TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Recommended information collection activity: Fostering medical device improvement: FDA activities and engagement with the voluntary Improvement Program	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Site manufacturer application	1	400	400	0.08 (5 minutes)	33
Aggregate data reporting	1	4	4	8	32
Summary of site appraisal	1	400	400	20	8,000
Total					8,065

[1] There are no capital or operating and maintenance costs associated with the information collection.

Site Manufacturer Application

In section IV.A of the guidance, we explain that manufacturers wishing to apply for an appraisal may do so at the third-party appraiser's application portal. As part of the VIP process (see section IV.D, *Process Flow,* of the guidance), the site manufacturers' application information is provided to FDA by the third-party appraiser. We assume it will take the third-party appraiser approximately 5 minutes to notify FDA of the availability of each application. Such notification is provided via email and FDA may then access the information via the third-party appraiser's online portal.

Aggregate Data Reporting

As discussed in sections III and IV of the guidance, the third-party appraiser provides FDA with aggregated data across all participating manufacturer sites quarterly. We assume that it will take approximately 8 hours to prepare and submit the aggregate data.

Summary of Site Appraisal

In section IV.D of the guidance, we communicate that the third-party appraiser will provide FDA a summary of the appraisal result for each participating site. We assume an average of 20 hours is necessary to prepare and submit the summary.

This is a new information collection. Specifically, we are accounting for third-party appraiser burden to provide the site manufacturer's information to FDA under the VIP process. We believe associated recordkeeping by participating manufactures to be usual and customary business practice and have therefore not included estimates for VIP application activities by manufacturers. The estimated average burden per response is largely based on our experience with the program pilot and informal communications with participants.

Dated: July 25, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–16079 Filed 7–27–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–2966]

Biosimilar User Fee Rates for Fiscal Year 2024

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the rates for biosimilar user fees for fiscal year (FY) 2024. 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, 2023, through September 30, 2024.

FOR FURTHER INFORMATION CONTACT: Olufunmilayo (Funmi) Ariyo, Office of Financial Management, Food and Drug Administration, 4041 Powder Mill Rd., 6th Floor, Beltsville, MD 20705–4304, 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 2024, the base revenue amount is the FY 2023 total revenue amount excluding any operating reserve adjustment, which equates to the amount of $48,700,243. The FY 2024 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 2024 for the initial and annual BPD fee ($10,000), for the reactivation fee ($20,000), for an application requiring clinical data ($1,018,753) for an application not requiring clinical data ($509,377) and for the program fee ($177,397). These fees are effective on October 1, 2023, and will remain in effect through September 30, 2024. For applications that are submitted on or after October 1, 2023, the new fee schedule must be used.

II. Fee Revenue Amount for FY 2024

The base revenue amount for FY 2024 is $48,700,243 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 2024 Statutory Fee Revenue Adjustments for Inflation

BsUFA III specifies that the $48,700,243 is to be adjusted for inflation increases for FY 2024 using two separate adjustments: one for personnel compensation and benefits (PC&B) and one for non-PC&B costs (see section 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) 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 2024. The 3-year average is 3.9280 percent.

Table 1.--FDA PC&B Each Year and Percent Changes

	FY 2020	FY 2021	FY 2022	3-Year Average
Total PC&B	$2,875,592,000	$3,039,513,000	$3,165,477,000	
Total FTE	17,535	18,501	18,474	
PC&B per FTE	$163,992	$164,289	$171,348	
Percent Change from Previous Year	7.3063%	0.1811%	4.2967%	3.9280%

The statute specifies that this 3.9280 percent be multiplied by the proportion of PC&B costs to the total FDA costs of the process for the review of 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

	FY 2020	FY 2021	FY 2022	3-Year Average
Total PC&B	$25,445,175	$30,932,267	$34,065,826	
Total Costs	$56,798,694	$55,928,075	$68,521,689	
PC&B Percent	44.7989%	55.3072%	49.7154%	49.9405%

The payroll adjustment is 3.9280 percent from table 1 multiplied by 49.9405 percent (or 1.9617 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.[1]

[1] 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 3.--Annual and 3-Year Average Percent Change in CPI for Washington-Arlington-Alexandria Area

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

The statute specifies that this 3.8256 percent be multiplied by the proportion of all costs other than PC&B to total costs of the process for the review of biosimilar biological product applications obligated. Since 49.9405 percent was obligated for PC&B (as shown in table 2), 50.0595 percent is the portion of costs other than PC&B (100 percent minus 49.9405 percent equals 50.0595 percent). The non-payroll adjustment is 3.8256 percent times 50.0595 percent, 1.9151 percent.

Next, we add the payroll adjustment (1.9617 percent) to the nonpayroll adjustment (1.9151 percent), for a total inflation adjustment of 3.8768 percent (rounded) for FY 2024.

We then multiply the base revenue amount for FY 2024 ($48,700,243) by the inflation adjustment percentage (3.8768 percent), yielding an inflation adjustment of $1,888,011. Adding this amount yields an inflation-adjusted amount of $50,588,254.

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 2024 (see section 744H(c)(2) of the FD&C Act).

C. FY 2024 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 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.

In FY 2023, updates were made to refine the time reporting categories included within the CPA to reflect program changes in the current authorization period. As such, time reporting data and baseline capacity were revised to match the refinements. For FY 2024, additional updates were made including to account for additional activities that are also directly related to the direct review of biosimilar biological product applications and supplements as provided for in the statute. These updates include additional formal meeting types and the direct review of postmarketing commitments (PMC) and requirements (PMR) (see table 4), the direct review of risk evaluation and mitigation strategies (REMS), and the direct review of annual reports for approved biosimilar biological products. These updates necessitated an additional re-baselining of capacity.

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

3. *Assess the resource forecast in the context of additional internal factors:* program leadership examines operational, financial, and resourcing data to assess whether FDA will be able to utilize additional funds during the fiscal year and those 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.

The following section outlines the major components of the FY 2024 BsUFA III CPA. Table 4 summarizes the forecasted workload volumes for BsUFA III in FY 2024 based on predictive models, as well as historical actuals from FY 2022 for comparison.

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

Table 4.--BsUFA III Actual FY 2022 Workload Volumes & Predicted FY 2024 Workload Volumes

Workload Category	FY 2022 Actuals	FY 2024 Predictions
Original Biosimilar Supplements[1]	27	34
Manufacturing Supplements	80	73
Biosimilar Biological Product Applications	12	14
BsUFA Industry Meetings (BIA, BPD Type 1-4)	129	139
Participating BPD Programs[2]	108	120
Annual Reports[3]	41	47
PMR/PMC-Related Documents[3]	18	24
Active REMS Programs[3, 4]	0	0

[1] Includes Supplements with Clinical Data and Labeling Supplements
[2] The methodology for counting Participating BPD Programs has been updated and FY 2022 actuals are reported using the revised methodology. In the BsUFA fee notice for FY 2022 (86 FR 40567), Participating BPD Programs for FY 2022 were forecasted to be 131; using the same methodology as in FY 2022, the actuals would be 121.
[3] Represents activities related to the review of materials submitted to the application file after approval
[4] 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 2024 were then converted into estimated FTE needs for FDA's BsUFA III direct review-related work. The resulting expected FY 2024 FTE need for BsUFA III was compared to current onboard capacity for BsUFA III direct review-related work to determine the FY 2024 resource delta, as summarized in table 5.

Table 5.--FY 2024 BsUFA III Resource Delta

Current Resource Capacity	FY 2024 Resource Forecast	Predicted FY 2024 FTE Delta
74	83	9

The projected nine FTE delta was then assessed by FDA in the context of additional operational and internal factors to ensure that a fee adjustment is only made for resources that can be utilized in the fiscal year and for which funds are required to support additional review capacity. FDA determined that realistic expected net FTE gains could be funded through the expected FY 2024 collections amount without further adjustment from the CPA. As such, FDA determined that in FY 2024 the BsUFA fee amounts do not need adjustment from the CPA to provide funds for the realistic estimated net FTE gains.

Table 6.--FY 2024 BsUFA III CPA

Additional FTEs for FY 2024	Cost for Each Additional FTE	FY 2024 BsUFA III CPA
0	$336,269	$0

Although an adjustment to the fee amounts for resource needs by the CPA will not be made in FY 2024, FDA will evaluate the need for a fee adjustment from the CPA in future fiscal years and will make adjustments as warranted.

D. FY 2024 Additional Dollar Amount

For FY 2023 and FY 2024, BsUFA III provides 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 directs FDA to further increase the fee revenue and fees by the additional dollar amount, which is $320,569 for FY 2024 (see section 744H(b)(1)(G) of the FD&C Act).

Table 7.--Base Revenue Amount and Adjustments Prior to Operative Reserve Adjustment

Fee	Amount
Base Revenue Amount	$ 48,700,243
Inflation Adjustment	$ 1,888,011
Strategic Hiring and Retention Adjustment	$ 150,000
Capacity Planning Adjustment	$ -
Additional Dollar Amount	$ 320,569
Cumulative Revenue Amount Prior to Operative Reserve Adjustment	**$ 51,058,823**

E. FY 2024 Statutory Fee Revenue Adjustments for Operating Reserve

BsUFA III sets forth an operating reserve adjustment to the fee revenue and fees. Specifically, for FY 2024, 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 27 weeks of such operating reserves, to decrease such fee revenue and fees to provide for not more than 27 weeks of such operating reserves (see section 744H(c)(4) of the FD&C Act).

To calculate the 10-week and 27-week threshold amounts for the FY 2024 operating reserve adjustment, the estimated adjusted revenue amount (*i.e.,* the base revenue amount and adjustments prior to the operating reserve adjustment), $51,058,823 is divided by 52, resulting in a $981,900 cost of operation for 1 week (rounded to the nearest dollar). The 1-week value (981,900) is then multiplied by 10 weeks to generate the 10-week operating reserve threshold amount for FY 2024 of $9,819,004. The 1-week value is multiplied by 27 to generate the 27-week operating reserve threshold amount for FY 2024 of $26,511,312.

To calculate the estimated operating reserve of carryover user fees at the end of FY 2023, FDA estimated the operating reserves of carryover fees at the end of June 2023. The balance of operating reserves of carryover fees at the end of June 2023 is combined with the forecasted collections and obligations for the remainder of FY 2023 to generate a full year estimate for FY 2023. The estimated operating reserve of carryover user fees at the end of FY 2023 is $46,551,292.

The estimated operating reserve of carryover user fees at the end of FY 2023 of $46,551,292 is above the 27-week threshold allowable operating reserve of carryover user fees for FY 2024 of $26,511,312. As such, FDA is applying a downward operating reserve adjustment of $20,039,980 (rounded to the nearest dollar), an amount equivalent to a reduction of approximately 20 weeks of operations, to bring the operating reserve of carryover user fees to $26,511,312 or 27 weeks of operations at the start of FY 2024. With this operating reserve adjustment, the estimated adjusted revenue amount of $51,058,823 will be lowered by $20,039,980, yielding the FY 2024 target revenue amount of $31,019,000 (rounded to the nearest thousand), summarized below.

Table 8.--Total Estimated Adjusted Revenue Amount

Fee	Amount
Base Revenue Amount	$ 48,700,243
Inflation Adjustment	$ 1,888,011
Strategic Hiring and Retention Adjustment	$ 150,000
Capacity Planning Adjustment	$ -
Additional Dollar Amount	$ 320,569
Operating Reserve Adjustment	$ (20,039,980)
Total Revenue Amount (rounded to the nearest thousand dollars)	**$ 31,019,000**

III. Fee Amounts for FY 2024

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, a downward operating reserve adjustment is required for FY 2024. The operating reserve adjustment in subsequent years may not be as large. As such, the target revenue in FY 2024 may be lower than in prior or future years, and thereby the fee amounts may also be lower than in prior or future years.

A. Application Fees

In establishing the biosimilar biological product application fee amount for FY 2024, FDA assessed multiple modeling options. The model performing the best when tested against historical data forecasts 14 biosimilar biological product applications requiring clinical data submitted for approval in FY 2024 and 0 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 14 submissions will be assumed to equate to 13.25 full application equivalents.

For FY 2024 the biosimilar biological product application fee for applications requiring clinical data is $1,018,753. Applications not requiring clinical data pay half that fee, or $509,377. This is estimated to provide a total of $13,498,477 representing 44 percent (rounded to the nearest whole number) of the FY 2024 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 (21 U.S.C. 353(b)); 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 92 program fees will be invoiced for FY 2024. For products invoiced in the FY 2024 regular billing cycle, FDA anticipates that zero program fees will be refunded.

For FY 2024, the biosimilar biological product program fee is $177,397. This is estimated to provide a total of $16,320,524, representing 53 percent (rounded to the nearest whole number) of the FY 2024 target revenue amount.

C. Initial and Annual BPD Fees, and Reactivation Fees

To estimate the number of BPD fees to be paid in FY 2024, 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 2024. In FY 2024, FDA estimates approximately 23 new BPD programs, no reactivations (a single reactivation is weighted as two BPD fees), and approximately 97 BPD programs to pay the annual BPD fee, yielding a rounded total estimated equivalent of 120 BPD fees to be collected in FY 2024. The remainder of the target revenue of $1,199,999 or 4 percent is to be collected from the BPD fees. Dividing this amount by the estimated 120 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 2024

The fee rates for FY 2024 are displayed in table 9.

Table 9.--Fee Schedule for FY 2024

Fee Category	Fee Rates for FY 2024
Initial BPD	$10,000
Annual BPD	$10,000
Reactivation	$20,000
Applications	
Requiring clinical data	$1,018,753
Not requiring clinical data	$509,377
Program	$177,397

V. Fee Payment Options and Procedures

A. Initial BPD, Reactivation, and Application Fees

The fees established in the new fee schedule apply to FY 2024, *i.e.,* the period from October 1, 2023, through September 30, 2024. 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, 1005 Convention Plaza, St. Louis, MO 63101. (Note: this U.S. Bank address is for courier delivery only. If you have any questions concerning courier delivery, contact U.S. Bank at 314–418–4013. This telephone number is only for questions about courier delivery). Please make sure that the FDA post office box number (P.O. Box 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 2024 annual BPD and program fees under the new fee schedule in August 2023. Under section 744H(a)(1)(B)(ii) and (a)(3)(B) of the FD&C Act, annual BPD and program fees will be due on October 2, 2023.

If sponsors join the BPD program after the annual BPD invoices have been issued in August 2023, FDA will issue invoices in December 2023 to sponsors subject to fees for FY 2024 that qualify for the annual BPD fee after the August 2023 billing. FDA will issue invoices in December 2024 for any products that qualify for the annual program fee after the August 2023 billing.

C. Waivers and Refunds

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 24, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–15918 Filed 7–27–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–2896]

Food Safety Modernization Act Domestic and Foreign Facility Reinspection, Recall, and Importer Reinspection Fee Rates for Fiscal Year 2024

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the fiscal year (FY) 2024 fee rates for certain domestic and foreign facility reinspections, failures to comply with a recall order, and importer reinspections that are authorized by the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the FDA Food Safety Modernization Act (FSMA).

DATES: These fees are effective on October 1, 2023, and will remain in effect through September 30, 2024.

FOR FURTHER INFORMATION CONTACT: Olufunmilayo Ariyo, Office of Food Policy and Response, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 240–402–4989, *FSMAFeeStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Section 107 of the FSMA (Pub. L. 111–353) added section 743 to the FD&C Act (21 U.S.C. 379j–31) to provide FDA with the authority to assess and collect fees from, in part: (1) the responsible party for each domestic facility and the U.S. agent for each foreign facility subject to a reinspection to cover reinspection-related costs; (2) the responsible party for a domestic facility and an importer who does not comply with a recall order to cover food [1] recall activities associated with such order; and (3) each importer subject to a reinspection to cover reinspection-related costs (sections 743(a)(1)(A), (B), and (D) of the FD&C Act). Section 743 of the FD&C Act directs FDA to establish fees for each of these activities based on an estimate of 100 percent of the costs of each activity for each year (sections 743(b)(2)(A)(i), (ii), and (iv)), and these fees must be made available solely to pay for the costs of each activity for which the fee was incurred (section 743(b)(3)). These fees are effective on October 1, 2023, and will remain in effect through September 30, 2024. Section 743(b)(2)(B)(iii) of the FD&C Act directs FDA to develop a proposed set of guidelines in consideration of the burden of fee amounts on small businesses. As a first step in developing these guidelines, FDA invited public comment on the potential impact of the fees authorized by section 743 of the FD&C Act on small businesses (76 FR 45818, August 1, 2011). The comment period for this request ended November 30, 2011. As stated in FDA's September 2011 ''Guidance for Industry: Implementation of the Fee Provisions of Section 107 of the FDA Food Safety Modernization Act,'' (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-implementation-fee-provisions-section-107-fda-food-safety-modernization-act*), because FDA recognizes that for small businesses the full cost recovery of FDA reinspection or recall oversight could impose severe economic hardship, FDA intends to consider reducing certain fees for those firms. FDA does not intend to issue invoices for reinspection or recall order fees until FDA publishes a guidance document outlining the process through which firms may request a reduction in fees.

In addition, as stated in the September 2011 Guidance, FDA is in the process of considering various issues associated with the assessment

[1] The term ''food'' for purposes of this document has the same meaning as such term in section 201(f) of the FD&C Act (21 U.S.C. 321(f)).