premarket approval fees. An applicant may also request a fee waiver for their first premarket application or premarket report (section 738(d) of the FD&C Act).

B. Premarket Notification Submission Fee Reduction

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

C. Annual Establishment Registration Fee Waiver

For FY 2025, there is no small business waiver for the annual establishment registration fee; all establishments pay the same fee.

X. Refunds

To qualify for consideration for a refund, a person shall submit to FDA a written request for a refund not later than 180 days after such fee is due. FDA has discretion to refund a fee or a portion of the fee. A determination by FDA concerning a refund shall not be reviewable. For more information on qualifying and submitting a refund, see section 738(a)(2)(D) of the FD&C Act.

Dated: July 26, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–16883 Filed 7–30–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3423]

Biosimilar 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 biosimilar user fees for fiscal year (FY) 2025. 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. 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 20993, 240–402–4989, and the User Fees Support Staff at *OO-OFBAP-OFM-UFSS-Government@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 2025, the base revenue amount is the FY 2024 total revenue amount excluding any operating reserve adjustment, which equates to the amount of $51,058,823. The FY 2025 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 2025 for the initial and annual BPD fee ($10,000), for the reactivation fee ($20,000), for an application requiring clinical data ($1,471,118) for an application not requiring clinical data ($735,559) and for the program fee ($256,168). 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 $51,058,823 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 2025 Statutory Fee Revenue Adjustments for Inflation

BsUFA III specifies that the $51,058,823 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 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 2025. The 3-year average is 3.8539 percent.

TABLE 1—FDA PC&B EACH YEAR AND PERCENT CHANGES

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

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 biosimilar biological product applications. Table 2 shows the PC&B and the total obligations for the process for the review of biosimilar biological product 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 BIOSIMILAR BIOLOGICAL PRODUCT APPLICATIONS

	2021	2022	2023	3-Year average
Total PC&B (proportion of costs)	$30,932,267	$34,065,826	$45,893,774	
Total Costs	$55,928,075	$68,521,689	$86,101,288	
PC&B percent	55.3072%	49.7154%	53.3021%	52.7749%

The payroll adjustment is 3.8539 percent from table 1 multiplied by 52.7749 percent (or 2.0339 percent).

The statute specifies that the portion of the inflation adjustment for nonpayroll 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 PC&B costs to total costs of the process for the review of biosimilar biological product applications for the first 3 years of the preceding 4 fiscal years (see section 744H(c)(1)(B) of the FD&C Act). 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

Fiscal year	2021	2022	2023	3-Year average
Annual CPI	277.728	296.117	305.317	
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 biosimilar biological product applications obligated. Since 52.7749 percent was obligated for PC&B (as shown in table 2), 47.2251 percent is the portion of costs other than PC&B (100 percent minus 52.7749 percent equals 47.2251 percent). The non-payroll adjustment is 4.5616 percent times 47.2251 percent, 2.1542 percent.

Next, we add the payroll adjustment (2.0339 percent) to the nonpayroll adjustment (2.1542 percent), for a total inflation adjustment of 4.1881 percent (rounded) for FY 2025.

We then multiply the base revenue amount for FY 2025 ($51,058,823) by the inflation adjustment percentage (4.1881 percent), yielding an inflation adjustment of $2,138,395. Adding this amount yields an inflation-adjusted amount of $53,197,218.

B. Strategic Hiring and Retention Adjustment

The statute specifies that for each fiscal year, after the annual base revenue is adjusted for inflation, FDA shall further increase the fee revenue and fees by the strategic hiring and retention adjustment, which is $150,000 for FY 2025 (see section 744H(c)(2) of the FD&C Act).

C. FY 2025 Statutory Fee Revenue Adjustments for Capacity Planning

The statute specifies that the fee revenue and fees shall be further adjusted to reflect changes in the resource capacity needs for the process for the review of biosimilar biological product applications (see section 744H(c)(3) of the FD&C Act). Following a process agreed upon by FDA and

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

[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 BsUFA II reauthorization discussions and subsequently required in statute, FDA established the capacity planning adjustment methodology and first applied it in the setting of FY 2021 fees. The establishment of this methodology is described in the **Federal Register** at 85 FR 47220. 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.

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 a step within the managerial adjustment process. The FY 2025 resource capacity number includes an estimate of the onboard capacity for direct review-related 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 needs 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 consists of four steps:

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

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.

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-related 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 exceeding 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 fiscal year 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.

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.

The following section outlines the major components of the FY 2025 BsUFA III CPA. Table 4 summarizes the forecasted workload volumes for BsUFA III in FY 2025 based on predictive models, as well as historical actuals from FY 2023 for comparison.

TABLE 4—BSUFA III ACTUAL FY 2023 WORKLOAD VOLUMES & PREDICTED FY 2025 WORKLOAD VOLUMES

Workload category	FY 2023 actuals	FY 2025 predictions
Original Biosimilar Supplements [1]	40	48
Manufacturing Supplements	92	95
Biosimilar Biological Product Applications	19	17
BsUFA Industry Meetings (BIA, BPD Type 1–4)	130	150
Participating BPD Programs [2]	114	111
Annual Reports [3]	48	52
PMR/PMC-Related Documents [3]	23	31
Active REMS Programs [2 3]	0	1

[1] Includes Supplements with Clinical Data and Labeling Supplements.
[2] Represents activities related to the review of materials submitted to the application file after approval.
[3] Represents the number of Active 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 FDA's BsUFA III direct review-related work. The resulting expected FY 2025 FTE need for BsUFA III was compared to current onboard capacity for BsUFA III direct review-related work to determine the FY 2025 resource delta, as summarized in table 5.

TABLE 5—FY 2025 BSUFA III RESOURCE DELTA

Current resource capacity	FY 2025 resource forecast	Predicted FY 2025 FTE delta
84	96	12

The projected 12 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 which can be utilized in the fiscal year and for which

funds are required to support additional review capacity. In prior years, FDA adjusted the BsUFA FTE delta to 0 FTEs as there were additional funds available to support the needed FTEs. Due to large downward operating reserve adjustments in prior years, additional funds are needed to sustain additional FTE positions. BsUFA has also experienced sustained growth in review workload over recent years which is expected to continue. As such, FDA is adjusting the FTE delta to 7 FTE to provide a modest adjustment to support the sustained increases in review workload.

TABLE 6—FY 2025 BSUFA III CPA

Additional FTEs for FY 2025	Cost for each additional FTE	FY 2024 BsUFA III CPA
7	$380,675	$2,664,725

D. FY 2025 Additional Dollar Amount

For FY 2023 and FY 2024, BsUFA III provided an additional dollar amount for additional FTE for the biosimilar biological product review program to support enhancements outlined in the BsUFA III Commitment Letter. For FY 2024, the statute directed FDA to further increase the fee revenue and fees by the additional dollar amount, which was $320,569 for FY 2024 (see section 744H(b)(1)(G) of the FD&C Act). For FY 2025 no additional amount is specified in statute.

TABLE 7—BASE REVENUE AMOUNT AND ADJUSTMENTS PRIOR TO OPERATIVE RESERVE ADJUSTMENT

Fee	Amount
Base Revenue Amount (Section 744H(b)–(c) of the FD&C Act)	$51,058,823
Inflation Adjustment (Section 744H(c)(1) of the FD&C Act)	2,138,395
Strategic Hiring and Retention Adjustment (Section 744H(c)(2) of the FD&C Act)	150,000
Capacity Planning Adjustment (Section 744H(c)(3) of the FD&C Act)	2,664,725
Additional Dollar Amount	.....
Cumulative Revenue Amount Prior to Operative Reserve Adjustment	56,011,943

E. FY 2025 Statutory Fee Revenue Adjustments for Operating Reserve

BsUFA III sets forth an operating reserve adjustment to the fee revenue and fees. Specifically, for FY 2025, the statute directs FDA: (1) to increase the fee revenue and fees if such an adjustment is necessary to provide for at least 10 weeks of operating reserves of carryover user fees for the process for the review of biosimilar biological product applications and (2) if FDA has carryover balances for such process in excess of 21 weeks of such operating reserves, to decrease such fee revenue and fees to provide for not more than 21 weeks of such operating reserves (see section 744H(c)(4) of the FD&C Act).

To calculate the 10-week and 21-week threshold amounts for the FY 2025 operating reserve adjustment, the estimated adjusted revenue amount (*i.e.,* the base revenue amount and adjustments prior to the operating reserve adjustment), $56,011,943 is divided by 52, resulting in a $1,077,153 cost of operation for 1 week (rounded to the nearest dollar). The 1-week value ($1,077,153) is then multiplied by 10 weeks to generate the 10-week operating reserve threshold amount for FY 2025 of $10,771,528. The 1-week value is multiplied by 21 to generate the 21-week operating reserve threshold amount for FY 2025 of $22,620,208.

To calculate the estimated operating reserve of carryover user fees at the end of FY 2024, FDA estimated the operating reserves of carryover fees at the end of June 2024. The balance of operating reserves of carryover fees at the end of June 2024 is combined with the forecasted collections and obligations for the remainder of FY 2024 to generate a full year estimate for FY 2024. The estimated operating reserve of carryover user fees at the end of FY 2024 is $14,245,046.

The estimated operating reserve of carryover user fees at the end of FY 2024 of $14,245,046 is below the 21-week threshold allowable operating reserve of carryover user fees for FY 2025 of $22,620,208 and above the 10-week minimum operating reserve carryover user fees for FY 2025 of $10,771,528. As such, FDA is not applying a downward or upward operating reserve adjustment at the start of FY 2025, summarized below.

TABLE 8—TOTAL ESTIMATED ADJUSTED REVENUE AMOUNT

Fee	Amount
Base Revenue Amount (Section 744H(b)–(c) of the FD&C Act)	$51,058,823
Inflation Adjustment (Section 744H(c)(1) of the FD&C Act)	2,138,395
Strategic Hiring and Retention Adjustment (Section 744H(c)(2) of the FD&C Act)	150,000
Capacity Planning Adjustment (Section 744H(c)(3) of the FD&C Act)	2,664,725
Additional Dollar Amount	.....
Operating Reserve Adjustment	.....
Total Revenue Amount in sections 744H(b)–(c), 744H(c)(1), (2), (3) of the FD&C Act	56,011,943
Total Revenue Amount in sections 744H(b)–(c), 744H(c)(1), (2), (3) of the FD&C Act (rounded to the nearest thousand dollars)	56,012,000

III. Fee Amounts for FY 2025

Under section 744H(b)(2)(A) of the FD&C Act, FDA must determine the percentage of the total revenue amount for a fiscal year to be derived from: (1) initial and annual BPD fees, and reactivation fees; (2) biosimilar biological product application fees; and (3) biosimilar biological product program fees. As described above, an operating reserve adjustment is not required for FY 2025.

A. Application Fees

In establishing the biosimilar biological product application fee amount for FY 2025, FDA assessed multiple modeling options. Considering available factors, FDA selected a model that forecasts 17 biosimilar biological product applications requiring clinical data submitted for approval in FY 2025 and zero applications that do not require clinical data. Given recent years' data regarding biosimilar biological product applications that are refused to file and withdrawals before filing, the 17 submissions will be assumed to equate to 16.25 full application equivalents.

For FY 2025 the biosimilar biological product application fee for applications requiring clinical data is $1,471,118. Applications not requiring clinical data pay half that fee, or $735,559. This is estimated to provide a total of $23,905,668 representing 43 percent (rounded to the nearest whole number) of the FY 2025 target revenue amount.

B. Biosimilar Biological Product Program Fee

Under BsUFA III, FDA assesses biosimilar biological product program fees (''program fees''). An applicant in a biosimilar biological product application shall not be assessed more than five program fees for a fiscal year for biosimilar biological products identified in a single biosimilar biological product application (see section 744H(a)(3)(D) of the FD&C Act). Applicants are assessed a program fee for a fiscal year for biosimilar biological products that are identified in a biosimilar biological product application approved as of October 1 of such fiscal year; that may be dispensed only under prescription pursuant to section 503(b) of the FD&C Act; and that, as of October 1 of such fiscal year, do not appear on a list developed and maintained by FDA of discontinued biosimilar biological products. An approved biosimilar biological product that appears on the list of discontinued biosimilar biological products as of October 1 of a fiscal year would also be assessed the program fee if it is removed from the discontinued list during the fiscal year and the other statutory criteria for fee assessment are satisfied (see section 744H(a)(3)(E)(iii) of the FD&C Act).

Based on available information, FDA estimates that 121 program fees will be invoiced for FY 2025. For products invoiced in the FY 2025 regular billing cycle, FDA anticipates that zero program fees will be refunded.

For FY 2025, the biosimilar biological product program fee is $256,168. This is estimated to provide a total of $30,996,328, representing 55 percent (rounded to the nearest whole number) of the FY 2025 target revenue amount.

C. Initial and Annual BPD Fees, and Reactivation Fees

To estimate the number of BPD fees to be paid in FY 2025, FDA must consider the number of new BPD programs, the number of current BPD programs, and the number of BPD programs that will be reactivated. These estimates provide information that, when aggregated, allows FDA to set BPD fees (initial BPD fees, annual BPD fees, reactivation fees).

FDA analyzed available data to estimate the total number of BPD programs for FY 2025. In FY 2025, FDA estimates approximately 23 new BPD programs, no reactivations (a single reactivation is weighted as two BPD fees), and approximately 88 BPD programs to pay the annual BPD fee, yielding a rounded total estimated equivalent of 111 BPD fees to be collected in FY 2025. The remainder of the target revenue of $1,110,000 or 2 percent is to be collected from the BPD fees. Dividing this amount by the estimated 111 BPD fees to be paid equals an initial BPD and annual BPD fee amount of $10,000 (rounded to the nearest dollar). The reactivation fee is set at twice the initial/annual BPD amount at $20,000 (rounded to the nearest dollar).

IV. Fee Schedule for FY 2025

The fee rates for FY 2025 are displayed in table 9.

TABLE 9—FEE SCHEDULE FOR FY 2025

Fee category	Fee rates for FY 2025
Initial BPD	$10,000
Annual BPD	10,000
Reactivation	20,000
Applications:	
Requiring Clinical Data	1,471,118
Not Requiring Clinical Data	735,559
Program Fee	256,168

V. Fee Payment Options and Procedures

A. Initial BPD, Reactivation, and Application Fees

The fees established in the new fee schedule apply to FY 2025, *i.e.,* the period from October 1, 2024, through September 30, 2025. The initial BPD fee for a product is due when the sponsor submits an IND that FDA determines is intended to support a biosimilar biological product application for the product or within 7 calendar days after FDA grants the first BPD meeting for the product, whichever occurs first. Sponsors who have discontinued participation in the BPD program for a product or have been administratively removed from the BPD program for a product, and seek to resume participation in the BPD program for the product must pay all annual BPD fees previously assessed for such product and still owed and the reactivation fee by the earlier of the following dates: no later than 7 calendar days after FDA grants the sponsor's request for a BPD meeting for that product, or 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 application fee for a biosimilar biological product is due upon submission of the application (see section 744H(a)(2)(C) of the FD&C Act).

To make a payment of the initial BPD, reactivation, or application fee, complete the Biosimilar User Fee Cover Sheet, available on FDA's website (*https://www.fda.gov/bsufa*) and generate a user fee identification (ID) number. Payment must be made in U.S. currency by electronic check, check, bank draft, U.S. postal money order, or wire transfer. 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 *www.pay.gov,* a web-based payment application, for online electronic payment. The *www.pay.gov* feature is available on the FDA website after the user fee ID number is generated. 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 *www.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 979108, 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 979108, 3180 Rider Trail South, Earth City, MO 63045. (Note: this U.S. Bank address is for courier delivery only. If you have any questions concerning courier delivery, contact U.S. Bank at 800–495–4981 (this telephone number is only for questions about courier delivery). Please make sure that the FDA post office box number (P.O. Box 979108) and ID number 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. The originating financial institution may charge a wire transfer fee. Include applicable wire transfer fees with payment to ensure fees are fully paid. Questions about wire transfer fees should be addressed to the financial institution. The following account information should be used to send payments by wire transfer: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No: 75060099, Routing No: 021030004, SWIFT: FRNYUS33. FDA's tax identification number is 53–0196965.

B. Annual BPD and Program Fees

FDA will issue invoices with payment instructions for FY 2025 annual BPD and program fees under the new fee schedule in August 2024. Under sections 744H(a)(1)(B)(ii) and 744H(a)(3)(B) of the FD&C Act, annual BPD and program fees will be due on October 1, 2024.

If sponsors join the BPD program after the annual BPD invoices have been issued in August 2024 FDA will issue invoices in December 2024 to sponsors subject to fees for FY 2025 that qualify for the annual BPD fee after the August 2024 billing. FDA will issue invoices in December 2025 for any products that qualify for the annual program fee after the August 2024 billing.

C. Waivers and Returns

To qualify for consideration for a small business waiver under section 744H(d) of the FD&C Act, or the return of any fee paid under section 744H of the FD&C Act, including if the fee is claimed to have been paid in error, a person shall submit to FDA a written request justifying such waiver or return and, except as otherwise specified in section 744H of the FD&C Act, such written request shall be submitted to FDA not later than 180 days after such fee is due. Such written request shall include any legal authorities under which the request is made. See section 744H(h) of the FD&C Act.

Dated: July 26, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–16884 Filed 7–30–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3404]

Generic Drug User Fee Rates for Fiscal Year 2025

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Federal Food, Drug, and Cosmetic Act (FD&C Act or statute), as amended by the Generic Drug User Fee Amendments of 2022 (GDUFA III), authorizes the Food and Drug Administration (FDA, Agency, or we) to assess and collect fees for abbreviated new drug applications (ANDAs); drug master files (DMFs); generic drug active pharmaceutical ingredient (API) facilities, finished dosage form (FDF) facilities, and contract manufacturing organization (CMO) facilities; and generic drug applicant program user fees. In this document, FDA is announcing fiscal year (FY) 2025 rates for GDUFA III fees. These fees are effective on October 1, 2024, and will remain in effect 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; or the User Fees Support Staff at *OO-OFBAP-OFM-UFSS-Government@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Sections 744A and 744B of the FD&C Act (21 U.S.C. 379j–41 and 379j–42), as amended by GDUFA III, authorize FDA to assess and collect fees associated with human generic drug products. Fees are assessed on: (1) certain types of applications for human generic drug products; (2) certain facilities where APIs and FDFs are produced; (3) certain DMFs associated with human generic drug products; and (4) generic drug applicants who own one or more approved ANDAs (the program fee) (see section 744B(a)(2) through (5) of the FD&C Act). For more information about GDUFA III, please refer to the FDA website (*https://www.fda.gov/gdufa*).

For FY 2025, the generic drug user fee rates are ANDA ($321,920), DMF ($95,084), domestic API facility ($41,580), foreign API facility ($56,580), domestic FDF facility ($231,952), foreign FDF facility ($246,952), domestic CMO facility ($55,668), foreign CMO facility ($70,668), large size operation generic drug applicant program ($1,891,664), medium size operation generic drug applicant program ($756,666), and small business generic drug applicant program ($189,166). These fees are effective on October 1, 2024, and will remain in effect through September 30, 2025. The fee rates for FY 2025 are set out in table 1.