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calendar days after FDA issues the invoice, FDA will consider the submission of registration information to have been withdrawn and adjust the invoice to reflect that no fee is due.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.

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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)

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 2024 is $1,256,844,387. The FY 2024 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)(F) 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 2024 for an application requiring covered clinical data [1] ($4,048,695), for an application not requiring covered clinical data ($2,024,348), and for the prescription drug program fee ($416,429). These fees are effective on October 1, 2023, and will remain in effect through September 30, 2024. For applications that are submitted on or after October 1, 2023, the new fee schedule must be used.

II. Fee Revenue Amount for FY 2024

The base revenue amount for FY 2024 is $1,256,844,387 (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 2024 Statutory Fee Revenue Adjustments for Inflation

PDUFA VII specifies that the $1,256,844,387 is to be adjusted for inflation increases for FY 2024 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 2024. The 3-year average is 3.9280 percent.

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

	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%

The statute specifies that this 3.9280 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.

TABLE 2—PC&B AS A PERCENT OF TOTAL COST OF THE PROCESS FOR THE REVIEW OF HUMAN DRUG APPLICATIONS

	FY 2020	FY 2021	FY 2022	3-Year average
Total PC&B	$891,395,106	$959,387,333	$931,302,114	
Total Costs	$1,471,144,928	$1,499,064,056	$1,480,601,875	
PC&B Percent	60.5919%	63.9991%	62.9002%	62.4971%

The payroll adjustment is 3.9280 percent from table 1 multiplied by 62.4971 percent resulting in 2.4549 percent.

The statute specifies that the portion of the inflation adjustment for non-payroll costs is the average annual percent change that occurred in the Consumer Price Index for urban consumers (Washington-Arlington-Alexandria, DC-VA-MD-WV; 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 costs other than personnel compensation and benefits costs to total costs of the process for the review of human drug applications (as defined in section 735(6)) for the first 3 years of the preceding 4 fiscal years (see section 736(c)(1)(A) and (B)(ii)). Table 3 provides the summary data for the percent changes in the specified CPI for

[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).

the Washington-Arlington-Alexandria area.[2]

TABLE 3—ANNUAL AND 3-YEAR AVERAGE PERCENT CHANGE IN CPI FOR WASHINGTON-ARLINGTON-ALEXANDRIA AREA

	FY 2020	FY 2021	FY 2022	3-Year average
Annual CPI	267.16	277.73	296.12	.....
Annual Percent Change	0.8989%	3.9568%	6.6212%	3.8256%

The statute specifies that this 3.8256 percent be multiplied by the proportion of all costs other than PC&B to total costs of the process for the review of human drug applications obligated. Because 62.4971 percent was obligated for PC&B (as shown in table 2), 37.5029 percent is the portion of costs other than PC&B (100 percent minus 62.4971 percent equals 37.5029 percent). The non-payroll adjustment is 3.8256 percent times 37.5029 percent, or 1.4347 percent.

Next, we add the payroll adjustment (2.4549 percent) to the non-payroll adjustment (1.4347 percent), for a total inflation adjustment of 3.8896 percent (rounded) for FY 2024.

We then multiply the base revenue amount for FY 2024 ($1,256,844,387) by 3.8896 percent, which produces an inflation adjustment amount of $48,886,219. Adding this amount to the base revenue amount yields an inflation-adjusted base revenue amount of $1,305,730,606.

B. FY 2024 Strategic Hiring and Retention Adjustment

For each fiscal year, after the annual base revenue established in section II is adjusted for inflation in accordance with section II.A above, the statute directs FDA to further increase the fee revenue and fees to support strategic hiring and retention. For FY 2024, this amount is $4,000,000 (see section 736(c)(2)(A) of the FD&C Act).

C. FY 2024 Statutory Fee Revenue Adjustments for Capacity Planning

The statute specifies that after the base revenue amount for FY 2024 of $1,256,844,387 has been adjusted as described in sections II.A and II.B above, this amount shall be further adjusted to reflect changes in the resource capacity needs for the process of human drug application reviews (see section 736(c)(3) of the FD&C Act). Following a process required in statute, FDA established a new CPA methodology and first applied it in the setting of FY 2021 fees. The establishment of this methodology is described in the **Federal Register** of August 3, 2020 (85 FR 46651). This methodology includes a continuous, iterative improvement approach, under which the Agency intends to refine its data and estimates for the core review activities to improve their accuracy over time.

In FY 2023, updates were made to refine the time reporting categories included within the CPA to reflect program changes in the current authorization period. As such, the time reporting data and baseline capacity were revised to match the refinements. For FY 2024 fees, additional updates were made to account for additional activities that are also directly related to the direct review of applications and supplements as provided for in the statute. The updates include additional formal meeting types and the direct review of postmarketing commitments (PMC) and requirements (PMR) (see tables 4 and 7), the direct review of risk evaluation and mitigation strategies, and the direct review of annual reports for approved prescription drug products. The Center for Biologics Evaluation and Research (CBER) CPA was also updated to reflect the PDUFA VII revision of the definition of ''human drug application'' and ''prescription drug product'' to include allergenic products licensed on or after October 1, 2022. These additions necessitated an additional re-baselining of capacity.

The CPA methodology includes four steps:

1. *Forecast workload volumes:* predictive models estimate the volume of workload for the upcoming FY.

2. *Forecast the resource needs:* forecast algorithms are generated utilizing time reporting data. These algorithms estimate the required demand in FTEs[3] for direct review-related effort. This is then compared to current available resources for the direct review-related workload.

3. *Assess the resource forecast in the context of additional internal factors:* program leadership examines operational, financial, and resourcing data to assess whether FDA will be able to utilize additional funds during the FY, and the funds are required to support additional review capacity. FTE amounts are adjusted, if needed.

4. *Convert the FTE need to dollars:* utilizing FDA's fully loaded FTE cost model, the final feasible FTEs are converted to an equivalent dollar amount.

To determine the FY 2024 CPA, FDA calculated a CPA for the Center for Drug Evaluation and Research (CDER) and CBER individually. The final Center-level results were then combined to determine the total FY 2024 PDUFA CPA. The following section outlines the major components of each Center's FY 2024 PDUFA CPA.

Table 4 summarizes the forecasted workload volumes for CDER in FY 2024 based on predictive models, as well as historical actuals from FY 2022 for comparison.

TABLE 4—CDER ACTUAL FY 2022 WORKLOAD VOLUMES AND PREDICTED FY 2024 WORKLOAD VOLUMES

Workload category	FY 2022 actuals	FY 2024 predictions
Efficacy Supplements	236	203
Labeling Supplements	902	714
Manufacturing Supplements	2,084	2,174
NDA/BLA[1] Original	128	1,136
PDUFA Industry Meetings (including WROs[2])	3,647	3,504

[2] The data are published by the Bureau of Labor Statistics and can be found on its website at: *https://data.bls.gov/pdq/SurveyOutputServlet?data_tool=dropmap&series_id=CUURS35ASA0,CUUSS35ASA0.*

[3] Full-time equivalents refer to a paid staff year, rather than a count of individual employees.

TABLE 4—CDER ACTUAL FY 2022 WORKLOAD VOLUMES AND PREDICTED FY 2024 WORKLOAD VOLUMES—Continued

Workload category	FY 2022 actuals	FY 2024 predictions
Active Commercial INDs[3]	9,535	10,632
Annual Reports[4]	3,394	3,504
PMR/PMC-Related Documents[4]	1,567	1,631
Active REMS Programs[4 5]	21	20

[1] New drug applications (NDA)/biological license applications (BLA).
[2] Written responses only (WROs).
[3] For purpose of the CPA, this is defined as an active commercial investigational new drug (IND) for which a document has been received in the past 18 months.
[4] Represents activities related to the review of materials submitted to the application file after approval.
[5] Represents the percentage of active risk evaluation and management strategy (REMS) programs proportional to Center and User Fee by total number of qualifying products with the exclusion of the Opioid Shared System.

Utilizing the resource forecast algorithms, the forecasted workload volumes for FY 2024 were then converted into estimated FTE needs for CDER's PDUFA direct review-related work. The resulting expected FY 2024 FTE need for CDER was compared to current resource capacity for direct review related work to determine the FY 2024 resource delta, as summarized in table 5. Hiring and re-baselining of current resource capacity resulted in an increase of both the resource capacity and resource forecast relative to prior years.

TABLE 5—CDER FY24 PDUFA RESOURCE DELTA

Center	Current resource capacity	FY 2024 resource forecast	Predicted FY 2024 FTE delta
CDER	1,931	2,001	70

The projected 70 FTE delta was then assessed by FDA in the context of additional operational and internal factors to ensure that a fee adjustment is only made for resources that can be utilized in the fiscal year and for which funds are required to support additional review capacity. After accounting for funded vacancies that are intended to address direct review workload that is within scope of the workload accounted for by the capacity planning adjustment, CDER's delta was adjusted to 38 FTE. The FY 2024 PDUFA CPA for CDER is therefore $12,778,222, as summarized in table 6.

TABLE 6—CDER FY 2024 PDUFA CPA

Center	Additional FTEs for FY 2024	Cost for each additional FTE	CDER FY 2024 PDUFA CPA
CDER	38	$336,269	$12,778,222

To calculate the FY 2024 PDUFA CPA for CBER, FDA followed the approach outlined above. Table 7 summarizes the forecasted workload volumes for CBER in FY 2024 as well as the corresponding historical actuals from FY 2022 for comparison.

TABLE 7—CBER ACTUAL FY 2022 WORKLOAD VOLUMES AND PREDICTED FY 2024 WORKLOAD VOLUMES

Workload category	FY 2022 actuals	FY 2024 predictions
Efficacy Supplements	22	23
Labeling Supplements	52	45
Manufacturing Supplements	684	692
NDA/BLA[1] Original	13	11
PDUFA Industry Meetings (including WROs[2])	635	715
Active Commercial INDs[3]	1,694	1,974
Annual Reports[4]	292	304
PMR/PMC-Related Documents[4]	140	151
Active REMS Programs[4 5]	2	2

[1] New drug applications (NDA)/biological license applications (BLA).
[2] Written responses only (WROs).
[3] For purpose of the CPA, this is defined as an active commercial investigational new drug (IND) for which a document has been received in the past 18 months.
[4] Represents activities related to the review of materials submitted to the application file after approval.
[5] Represents the percentage of active REMS programs proportional to Center and User Fee by total number of qualifying products with the exclusion of the Opioid Shared System.

The forecasted CBER PDUFA workload for FY 2024 was then converted into expected FTE resources and compared to current resource capacity for PDUFA direct review work, as summarized in table 8. Hiring and re-baselining of current resource capacity resulted in an increase of both the resource capacity and resource forecast relative to prior years.

TABLE 8—CBER FY 2024 PDUFA RESOURCE DELTA

Center	Current resource capacity	FY 2024 resource forecast	Predicted FY 2024 FTE delta
CBER	408	452	44

The projected 44 FTE delta for CBER was also assessed in the context of other operational and financial factors that may impact the need and/or feasibility of obtaining the additional resources. After considering subject matter expert input on industry trends and workload, reviewing the historical accuracy of workload forecasts, accounting for historical net FTE gains within CBER and the hiring necessary to meet the hiring commitments set forth for FY 2024 in the PDUFA VII commitment letter, and subtracting previously funded PDUFA vacancies aligned with CPA-covered activities, CBER determined that an adjustment of 34 additional FTEs for FY 2024 is needed. The FY 2024 CPA for CBER is therefore $11,157,847, as summarized in table 9.

TABLE 9—CBER FY 2024 PDUFA CPA

Center	Additional FTEs for FY 2024	Cost for each additional FTE	CBER FY 2024 CPA
CBER	34	$328,172	$11,157,847

The CDER and CBER CPA amounts were then added together to determine the PDUFA CPA for FY 2024 of $23,936,069, as outlined in table 10. FDA will track the utilization of the CPA funds to ensure they are supporting the organizational components engaged in PDUFA direct review work to enhance resources and expand staff capacity and capability. Should FDA be unable to utilize any amounts of the CPA funds during the fiscal year, it will not spend those funds and the unspent funds will be transferred to the carryover balance at the end of the fiscal year.

TABLE 10—FY 2024 PDUFA CPA

Center	FY 2024 PDUFA CPA
CDER	$12,778,222
CBER	11,157,847
Total	23,936,069

D. FY 2024 Statutory Fee Revenue Adjustments for Additional Dollar Amounts

PDUFA VII provides an additional dollar amount for each of the 5 fiscal years covered by PDUFA VII for additional FTE to support enhancements outlined in the PDUFA VII commitment letter. The additional dollar amount for FY 2024 as outlined in statute is $25,097,671 (see section 736(b)(1)(F) of the FD&C Act). This amount will be added to the total FY 2024 PDUFA VII revenue amount.

TABLE 11—BASE REVENUE AMOUNT AND SECTION 736(c)(1) THROUGH (3) ADJUSTMENT AMOUNTS

Fee	Amount
Statutory Fee Revenue Base Amount (section 736(b)(3) of the FD&C Act)	$1,256,844,387
Statutory Fee Revenue Adjustments for Inflation (section 736(c)(1) of the FD&C Act)	48,886,219
Strategic Hiring and Retention Adjustment (section 736(c)(2)(A) of the FD&C Act)	4,000,000
Statutory Fee Revenue Adjustments for Capacity Planning (section 736(c)(3) of the FD&C Act)	23,936,069
Statutory Fee Revenue Adjustments for Additional Dollar Amounts (section 736(b)(1)(F) of the FD&C Act)	25,097,671
Cumulative Revenue Amount after Adjustments in sections 736(c)(1), (2), (3), and (4) of the FD&C Act	1,358,764,346

E. FY 2024 Statutory Fee Revenue Adjustments for Operating Reserve

PDUFA VII provides for an operating reserve adjustment that may result in an increase or decrease in fee revenue and fees for a given FY (see section 736(c)(4) of the FD&C Act). For FY 2024, FDA is required to further increase fee revenue and fees if an adjustment is necessary to provide for at least 9 weeks of operating reserves of carryover user fees (see section 736(c)(4)(A)(i) of the FD&C Act). If FDA has carryover balances of user fees in excess of 14 weeks of operating reserves, FDA is required to decrease fee

revenue and fees to provide for not more than 14 weeks of operating reserves of carryover user fees (see section 736(c)(4)(B) of the FD&C Act).

To determine the dollar amounts for the 9-week and 14-week operating reserve thresholds, the adjustments (inflation, strategic hiring and retention, capacity planning, and additional dollar amount) discussed in sections II.A, II.B, II.C, and II.D are applied to the FY 2024 base revenue (see section 736(c)(4)(A) of the FD&C Act), resulting in $1,358,764,346. This amount is then divided by 52 to generate the 1-week operating amount of $26,130,084. The 1-week operating amount is then multiplied by 9 and 14. This results in a 9-week threshold amount of $235,170,752 and a 14-week threshold amount of $365,821,170.

To determine the FY 2023 end-of-year operating reserves of carryover user fees, the Agency assessed the operating reserve of carryover fees at the end of June 2023 and forecast collections and obligations in the fourth quarter of FY 2023 combined. This provides an estimated end-of-year FY 2023 operating reserve of carryover user fees of $321,648,510, which equates to 12.3 weeks of operations.[4]

Because the estimated FY 2023 end-of-year operating reserves of carryover user fees are within the 9-week and 14-week thresholds, FDA will not increase or reduce the FY 2024 fees or fee revenue under the statutory provision for operating reserve adjustments.

TABLE 12—BASE REVENUE AMOUNT AND SECTION 736(c)(1) THROUGH (4) ADJUSTMENT AMOUNTS

Fee	Amount
Statutory Fee Revenue Base Amount (section 736(b)(3) of the FD&C Act)	$1,256,844,387
Statutory Fee Revenue Adjustments for Inflation (section 736(c)(1) of the FD&C Act)	48,886,219
Strategic Hiring and Retention Adjustment (section 736(c)(2)(A) of the FD&C Act)	4,000,000
Statutory Fee Revenue Adjustments for Capacity Planning (section 736(c)(3) of the FD&C Act)	23,936,069
Statutory Fee Revenue Adjustments for Additional Dollar Amounts (section 736(b)(1)(F) of the FD&C Act)	25,097,671
Operating Reserve Adjustment (section 736(c)(4) of the FD&C Act)	.....
Cumulative Revenue after Adjustments in sections 736(c)(1), (2), (3), and (4) of the FD&C Act	1,358,764,346

F. FY 2024 Statutory Fee Revenue Adjustments for Additional Direct Cost

PDUFA VII specifies that an additional direct cost of $63,339,404 is to be added to the total FY 2024 PDUFA revenue amount (see section 736(c)(5) of the FD&C Act). With respect to target revenue for FY 2024, adding the additional direct cost amount of $63,339,404 to the inflation, strategic hiring and retention, CPA, additional dollar amount, and operating reserve adjustment of $1,358,764,346 results in the total revenue amount of $1,422,104,000 (rounded to the nearest thousand dollars).

TABLE 13—TOTAL ESTIMATED ADJUSTED REVENUE AMOUNT

Statutory Fee Revenue Base Amount (section 736(b)(3) of the FD&C Act)	$1,256,844,387
Statutory Fee Revenue Adjustments for Inflation (section 736(c)(1) of the FD&C Act)	48,886,219
Strategic Hiring and Retention Adjustment (section 736(c)(2)(A) of the FD&C Act)	4,000,000
Statutory Fee Revenue Adjustments for Capacity Planning (section 736(c)(3) of the FD&C Act)	23,936,069
Statutory Fee Revenue Adjustments for Additional Dollar Amounts (section 736(b)(1)(F) of the FD&C Act)	25,097,671
Operating Reserve Adjustment (section 736(c)(4) of the FD&C Act)	.....
Additional Direct Cost (section 736(c)(5) of the FD&C Act)	63,339,404
Cumulative Revenue Amount after Adjustments in sections 736(c)(1), (2), (3), and (4) of the FD&C Act	1,422,104,000

III. Application Fee Calculations

A. Application Fee Revenues and Application Fees

Application fees will be set to generate 20 percent of the total revenue amount, amounting to $284,420,800 in FY 2024.

B. Estimate of the Number of Fee-Paying Applications and Setting the Application Fees

Historically, FDA has estimated the total number of fee-paying full application equivalents (FAEs) it expects to receive during the next fiscal year by averaging the number of fee-paying FAEs received in the three most recently completed fiscal years. For FY 2024 fee setting, the 3 relevant fiscal years are FYs 2020,[5] 2021, and 2022. Prior year FAE totals are updated annually to reflect refunds and waivers processed after the close of the fiscal year.

In estimating the number of fee-paying FAEs, an application requiring covered clinical data[6] counts as one FAE. An application not requiring covered clinical data counts as one-half of an FAE. An application that is withdrawn before filing, or refused for filing, counts as one-fourth of an FAE if the applicant initially paid a full application fee, or one-eighth of an FAE if the applicant initially paid one-half of the full application fee amount.

As table 14 shows, the average number of fee-paying FAEs received annually in FY 2020 through FY 2022 is 70.25. FDA will set fees for FY 2024 based on this estimate as the number of full application equivalents that will be subject to fees.

[4] For purposes of the operating reserve adjustment under PDUFA VII, the operating reserve of carryover user fees includes only user fee funds that are available for obligation. FDA excludes from the operating reserve of carryover user fee funds that were collected prior to 2010 and that are held by FDA, but which are considered unavailable for obligation due to lack of an appropriation ($78,850,995).

[5] FY 2020 data was omitted in FY 2022 methodology as FDA took into account the global COVID–19 pandemic situation at the time. However, after reviewing the data trend, FY 2020 data is included in this year's methodology given the higher FAE count for FY 2021. See table 14.

[6] As defined in section 736(a)(1)(A)(i) of the FD&C Act.

TABLE 14—FEE-PAYING FAES

	FY 2020	FY 2021	FY 2022	3-Year average
Fee-Paying FAEs	65.25	90.50	55.00	70.25

Note: Prior year FAE totals are updated annually to reflect refunds and waivers processed after the close of the fiscal year.

The FY 2024 application fee is estimated by dividing the average number of full applications that paid fees from FY 2020 through FY 2022, 70.25, into the fee revenue amount to be derived from application fees in FY 2024, $284,420,800. The result is a fee of $4,048,695 per full application requiring clinical data, and $2,024,348 per application not requiring clinical data.

IV. Fee Calculation for Prescription Drug Fees

PDUFA VII assesses prescription drug program fees for certain prescription drug products. Program fees will be set to generate 80 percent of the total target revenue amounting to $1,137,683,200 in FY 2024.

An applicant will not be assessed more than five program fees for a FY for prescription drug products identified in a single approved NDA or BLA (see section 736(a)(2)(C) of the FD&C Act). Applicants are assessed a program fee for a fiscal year for user fee eligible prescription drug products identified in a human drug application approved as of October 1 of such fiscal year. Additionally, applicants are assessed a program fee for a product that is not a prescription drug product on October 1 because it is included in the discontinued section of the Orange Book or the CDER/CBER Billable Biologics List on that date, if the product becomes a fee-eligible prescription drug product during the fiscal year.

FDA estimates 2,928 program fees will be invoiced in FY 2024 before factoring in waivers, refunds, exceptions, and exemptions. FDA approximates that there will be 55 waivers and refunds granted. In addition, FDA approximates that another 41 program fees will be exempted in FY 2024 based on the orphan drug exemption in section 736(k) of the FD&C Act.

PDUFA VII changed the definition of the same product exception for program fees. FDA determined that 102 products may be eligible for the pharmaceutical equivalence same product exception. An additional exception for program fees for skin-test diagnostic products is included in the PDUFA VII. FDA has determined that there are nine skin-test diagnostic application products that may be eligible for the exception for skin diagnostic tests. FDA estimates 2,730 program fees in FY 2024, after allowing for an estimated 198 waivers and reductions, including the orphan drug exemptions, excepted and exempted fee-liable products. The FY 2024 prescription drug program fee rate is calculated by dividing the adjusted total revenue from program fees ($1,137,683,200) by the estimated 2,730 program fees, resulting in a FY 2024 program fee of $416,734 (rounded to the nearest dollar).

V. Fee Schedule for FY 2024

The fee rates for FY 2024 are displayed in table 15.

TABLE 15—FEE SCHEDULE FOR FY 2024

Fee category	Fee rates for FY 2024
Application:	
Requiring clinical data	$4,048,695
Not requiring clinical data	2,024,348
Program	416,734

VI. Fee Payment Options and Procedures

A. Application Fees

The appropriate application fee established in the new fee schedule must be paid for any application subject to fees under PDUFA VII that is submitted on or after October 1, 2023. Payment must be made in U.S. currency by electronic check, check, bank draft, wire transfer, or U.S. postal money order payable to the order of the Food and Drug Administration. 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).

FDA has partnered with the U.S. Department of the Treasury to use *Pay.gov,* a web-based payment application, for online electronic payment. The *Pay.gov* feature is available on the FDA website after completing the Prescription Drug User Fee Cover Sheet and generating the user fee ID number. 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 an invoice is located, ''Pay Now'' should be selected to be redirected to *Pay.gov*. Electronic payment options are based on the balance due. Payment by credit card is available for balances that are 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.

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.

For payments made by wire transfer, include the unique user fee ID number to ensure that the payment is applied to the correct fee(s). Without the unique user fee ID number, the payment may not be applied, which could result in FDA not filing an application and other penalties. Note: the originating financial institution may charge a wire transfer fee, especially for international wire transfers. Applicable wire transfer fees must be included with payment to ensure fees are paid in full. Questions about wire transfer fees should be addressed to the financial institution. The account information for wire transfers is as follows: U.S. Department 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.

B. Prescription Drug Program Fees

FDA will issue invoices and payment instructions for FY 2024 program fees under the new fee schedule in August 2023. Under section 736(a)(2)(A)(i) of the FD&C Act, prescription drug program fees are due on October 2, 2023.

FDA will issue invoices in December 2024 for products that qualify for FY 2024 program fee assessments after the October 2023 billing.

C. Fee Waivers and Refunds

To qualify for consideration for a waiver or reduction under section 736(d) of the FD&C Act, an exemption under section 736(k) of the FD&C Act, or the return of an application or program fee paid under section 736 of the FD&C Act, including if the fee is claimed to have been paid in error, a person must submit to FDA a written request justifying such waiver, reduction, exemption or return not later than 180 days after such fee is due (section 736(i) of the FD&C Act). A request submitted under this paragraph must include any legal authorities under which the request is made.

Dated: July 24, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–15911 Filed 7–27–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–0466]

Clinical Considerations for Studies of Devices Intended To Treat Opioid Use Disorder; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled ''Clinical Considerations for Studies of Devices Intended to Treat Opioid Use Disorder.'' Design of clinical studies for devices intended to treat opioid use disorder (OUD) is challenging. This guidance provides recommendations for the design of pivotal clinical studies for devices intended to treat opioid use disorder (''OUD device studies'') and used to support marketing submissions. These recommendations are applicable to the design and development of clinical studies to provide a reasonable assurance of safety and effectiveness for a device intended to treat OUD. This draft guidance is not final nor is it for implementation at this time.

DATES: Submit either electronic or written comments on the draft guidance by October 26, 2023 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2023–D–0466 for ''Clinical Considerations for Studies of Devices Intended to Treat Opioid Use Disorder.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov*. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Clinical Considerations for Studies of Devices Intended to Treat Opioid Use Disorder'' to the Office of Policy, Guidance and Policy Development, Center for Devices