per FTE positions at FDA for the first 3 of the preceding 4 fiscal years, multiplied by the proportion of PC&B costs to total FDA costs of the process for the review of human drug applications for the first 3 of the preceding 4 fiscal years (see section 736(c)(1)(A) and (B)(i) of the FD&C Act).

Table 1 summarizes the actual cost and FTE data for the specified fiscal years, provides the percent changes from the previous fiscal years, and provides the average percent changes over the first 3 of the 4 fiscal years preceding FY 2025. The 3-year average is 3.8539 percent.

TABLE 1—FDA PERSONNEL COMPENSATION AND BENEFITS (PC&B) EACH YEAR AND PERCENT CHANGES

	2021	2022	2023	3-Year average
Total PC&B	$3,039,513,000	$3,165,477,000	$3,436,513,000	.....
Total FTEs	18,501	18,474	18,729	.....
PC&B per FTE	$164,289	$171,348	$183,486	.....
Percent Change from Previous Year	0.1811%	4.2967%	7.0838%	3.8539%

The statute specifies that this 3.8539 percent be multiplied by the proportion of PC&B costs to the total FDA costs of the process for the review of human drug applications. Table 2 shows the PC&B and the total obligations for the process for the review of human drug applications for the first 3 of the preceding 4 fiscal years.

[1] As used herein, ''covered clinical data'' is ''clinical data (other than bioavailability or bioequivalence studies) with respect to safety or effectiveness [that] are required for approval'' (see section 736(a)(1)(A) of the FD&C Act).