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Lauren K. Roth,

Associate Commissioner for Policy.

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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).

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

	2021	2022	2023	3-Year average
Total PC&B (proportion of costs)	$959,387,333	$931,302,114	$1,040,590,183	
Total Costs	$1,499,064,056	$1,480,601,875	$1,686,733,841	
PC&B percent	63.9991%	62.9002%	61.6926%	62.8640%

The payroll adjustment is 3.8539 percent from table 1 multiplied by 62.8640 percent from table 2 resulting in 2.4227 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 the Washington-Arlington-Alexandria area.[2]

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

	2021	2022	2023	3-Year average
Annual CPI	277.73	296.12	305.32	
Annual Percent Change	3.9568%	6.6212%	3.1069%	4.5616%

The statute specifies that this 4.5616 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 62.8640 percent was obligated for PC&B (as shown in table 2), 37.1360 percent is the portion of costs other than PC&B (100 percent minus 62.8640 percent equals 37.1360 percent). The non-payroll adjustment is 4.5616 percent times 37.1360 percent, or 1.6940 percent.

Next, we add the payroll adjustment (2.4227 percent) to the non-payroll adjustment (1.6940 percent), for a total inflation adjustment of 4.1167 percent (rounded) for FY 2025.

We then multiply the base revenue amount for FY 2025 ($1,358,764,346) by 4.1167 percent, which produces an inflation adjustment amount of $55,936,252. Adding this amount to the base revenue amount yields an inflation-adjusted base revenue amount of $1,414,700,598.

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

Fee	Amount
Statutory Fee Revenue Base Amount (section 736(b)(3) of the FD&C Act)	$1,358,764,346
Inflation Adjustment (section 736(c)(1) of the FD&C Act)	55,936,252
Revenue Amount after Adjustments in sections 736(c)(1) of the FD&C Act	1,414,700,598

B. FY 2025 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, the statute directs FDA to further increase the fee revenue and fees to support strategic hiring and retention. For FY 2025, this amount is $4,000,000 (see section 736(c)(2)(A) of the FD&C Act).

TABLE 5—BASE REVENUE AMOUNT AND SECTION 736(c)(1) THROUGH (2) ADJUSTMENT AMOUNTS

Fee	Amount
Statutory Fee Revenue Base Amount (section 736(b)(3) of the FD&C Act)	$1,358,764,346
Inflation Adjustment (section 736(c)(1) of the FD&C Act)	55,936,252
Strategic Hiring and Retention Adjustment (section 736(c)(2) of the FD&C Act)	4,000,000
Revenue Amount after Adjustments in sections 736(c)(1) and (2) of the FD&C Act	1,418,700,598

C. FY 2025 Statutory Fee Revenue Adjustments for Capacity Planning

The statute specifies that after the base revenue amount for FY 2025 of $1,358,764,346 has been adjusted as described in sections II.A and II.B, 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 agreed upon by FDA and

[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.*

industry during PDUFA VI reauthorization discussions and subsequently 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. An adjustment for workload has been a critical aspect of the PDUFA program since PDUFA III in FY 2003 as it enables the program to adjust to shifts in review workload resulting from industry submissions to the Agency. The annual adjustment process allows greater accuracy than would be expected if workload adjustments were fixed at the start of the reauthorization period. The capacity planning adjustment is an evolution of the PDUFA workload adjuster and was implemented through a process agreed to by FDA and industry during PDUFA VI. The capacity planning adjustment builds on the concepts of the workload adjuster but realizes enhancements including the use of leading indicators of workload, use of full-time reporting data, the introduction of a managerial adjustment process as an internal check on the reasonableness of any adjustment, outputs measured in full-time equivalent employees, and the incorporation of adjustments into the base revenue amounts to ensure sustainability of payroll to support any new hires.

Improvements adopted for the FY 2025 CPA include the incorporation of hiring plans and attrition estimates within the capacity calculation. In prior years, the impacts of expected hiring on the review capacity of the program were considered within a step in the managerial adjustment process. The FY 2025 resource capacity number includes an estimate of the onboard capacity for direct review work, as well as an estimate of the additional capacity that would be provided from any additional positions expected to be added through the course of FY 2024. No additional deduction for positions planned to be added prior to the end of FY 2024 then need to be deducted within the managerial adjustment moving forward. Because of this change, the resource capacity numbers presented in this **Federal Register** Notice cannot be directly compared to those provided in prior years' fee-setting notices.

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.

The current available resources for the direct review related workload (presented as current resource capacity below) is a measure of the percentage of time onboard staff report to direct review workload activities, plus a percentage of the additional positions that are targeted to be hired within the remainder of FY 2024. Of note, the current resource capacity is not directly a function of the change in submission volume from one year to the next, but rather a summation of the percent of total staff time plus vacancies estimated to be available for direct review work. As time reporting is a direct input into the current review capacity calculations, the current review capacity may be impacted by factors such as shifts in the level of effort required for review work, staff reporting time exceed their tour of duty, or other shifts impacting the workload of the program.

3. *A managerial adjustment to 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 whether the funds are required to support additional review capacity. FTE amounts are adjusted, if needed.

The managerial adjustment process includes consideration of prior years' forecast performance, future year considerations, hiring capacity considerations, and other relevant considerations. While in some years FDA has over forecasted some submission volumes, it has managerially adjusted down the FTE delta considerably to take relatively small adjustments. For example, in FY23 CDER had a forecasted delta of 151 FTE but only took an adjustment for 27 FTE.

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. The fully loaded FTE cost model is higher in FY 2025 than in prior years primarily due to the impact of inflation.

To determine the FY 2025 CPA, FDA calculated a CPA for the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) individually. The final center-level results were then combined to determine the total FY 2025 PDUFA CPA. The following section outlines the major components of each center's FY 2025 PDUFA CPA.

Table 6 summarizes the forecasted workload volumes for CDER in FY 2025 based on predictive models, as well as historical actuals from FY 2023 for comparison.

TABLE 6—CDER ACTUAL FY 2023 WORKLOAD VOLUMES AND PREDICTED FY 2025 WORKLOAD VOLUMES

Workload category	FY 2023 actuals	FY 2025 predictions
Efficacy Supplements	232	233
Labeling Supplements	917	1,191
Manufacturing Supplements	2,372	2,320
NDA/BLA[1] Original	145	133
PDUFA Industry Meetings (including WROs[2])	3,570	3,783
Active Commercial INDs[3]	9,882	10,788
Annual Reports[4]	3,465	3,556
PMR/PMC-Related Documents[4]	1,696	1,605
Active REMS Programs[4 5]	23	23

[1] New drug applications (NDA)/biological license applications (BLA).
[2] Written responses only (WROs).

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

[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 2025 were then converted into estimated FTE needs for CDER's PDUFA direct review related work. The resulting expected FY 2025 FTE need for CDER was compared to current resource capacity for direct review related work to determine the FY 2025 resource delta, as summarized in table 7. Hiring and inclusion of hiring plans into the current resource capacity increased the value over prior years.

TABLE 7—CDER FY 2025 PDUFA RESOURCE DELTA

Center	Current resource capacity	FY 2025 resource forecast	Predicted FY 2025 FTE delta
CDER	2,055	2,078	23

The projected 23 FTEs delta was then assessed by FDA through the managerial adjustment process to ensure that any 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. FDA observes that the CDER delta has been declining each year as measured by the CPA. This indicates that resources are coming into approximate alignment with the workload as measured by the CPA. The adjusted 23 FTE delta would represent about 1 percent growth above the current resource capacity of 2,055. FDA notes, however, that through the managerial adjustment process it was observed that review work related to rare and/or orphan disease conditions has been growing disproportionality. After consideration of additional negotiated positions to be added in FY 2025 that overlap with the scope of the CPA (3), and other factors related to the CPA, CDER is adjusting the FTE delta to 4 FTE. These 4 FTEs positions will be allocated in a manner to address the growth in workload resulting from rare and/or orphan disease conditions. The FY 2025 PDUFA CPA for CDER is therefore $1,522,700, as summarized in table 8.

TABLE 8—CDER FY 2025 PDUFA CPA

Center	Additional FTEs for FY 2025	Cost for each additional FTE	CDER FY 2025 PDUFA CPA
CDER	4	$380,675	$1,522,700

To calculate the FY 2025 PDUFA CPA for CBER, FDA followed the approach outlined above. Table 9 summarizes the forecasted workload volumes for CBER in FY 2025 as well as the corresponding historical actuals from FY 2023 for comparison.

TABLE 9—CBER ACTUAL FY 2023 WORKLOAD VOLUMES AND PREDICTED FY 2025 WORKLOAD VOLUMES

Workload category	FY 2023 actuals	FY 2025 predictions
Efficacy Supplements	25	30
Labeling Supplements	58	62
Manufacturing Supplements	752	767
NDA/BLA[1] Original	14	15
PDUFA Industry Meetings (including WROs[2])	756	778
Active Commercial INDs[3]	1,829	2,027
Annual Reports[4]	314	319
PMR/PMC-Related Documents[4]	143	188
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 2025 was then converted into expected FTE resources and compared to current resource capacity for PDUFA direct review work, as summarized in table 10. Hiring and inclusion of hiring plans into the current resource capacity increased the value over prior years.

TABLE 10—CBER FY 2025 PDUFA RESOURCE DELTA

Center	Current resource capacity	FY 2025 resource forecast	Predicted FY 2025 FTE delta
CBER	492	507	15

The projected 15 FTEs delta for CBER was also assessed by FDA through the managerial adjustment process to ensure the need and/or feasibility of obtaining the additional resources. After considering additional negotiated positions to be added in FY 2025 that overlap with the scope of the CPA (12), current statuses for PDUFA vacancies, and other factors related to the CPA, CBER adjusted the FTE delta to 0 additional FTEs for FY 2025. The FY 2025 CPA for CBER is therefore $0, as summarized in table 11.

TABLE 11—CBER FY 2025 PDUFA CPA

Center	Additional FTEs for FY 2025	Cost for each additional FTE	CBER FY 2025 CPA
CBER	0	$372,270	$0

The CDER and CBER CPA amounts were then added together to determine the PDUFA CPA for FY 2025 of $1,522,700, as outlined in table 12. 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 12—FY 2025 PDUFA CPA

Center	FY 2025 PDUFA CPA
CDER	$1,522,700
CBER	0
Total	1,522,700

TABLE 13—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)	$1,358,764,346
Inflation Adjustment (section 736(c)(1) of the FD&C Act)	55,936,252
Strategic Hiring and Retention Adjustment (section 736(c)(2) of the FD&C Act)	4,000,000
Capacity Planning Adjustment (section 736(c)(3) of the FD&C Act)	1,522,700
Revenue Amount after Adjustments in sections 736(c)(1), (2), and (3) of the FD&C Act	1,420,223,298

D. FY 2025 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 FTEs to support enhancements outlined in the PDUFA VII commitment letter. The additional dollar amount for FY 2025 as outlined in statute is $14,154,169 (see section 736(b)(1)(G)(iii) of the FD&C Act). This amount will be added to the total FY 2025 PDUFA VII revenue amount.

TABLE 14—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)	$1,358,764,346
Inflation Adjustment (section 736(c)(1) of the FD&C Act)	55,936,252
Strategic Hiring and Retention Adjustment (section 736(c)(2) of the FD&C Act)	4,000,000
Capacity Planning Adjustment (section 736(c)(3) of the FD&C Act)	1,522,700
Additional Dollar Amounts Adjustment (section 736(b)(1)(G) of the FD&C Act)	14,154,169
Cumulative Revenue Amount after Adjustments in sections 736(c)(1), (2), and (3) of the FD&C Act	1,434,377,467

E. FY 2025 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 2025, FDA is required to further increase fee revenue and fees if an adjustment is necessary to provide for at least 10 weeks of operating reserves of carryover user fees (see section 736(c)(4)(A)(iii) 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 10-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 2025 base revenue (see section 736(c)(4)(A) of the FD&C Act), resulting in $1,434,377,467. This amount is then divided by 52 to generate the 1-week operating amount of $27,584,182. The 1-week operating amount is then multiplied by 10 and 14. This results in a 10-week threshold amount of $275,841,821 and a 14-week threshold amount of $386,178,549.

To determine the FY 2024 end-of-year operating reserves of carryover user fees, the Agency assessed the operating reserve of carryover fees at the end of June 2024 and forecasted collections and obligations in the fourth quarter of FY 2024 combined. This provides an estimated end-of-year FY 2024 operating reserve of carryover user fees of $270,834,409, which equates to 9.82 weeks of operations.[4]

Because the estimated FY 2024 end-of-year operating reserves of carryover user fees does not exceed the 14-week threshold amount, FDA will not reduce the FY 2025 fees or fee revenue. However, because the estimated FY 2024 end-of-year operating reserves of carryover user fees of $270,834,409 is below the 10-week threshold amount of $275,841,821, FDA will apply an operating reserve adjustment of $5,007,412 to increase the fee revenue and fees for FY 2025.

TABLE 15—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)	$1,358,764,346
Inflation Adjustment (section 736(c)(1) of the FD&C Act)	55,936,252
Strategic Hiring and Retention Adjustment (section 736(c)(2) of the FD&C Act)	4,000,000
Capacity Planning Adjustment (section 736(c)(3) of the FD&C Act)	1,522,700
Additional Dollar Amounts Adjustment (section 736(b)(1)(G) of the FD&C Act)	14,154,169
Operating Reserve Adjustment (section (736(c)(4) of the FD&C Act)	5,007,412
Cumulative Revenue Amount after Adjustments in sections 736(c)(1), (2), (3), and (4) of the FD&C Act	1,439,384,879

F. FY 2025 Statutory Fee Revenue Adjustments for Additional Direct Cost

PDUFA VII specifies that an additional direct cost of $39,355,553 is to be added to the total FY 2025 PDUFA revenue amount (see section 736(c)(5)(ii) of the FD&C Act). With respect to target revenue for FY 2025, adding the additional direct cost amount of $39,355,553 to the inflation, strategic hiring and retention, CPA, additional dollar amount, and operating reserve adjustment results in the total revenue amount of $1,478,740,000 (rounded to the nearest thousand dollars).

TABLE 16—TOTAL ESTIMATED ADJUSTED REVENUE AMOUNT

Fee	Amount
Statutory Fee Revenue Base Amount (section 736(b)(3) of the FD&C Act)	$1,358,764,346
Inflation Adjustment (section 736(c)(1) of the FD&C Act)	55,936,252
Strategic Hiring and Retention Adjustment (section 736(c)(2)(B) of the FD&C Act)	4,000,000
Capacity Planning Adjustment (section 736(c)(3) of the FD&C Act)	1,522,700
Additional Dollar Amounts Adjustment (section 736(b)(1)(G) of the FD&C Act)	14,154,169
Operating Reserve Adjustment (section (736(c)(4) of the FD&C Act)	5,007,412
Additional Direct Cost Adjustment (section 736(c)(5) of the FD&C Act)	39,355,553
Cumulative Revenue Amount after Adjustments in sections 736(c)(1), (2), (3), (4), and (5) of the FD&C Act	1,478,740,432
Cumulative Revenue Amount after Adjustments in sections 736(c)(1), (2), (3), (4), and (5) of the FD&C Act (rounded to the nearest thousand)	1,478,740,000

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 $295,748,000 in FY 2025.

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

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 ten most recently completed fiscal years. For FY 2025 fee setting, the 10 relevant fiscal years are FY 2014–2023. While a 3-year average has been used in recent years' fee setting FRNs, FDA is using a 10-year average for FY 2025 to address volatility in the number of FAEs. Prior year FAE totals are

[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).

updated annually to reflect refunds and waivers processed after the close of the fiscal year.[5]

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 17 shows, the average number of fee-paying FAEs received annually in FY 2014 through FY 2023 is 68.619. FDA will set fees for FY 2025 based on this estimate as the number of full application equivalents that will be subject to fees.

TABLE 17—FEE-PAYING FAEs

	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	10-year average
Fee-Paying FAEs	73.375	81.956	70.483	79.750	68.875	80.000	56.750	78.875	45.125	51.000	68.619

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

The FY 2025 application fee is estimated by dividing the average number of full applications that paid fees from FY 2014 through FY 2023, 68.619, into the fee revenue amount to be derived from application fees in FY 2025, $295,748,000. The result is a fee of $4,310,002 per full application requiring clinical data, and $2,155,001 per application not requiring clinical data.

IV. Fee Calculation for Prescription Drug Program 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 $1,182,992,000 in FY 2025.

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 FY for user fee eligible prescription drug products identified in a human drug application approved as of October 1 of such FY. 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 FY.

FDA estimates 3,049 program fees will be invoiced in FY 2025 before factoring in waivers, refunds, exceptions, and exemptions. FDA approximates that there will be 81 waivers and refunds granted. Additionally, FDA approximates that another 39 program fees will be exempted in FY 2025 based on the orphan drug exemption in section 736(k) of the FD&C Act.

FDA estimates 2,929 program fees in FY 2025, after allowing for an estimated 120 waivers and reductions, including the orphan drug exemptions, excepted and exempted fee-liable products. The FY 2025 prescription drug program fee rate is calculated by dividing the adjusted total revenue from program fees ($1,182,992,000) by the estimated 2,929 program fees, resulting in a FY 2025 program fee of $403,889 (rounded to the nearest dollar).

V. Fee Schedule for FY 2025

The fee rates for FY 2025 are displayed in table 18.

TABLE 18—FEE SCHEDULE FOR FY 2025

Fee category	Fee rates for FY 2025
Application:	
Requiring clinical data	$4,310,002
Not requiring clinical data	2,155,001
Program	403,889

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, 2024. 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 FDA's 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, 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 phone number is designated for courier use only and is not intended for payment and billing inquiries. Please make sure that the FDA post office box number (P.O. Box 979107) is written on the

[5] In the PDUFA fee setting FRNs for FYs 2023 and 2024, this adjustment for refunds was erroneously excluded, resulting in an overstatement of the historical FAE data.

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

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 2025 program fees under the new fee schedule in August 2024. Under section 736(a)(2)(A)(i) of the FD&C Act, prescription drug program fees are due on October 1, 2024.

FDA will issue invoices in December 2025 for products that qualify for FY 2025 program fee assessments after the October 2024 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 26, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3383]

Food Safety Modernization Act Third-Party Certification Program User Fee Rate for Fiscal Year 2025

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the fiscal year (FY) 2025 annual fee rate for recognized accreditation bodies and accredited certification bodies, and the initial and renewal fee rate for accreditation bodies applying to be recognized in the third-party certification program that is authorized by the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the FDA Food Safety Modernization Act (FSMA). We are also announcing the fee rate for certification bodies that are applying to be directly accredited by FDA.

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

FOR FURTHER INFORMATION CONTACT:

For Questions Related to FSMA Program Fees: FSMAFeeStaff@fda.hhs.gov.

For Questions Related 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 Fees Support Staff at *OO-OFBAP-OFM-UFSS-Government@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 307 of FSMA (Pub. L. 111–353), Accreditation of Third-Party Auditors, amended the FD&C Act to create a new provision, section 808, under the same name. Section 808 of the FD&C Act (21 U.S.C. 384d) directs FDA to establish a program for accreditation of third-party certification bodies [1] conducting food safety audits and issuing food and facility certifications to eligible foreign entities (including registered foreign food facilities) that meet our applicable requirements. Under this provision, we established a system for FDA to recognize accreditation bodies to accredit certification bodies, except for limited circumstances in which we may directly accredit certification bodies to participate in the third-party certification program.

Section 808(c)(8) of the FD&C Act directs FDA to establish a reimbursement (user fee) program by which we assess fees and require reimbursement for the work FDA performs to establish and administer the third-party certification program under section 808 of the FD&C Act. The user fee program for the third-party certification program was established by a final rule entitled ''Amendments to Accreditation of Third-Party Certification Bodies To Conduct Food Safety Audits and To Issue Certifications To Provide for the User Fee Program'' (81 FR 90186, December 14, 2016).

The FSMA FY 2025 third-party certification program user fee rate announced in this notice is effective on October 1, 2024 and will remain in effect through September 30, 2025.

II. Estimating the Average Cost of a Supported Direct FDA Work Hour for FY 2025

FDA must estimate its costs for each activity in order to establish fee rates for FY 2025. In each year, the costs of salary (or personnel compensation) and benefits for FDA employees account for between 50 and 60 percent of the funds available to, and used by, FDA. Almost all the remaining funds (operating funds) available to FDA are used to support FDA employees by paying for rent, travel, utility, information technology, and other operating costs.

A. Estimating the Full Cost per Direct Work Hour in FY 2025

Full-time Equivalent (FTE) reflects the total number of regular straight-time hours—not including overtime or holiday hours—worked by employees, divided by the number of compensable hours applicable to each fiscal year. Annual leave, sick leave, compensatory time off, and other approved leave categories are considered ''hours worked'' for purposes of defining FTE employment.

In general, the starting point for estimating the full cost per direct work hour is to estimate the cost of an FTE or paid staff year. Calculating an Agency-wide total cost per FTE requires three primary cost elements: payroll, non-payroll, and rent.

We have used an average of past year cost elements to predict the FY 2025

[1] For the reasons explained in the third-party certification final rule (80 FR 74570 at 74578–74579, November 27, 2015), and for consistency with the implementing regulations for the third-party certification program in 21 CFR parts 1, 11, and 16, this notice uses the term ''third-party certification body'' rather than the term ''third-party auditor'' used in section 808(a)(3) of the FD&C Act.