in VQIP. If you subsequently pay the user fee, FDA will begin your benefits after we receive the full payment. The user fee may not be paid after December 31, 2025. For a subsequent year, if you do not pay the user fee before October 1, FDA will send a Notice of Intent to Revoke your participation in VQIP. If you do not pay the user fee within 30 days of the date of the Notice of Intent to Revoke, we will revoke your participation in VQIP.

Dated: July 25, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–14407 Filed 7–29–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–2245]

Prescription Drug User Fee Rates for Fiscal Year 2026

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) 2026. 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 2026.

DATES: These fees apply to the period from October 1, 2025, through September 30, 2026.

FOR FURTHER INFORMATION CONTACT: For more information on prescription drug fees, visit FDA's website at: *https://www.fda.gov/industry/fda-user-fee-programs/prescription-drug-user-fee-amendments. For questions relating to this notice:* Olufunmilayo Ariyo, Office of Financial Management, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 240–402–4989; or the User Fees Support Staff at *UFSS@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 2026 is $1,434,377,467. The FY 2026 base revenue amount is adjusted for (1) inflation, (2) strategic hiring and retention, and for (3) 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) [1] 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 2026 for an application requiring covered clinical data [2] ($4,682,003), for an application not requiring covered clinical data ($2,341,002), and for the prescription drug program fee ($442,213). These fees are effective on October 1, 2025, and will remain in effect through September 30, 2026. For applications that are submitted on or after October 1, 2025, the new fee schedule must be used.

II. Fee Revenue Amount for FY 2026

The base revenue amount for FY 2026 is $1,434,377,467 (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 2026 Statutory Fee Revenue Adjustments for Inflation

PDUFA VII specifies that the $1,434,377,467 is to be adjusted for inflation increases for FY 2026 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 2026. The 3-year average is 5.4494 percent.

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

	2022	2023	2024	3-year average
Total PC&B	$3,165,477,000	$3,436,513,000	$3,791,729,000	
Total FTEs	18,474	18,729	19,687	
PC&B per FTE	$171,348	$183,486	$192,601	

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

[2] 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 1—FDA PERSONNEL COMPENSATION AND BENEFITS (PC&B) EACH YEAR AND PERCENT CHANGES—Continued

	2022	2023	2024	3-year average
Percent Change from Previous Year	4.2967%	7.0838%	4.9677%	5.4494%

The statute specifies that this 5.4494 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

	2022	2023	2024	3-year average
Total PC&B (proportion of costs)	$931,302,114	$1,040,590,183	$1,139,962,844	
Total Costs	$1,480,601,875	$1,686,733,841	$1,772,198,497	
PC&B percent	62.9002%	61.6926%	64.3248%	62.9725%

The payroll adjustment is 5.4494 percent from table 1 multiplied by 62.9725 percent from table 2 resulting in 3.4316 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 (CPI) 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.[3]

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

	2022	2023	2024	3-year average
Annual CPI	296.117	305.317	315.186	
Annual Percent Change	6.6212%	3.1069%	3.2324%	4.3202%

The statute specifies that this 4.3202 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 62.9725 percent was obligated for PC&B (as shown in table 2), 37.0275 percent is the portion of costs other than PC&B (100 percent minus 62.9725 percent equals 37.0275 percent). The non-payroll adjustment is 4.3202 percent times 37.0275 percent, or 1.5997 percent.

Next, we add the payroll adjustment (3.4316 percent) to the non-payroll adjustment (1.5997 percent), for a total inflation adjustment of 5.0313 percent (rounded) for FY 2026.

We then multiply the base revenue amount for FY 2026 ($1,434,377,467) by 5.0313 percent, which produces an inflation adjustment amount of $72,167,833. Adding this amount to the base revenue amount yields an inflation-adjusted base revenue amount of $1,506,545,300.

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)	$1,434,377,467
Inflation Adjustment (section 736(c)(1) of the FD&C Act)	72,167,833
Revenue Amount after Adjustments in sections 736(c)(1) of the FD&C Act	1,506,545,300

B. FY 2026 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 2026, 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)	$1,434,377,467

[3] 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.*

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

Fee	Amount
Inflation Adjustment (section 736(c)(1) of the FD&C Act)	72,167,833
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	1,510,545,300

C. FY 2026 Statutory Fee Revenue Adjustments for Capacity Planning

The statute specifies that after the base revenue amount for FY 2026 of $1,434,377,467 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 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 CPA is an evolution of the PDUFA workload adjuster and was implemented through a process agreed to by FDA and industry during PDUFA VI. The CPA 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.

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 for direct review-related effort. This is then compared to current available resources for the direct review related workload.

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.

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.

FDA calculated workload models for the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) in the Fall of 2024.

Table 6 summarizes the forecasted workload volumes for CDER in FY 2026 based on predictive models, as well as historical actuals from FY 2024 for comparison.

TABLE 6—CDER ACTUAL FY 2024 WORKLOAD VOLUMES AND PREDICTED FY 2026 WORKLOAD VOLUMES

Workload category	FY 2024 Actuals	FY 2026 Predictions
Efficacy Supplements	257	241
Labeling Supplements	1,047	996
Manufacturing Supplements	2,463	2,574
NDA/BLA[1] Original	115	127
PDUFA Industry Meetings (including WROs[2])	4,028	3,843
Active Commercial INDs[3]	10,015	10,758
Annual Reports[4]	3,518	3,659
PMR/PMC-Related Documents[4]	1,770	1,583
Active REMS Programs[4 5]	25	25

[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.

Table 7 summarizes the forecasted workload volumes for CBER in FY 2026 based on predictive models, as well as the corresponding historical actuals from 2024 for comparison.

TABLE 7—CBER ACTUAL FY 2024 WORKLOAD VOLUMES AND PREDICTED FY 2026 WORKLOAD VOLUMES

Workload category	FY 2024 Actuals	FY 2026 Predictions
Efficacy Supplements	24	23
Labeling Supplements	61	61
Manufacturing Supplements	833	869
NDA/BLA [1] Original	12	13
PDUFA Industry Meetings (including WROs [2])	923	1,011
Active Commercial INDs [3]	1,873	2,104
Annual Reports [4]	311	315
PMR/PMC-Related Documents [4]	188	156
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.

FDA anticipates that any FTE gains could be funded through the expected FY 2026 collections amount without further adjustment from the CPA. As such, FDA determined that in FY 2026 the PDUFA fee amounts do not need adjustment from the CPA to provide funds for the program.

TABLE 8—FY 2026 PDUFA CPA

Center	FY 2026 PDUFA CPA
CDER	$0
CBER	0
Total	0

TABLE 9—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)	$1,434,377,467
Inflation Adjustment (section 736(c)(1) of the FD&C Act)	72,167,833
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)	0
Revenue Amount after Adjustments in sections 736(c)(1), (2), and (3) of the FD&C Act	1,510,545,300

D. FY 2026 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 2026 as outlined in statute is $4,864,860 (see section 736(b)(1)(G)(iv) of the FD&C Act). This amount will be added to the total FY 2026 PDUFA VII revenue amount.

TABLE 10—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)	$1,434,377,467
Inflation Adjustment (section 736(c)(1) of the FD&C Act)	72,167,833
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)	0
Additional Dollar Amounts Adjustment (section 736(b)(1)(G) of the FD&C Act)	4,864,860
Cumulative Revenue Amount after Adjustments in sections 736(c)(1), (2), and (3) of the FD&C Act	1,515,410,160

E. FY 2026 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 2026, 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 2026 base revenue (see section 736(c)(4)(A) of the FD&C Act), resulting in $1,515,410,160. This amount is then divided by 52 to generate the 1-week operating amount of $29,142,503. The 1-week operating amount is then multiplied by 10 and 14. This results in a 10-week threshold amount of $291,425,030 and a 14-week threshold amount of $407,995,042.

To determine the FY 2025 end-of-year operating reserves of carryover user fees, the Agency assessed the operating reserve of carryover fees at the end of June 2025 and forecasted collections and obligations in the fourth quarter of FY 2025 combined. This provides an estimated end-of-year FY 2025 operating reserve of carryover user fees of $299,623,185, which equates to 10.28 weeks of operations.[4]

Because the estimated FY 2025 end-of-year operating reserves of carryover user fees are within the 10-week and 14-week thresholds, FDA will not increase or reduce the FY 2026 fees or fee revenue under the statutory provision for operating reserve adjustments.

TABLE 11—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)	$1,434,377,467
Inflation Adjustment (section 736(c)(1) of the FD&C Act)	72,167,833
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)	0
Additional Dollar Amounts Adjustment (section 736(b)(1)(G) of the FD&C Act)	4,864,860
Operating Reserve Adjustment (section (736(c)(4) of the FD&C Act)	0
Cumulative Revenue Amount after Adjustments in sections 736(c)(1), (2), (3), and (4) of the FD&C Act	1,515,410,160

F. FY 2026 Statutory Fee Revenue Adjustments for Additional Direct Cost

PDUFA VII specifies that an additional direct cost of $40,627,674 is to be added to the total FY 2026 PDUFA revenue amount (see section 736(c)(5)(ii) of the FD&C Act). With respect to target revenue for FY 2026, adding the additional direct cost amount of $40,627,674 to the inflation, strategic hiring and retention, CPA, additional dollar amount, and operating reserve adjustment results in the total revenue amount of $1,556,038,000 (rounded to the nearest thousand dollars).

TABLE 12—TOTAL ESTIMATED ADJUSTED REVENUE AMOUNT

Fee	Amount
Statutory Fee Revenue Base Amount (section 736(b)(3) of the FD&C Act)	$1,434,377,467
Inflation Adjustment (section 736(c)(1) of the FD&C Act)	72,167,833
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)	0
Additional Dollar Amounts Adjustment (section 736(b)(1)(G) of the FD&C Act)	4,864,860
Operating Reserve Adjustment (section (736(c)(4) of the FD&C Act)	0
Additional Direct Cost Adjustment (section 736(c)(5) of the FD&C Act)	40,627,674
Cumulative Revenue Amount after Adjustments in sections 736(c)(1), (2), (3), (4), and (5) of the FD&C Act	1,556,037,834
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)	1,556,038,000

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 $311,207,600 in FY 2026.

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 2026 fee setting, the 10 relevant fiscal years are FY 2015–2024. Prior year FAE totals are 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 13 shows, the average number of fee-paying FAEs received annually in FY 2015 through FY 2024 is 66.469. FDA will set fees for FY 2026 based on this estimate as the number of

[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] 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.

full application equivalents that will be subject to fees.

TABLE 13—FEE-PAYING FAEs

	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	10-year average
Fee-Paying FAEs	81.956	70.483	79.750	68.875	80.000	56.750	78.875	45.125	49.500	53.375	66.469

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

The FY 2026 application fee is estimated by dividing the average number of full applications that paid fees from FY 2015 through FY 2024, 66.469, into the fee revenue amount to be derived from application fees in FY 2026, $311,207,600. The result is a fee of $4,682,003 per full application requiring clinical data, and $2,341,002 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 $1,244,830,400 in FY 2026.

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 2,971 program fees will be invoiced in FY 2026 before factoring in waivers, refunds, exceptions, and exemptions. FDA approximates that there will be 97 waivers and refunds granted. Additionally, FDA approximates that another 59 program fees will be exempted in FY 2026 based on the orphan drug exemption in section 736(k) of the FD&C Act.

FDA estimates 2,815 program fees in FY 2026, after allowing for an estimated 156 waivers and reductions, including the orphan drug exemptions, excepted and exempted fee-liable products. The FY 2026 prescription drug program fee rate is calculated by dividing the adjusted total revenue from program fees ($1,244,830,400) by the estimated 2815 program fees, resulting in a FY 2026 program fee of $442,213 (rounded to the nearest dollar).

V. Fee Schedule for FY 2026

The fee rates for FY 2026 are displayed in table 14.

TABLE 14—FEE SCHEDULE FOR FY 2026

Fee category	Fee rates for FY 2026
Application:	
Requiring clinical data	$4,682,003
Not requiring clinical data	2,341,002
Program	442,213

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, 2025. To pay, complete the Prescription Drug User Fee Cover Sheet, available at *https://userfees.fda.gov/OA_HTML/pdufaCAcdLogin.jsp,* and generate a user fee identification (ID) number. Payment must be made in U.S. currency by electronic check or wire transfer.[7] 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.

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 2026 program fees under the new fee schedule in August 2025. Under section 736(a)(2)(A)(i) of the FD&C Act, prescription drug program fees are due on October 1, 2025.

FDA will issue invoices in December 2026 for products that qualify for FY 2026 program fee assessments after the October 2025 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,

[7] *See* ''Change in Federal Payment and Collection Options'' announcement published in the **Federal Register** on June 27, 2025 (90 FR 27639).

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 25, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–2273]

Biosimilar User Fee Rates for Fiscal Year 2026

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the rates for biosimilar user fees for fiscal year (FY) 2026. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Biosimilar User Fee Amendments of 2022 (BsUFA III), authorizes FDA to assess and collect user fees for certain activities in connection with biosimilar biological product development; review of certain applications for approval of biosimilar biological products; and each biosimilar biological product approved in a biosimilar biological product application. BsUFA III directs FDA to establish, before the beginning of each fiscal year, the amount of initial and annual biosimilar biological product development (BPD) fees, the reactivation fee, and the biosimilar biological product application and program fees for such year.

DATES: These fees apply to the period from October 1, 2025, through September 30, 2026.

FOR FURTHER INFORMATION CONTACT: Olufunmilayo Ariyo, Office of Financial Management, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 240–402–4989, and the User Fees Support Staff at *UFSS@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Sections 744G, 744H, and 744I of the FD&C Act (21 U.S.C. 379j–51, 379j–52, and 379j–53), as amended by BsUFA III, authorize the collection of fees for biosimilar biological products. Under section 744H(a)(1)(A) of the FD&C Act, the initial BPD fee for a product is due when the sponsor submits an investigational new drug (IND) application that FDA determines is intended to support a biosimilar biological product application or within 7 calendar days after FDA grants the first BPD meeting, whichever occurs first. A sponsor who has paid the initial BPD fee is considered to be participating in FDA's BPD program for that product.

Under section 744H(a)(1)(B) of the FD&C Act, once a sponsor has paid the initial BPD fee for a product, the annual BPD fee is assessed beginning with the next fiscal year. The annual BPD fee is assessed for the product each fiscal year until the sponsor submits a marketing application for the product that is accepted for filing, the sponsor discontinues participation in FDA's BPD program for the product, or the sponsor has been administratively removed from the BPD program for the product.

Under section 744H(a)(1)(D) of the FD&C Act, if a sponsor has discontinued participation in FDA's BPD program or has been administratively removed from the BPD program for a product and wants to reengage with FDA on development of the product, the sponsor must pay all annual BPD fees previously assessed for such product and still owed, and a reactivation fee to resume participation in the program. The sponsor must pay the reactivation fee by the earlier of the following dates: (1) no later than 7 calendar days after FDA grants the sponsor's request for a BPD meeting for that product or (2) upon the date of submission by the sponsor of an IND describing an investigation that FDA determines is intended to support a biosimilar biological product application for that product. The sponsor will be assessed an annual BPD fee beginning in the next fiscal year after payment of the reactivation fee.

BsUFA III also authorizes fees for certain biosimilar biological product applications and for each biosimilar biological product identified in an approved biosimilar biological product application (section 744H(a)(2) and (3) of the FD&C Act). Under certain conditions, FDA will grant a small business a waiver of the biosimilar biological product application fee (section 744H(d)(1) of the FD&C Act).

For FY 2023 through FY 2027, the base revenue amounts for the total revenues from all BsUFA fees are established by BsUFA III. For FY 2026, the base revenue amount is the FY 2025 total revenue amount excluding any operating reserve adjustment, which equates to the amount of $56,011,943. The FY 2026 base revenue amount is to be adjusted by the inflation adjustment, strategic hiring and retention adjustment, capacity planning adjustment (CPA), operating reserve adjustment, and the additional dollar amount. Each of these adjustments will be discussed in the sections below.

This document provides fee rates for FY 2026 for the initial and annual BPD fee ($10,000), for the reactivation fee ($20,000), for an application requiring clinical data ($1,200,794) for an application not requiring clinical data ($600,397) and for the program fee ($209,097). These fees are effective on October 1, 2025, and will remain in effect through September 30, 2026. For applications that are submitted on or after October 1, 2025, the new fee schedule must be used.

II. Fee Revenue Amount for FY 2026

The base revenue amount for FY 2026 is $56,011,943 prior to adjustments for inflation, strategic hiring and retention, capacity planning, operating reserves, and the additional dollar amount (see section 744H(b) and (c) of the FD&C Act).

A. FY 2026 Statutory Fee Revenue Adjustments for Inflation

BsUFA III specifies that the $56,011,943 is to be adjusted for inflation increases for FY 2026 using two separate adjustments: one for personnel compensation and benefits (PC&B) and one for non-PC&B costs (see section 744H(c)(1) of the FD&C Act).

The component of the inflation adjustment for payroll costs shall be the average annual percent change in the cost of all PC&B paid per full-time equivalent (FTE [1]) 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 biosimilar biological product applications for the first 3 of the preceding 4 fiscal years (see section 744H(c)(1)(B) of the FD&C Act).

Table 1 summarizes the actual cost and FTE data for the specified fiscal years and provides the percent changes from the previous fiscal years and the average percent changes over the first 3 of the 4 fiscal years preceding FY 2026. The 3-year average is 5.4494 percent.

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