the FD&C Act). Noncompliance may include the following: (1) not initiating a recall as ordered by FDA; (2) not conducting the recall in the manner specified by FDA in the recall order; or (3) not providing FDA with requested information regarding the recall, as ordered by FDA.

B. Who will be responsible for paying this fee?

Section 743(a)(1)(B) of the FD&C Act states that the fee is to be paid by the responsible party for a domestic facility (as defined in section 415(b) of the FD&C Act) and an importer who does not comply with a recall order under section 423 or under section 412(f) of the FD&C Act. In other words, the party paying the fee would be the party that received the recall order.

C. How much will this fee be?

The fee is based on the number of direct hours spent on taking action in response to the firm's failure to comply with a recall order. Types of activities could include conducting recall audit checks, reviewing periodic status reports, analyzing the status reports and the results of the audit checks, conducting inspections, traveling to and from locations, and monitoring product disposition. The direct hours spent on each such recall will be billed at the appropriate hourly rate shown in table 2 of this document.

D. How must the fees be paid?

An invoice will be sent to the responsible party for paying the fee after FDA completes the work on which the invoice is based. Payment must be made within 30 days of the invoice date in U.S. currency by check, bank draft, or U.S. postal money order payable to the order of the Food and Drug Administration. Detailed payment information will be included with the invoice when it is issued.

V. What are the consequences of not paying these fees?

Under section 743(e)(2) of the FD&C Act, any fee that is not paid within 30 days after it is due shall be treated as a claim of the U.S. Government subject to provisions of subchapter II of chapter 37 of title 31, United States Code.

Dated: July 24, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–3059]

Generic Drug User Fee Rates for Fiscal Year 2024

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) 2024 rates for GDUFA III fees. 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 Financial Management, Food and Drug Administration, 4041 Powder Mill Rd., Rm. 62080, Beltsville, MD 20705–4304, 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 have 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 2024, the generic drug fee rates are ANDA ($252,453), DMF ($94,682), domestic API facility ($40,464), foreign API facility ($55,464), domestic FDF facility ($220,427), foreign FDF facility ($235,427), domestic CMO facility ($52,902), foreign CMO facility ($67,902), large size operation generic drug applicant program ($1,729,629), medium size operation generic drug applicant program ($691,852), and small business generic drug applicant program ($172,963). These fees are effective on October 1, 2023, and will remain in effect through September 30, 2024. The fee rates for FY 2024 are set out in table 1.

TABLE 1—FEE SCHEDULE FOR FY 2024

Generic drug fee category	Fees rates for FY 2024
Applications	
Abbreviated New Drug Application (ANDA)	$252,453
Drug Master File (DMF)	94,682
Facilities	
Active Pharmaceutical Ingredient (API)—Domestic	40,464
API—Foreign	55,464
Finished Dosage Form (FDF)—Domestic	220,427
FDF—Foreign	235,427
Contract Manufacturing Organization (CMO)—Domestic	52,902
CMO—Foreign	67,902
GDUFA Program	
Large size operation generic drug applicant	1,729,629
Medium size operation generic drug applicant	691,852
Small business generic drug applicant	172,963

II. Fee Revenue Amount for FY 2024

Under section 744B(b)(1)(B)(ii) of the FD&C Act, the base revenue amount for FY 2024 for GDUFA III is $582,500,000. Under section 744B(c)(1) of the FD&C Act, applicable inflation adjustments to base revenue shall be made beginning with FY 2024.

Under section 744B(c)(2) of the FD&C Act, beginning with FY 2024, FDA shall, in addition to the inflation adjustment, apply a capacity planning adjustment to further adjust, as needed, the fee revenue and fees to reflect changes in the resource capacity needs of FDA for human generic drug activities.

Under section 744B(c)(3) of the FD&C Act, beginning with FY 2024, FDA may, in addition to the inflation and capacity planning adjustments, apply an operating reserve adjustment to further increase the fee revenue and fees if necessary to provide operating reserves of carryover user fees for human generic drug activities for not more than the number of weeks specified in such section (or as applicable, shall apply such adjustment to decrease the fee revenues and fees to provide for not

more than 12 weeks of such operating reserves).

A. Inflation Adjustment

As noted, above, the base revenue amount for FY 2024 is $582,500,000. This is the total revenue amount specified for the prior fiscal year, FY 2023, pursuant to the statute (see section 744B(b)(1)(A) of the FD&C Act).[1] GDUFA III specifies that the $582,500,000 is to be adjusted for inflation for FY 2024 using two separate adjustments—one for personnel compensation and benefits (PC&B) and one for non-PC&B costs (see sections 744B(c)(1)(B) and (C) of the FD&C Act).

The component of the inflation adjustment for PC&B costs shall be the average annual percent change in the cost of all PC&B paid per full-time equivalent (FTE) position at FDA for the first 3 of the 4 preceding fiscal years, multiplied by the proportion of PC&B costs to total FDA costs of human generic drug activities for the first 3 of the preceding 4 fiscal years (see section 744B(c)(1)(B) of the FD&C Act).

Table 2 summarizes the actual cost and total FTEs for the specified fiscal years and provides the percent change from the previous fiscal year and the average percent change over the first 3 of the 4 fiscal years preceding FY 2024. The 3-year average is 3.9280 percent.

TABLE 2—FDA PERSONNEL COMPENSATION AND BENEFITS (PC&B) EACH YEAR AND PERCENT CHANGE

Fiscal year	2020	2021	2022	3-Year average
Total PC&B	$2,875,592,000	$3,039,513,000	$3,165,477,000	.....
Total FTEs	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 should be multiplied by the proportion of PC&B expended for human generic drug activities for the first 3 of the preceding 4 fiscal years. Table 3 shows the amount of PC&B and the total amount obligated for human generic drug activities from FY 2020 through FY 2022.

TABLE 3—PC&B AS A PERCENT OF FEE REVENUES SPENT ON HUMAN GENERIC DRUG ACTIVITIES OVER THE LAST 3 YEARS

Fiscal year	2020	2021	2022	3-Year average
PC&B	$397,392,785	$410,587,565	$391,922,747	.....
Non-PC&B	300,692,399	271,328,560	289,479,265	.....
Total Costs	698,085,185	681,916,125	681,402,012	.....
PC&B Percent	56.9261%	60.2109%	57.5171%	58.2180%
Non-PC&B Percent	43.0739%	39.7891%	42.4829%	41.7820%

The payroll adjustment is 3.9280 percent multiplied by 58.2180 percent (or 2.2868 percent).

The statute specifies that the portion of the inflation adjustment for non-PC&B costs for FY 2024 is the average annual percent change that occurred in the Consumer Price Index (CPI) for urban consumers (Washington-Arlington-Alexandria Area, DC-VA-MD-WV; not seasonally adjusted; all items; annual index) for the first 3 of the preceding 4 years of available data multiplied by the proportion of all costs other than PC&B costs to total costs of human generic drug activities for the first 3 years of the preceding 4 fiscal years (see section 744B(c)(1)(C) of the FD&C Act). Table 4 provides the summary data for the percent change in the specified CPI. 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 4—ANNUAL AND 3-YEAR AVERAGE PERCENT CHANGE IN CPI FOR WASHINGTON-ARLINGTON-ALEXANDRIA AREA

Year	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%

To calculate the inflation adjustment for non-pay costs, we multiply the 3-year average percent change in the CPI (3.8256 percent) by the proportion of all costs other than PC&B to total costs of human generic drug activities obligated. Because 58.2180 percent was obligated for PC&B as shown in table 3, 41.7820 percent is the portion of costs other than PC&B. The non-pay adjustment is 3.8256 percent times 41.7820 percent, or 1.5984 percent.

To complete the inflation adjustment for FY 2024, we add the PC&B component (2.2868 percent) to the non-PC&B component (1.5984 percent) for a total inflation adjustment of 3.8852 percent (rounded), and then add 1,

[1] Under section 744B(b)(1)(B)(ii), the base revenue amount for a fiscal year is equal to the total revenue amount established for the previous fiscal year, not including any adjustments for such previous fiscal year under section 744B(c)(3). For FY 2023, adjustments under section 744B(c)(3) were inapplicable.

making an inflation adjustment multiple of 1.038852. We then multiply the base revenue amount for FY 2024 ($582,500,000) by 1.038852, yielding an inflation-adjusted amount of $605,131,290.

B. FY 2024 Statutory Fee Revenue Adjustments for Capacity Planning

The statute specifies that after the base revenue amount for FY 2024 of $582,500,000 has been adjusted for inflation as described in section A above, the resulting amount shall be further adjusted to reflect changes in the resource capacity needs for human generic drug activities (see section 744B(c)(2) of the FD&C Act). Following a process required in the statute, FDA established the capacity planning adjustment (CPA) methodology that is derived from the methodology and recommendations made in the report titled ''Independent Evaluation of the GDUFA Resource Capacity Planning Adjustment Methodology: Evaluation and Recommendations'' as announced in the **Federal Register** of August 3, 2020, and incorporating approaches and attributes determined appropriate by the Agency, except that the workload drivers are limited to those specified in the GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2023–2027 (GDUFA III Commitment Letter).[2] 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 the accuracy of its data and estimates over time.[3]

The CPA methodology consists of 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[4] 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 whether the additional 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.

Table 5 summarizes the forecasted workload volumes for the Center for Drug Evaluation and Research (CDER) for FY 2024 based on predictive models, as well as historical actuals from FY 2022 for comparison.

TABLE 5—CDER ACTUAL FY 2022 WORKLOAD VOLUMES AND PREDICTED FY 2024 WORKLOAD VOLUMES

Workload driver category	FY 2022 actuals	FY 2024 predictions
ANDA Originals[1]	813	801
ANDA Supplements[2]	9,716	10,434
Pre-ANDA Meetings	132	103
Controlled Correspondences[3]	3,677	3,505
Suitability Petitions	21	25
Annual Reports[4]	11,826	12,624
Active REMS Programs[4 5]	45	45

[1] Excludes response to refused to receive (RTR) and Orig-2+. ANDA Original and Resubmissions/Amendments captured in time reporting data.
[2] Includes changes being effected and prior approval supplement Manufacturing and Labeling Supplements. PAS exclude response to RTRs, risk evaluation and mitigation strategies (REMS) and Bioequivalence Supplements. ANDA Supplement and Resubmissions/Amendments captured in time reporting data.
[3] Includes all requesting controlled correspondences.
[4] Represents post-marketing safety activities developed in alignment with Prescription Drug User Fee Act and biosimilar user fee amendments as applicable.
[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.

Utilizing the resource forecast algorithms, the forecasted workload volumes for FY 2024 were then converted into estimated FTE needs for FDA's GDUFA direct review-related work. The resulting expected FY 2024 FTE need for GDUFA was compared to current onboard capacity for GDUFA direct review-related work to determine the FY 2024 resource delta, as summarized in table 6.

TABLE 6—CDER FY 2024 GDUFA RESOURCE DELTA

Center	Current resource capacity	FY 2024 resource forecast	Predicted FY 2024 FTE delta
CDER	1,024	1,059	35

The projected 35 FTE delta was assessed by FDA in the context of additional operational and internal factors to ensure that a fee adjustment is only made for resources that can be utilized in the fiscal year and for which funds are required to support additional review capacity.

After assessing current hiring capacity and existing funded vacancies, CDER adjusted the 35 FTE delta to 25 FTEs.

[2] Section 744B(c)(2)(B) of the FD&C Act; see also section VIII.B.2.e. of the GDUFA III Commitment Letter available at *https://www.fda.gov/media/153631/download*.

[3] For example, starting with FY 2025, FDA will aim to refine the CPA methodology to reflect a more comprehensive assessment of the applicable workload drivers across the Agency.

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

The adjusted 25 FTE delta was then assessed by FDA to determine if the delta exceeded the CPA cap as specified in statute (section 744B(c)(2)(C)(ii)) which articulates that for FY 2024, the CPA shall not exceed 3 percent of inflation-adjusted base revenue, except that the CPA cap may be increased to 4 percent of inflation-adjusted base revenue if the following conditions are met during the period from April 1, 2021 through March 31, 2023: (1) the total number of ANDAs submitted was greater than or equal to 2,000 or (2) 35 percent or more of ANDAs submitted related to complex products (as defined in section XI of the letters described in section 3001(b) of the Generic Drug User Fee Amendments of 2022).[5]

Table 7 summarizes the total number of ANDAs submitted and the percentage of such applications that were related to complex products from April 1, 2021 through March 31, 2023:

TABLE 7—GDUFA CPA CAP ASSESSMENT METRICS

Abbreviated New Drug Applications Submitted between April 1, 2021 through March 31, 2023	1,675
Percentage of Abbreviated New Drug Applications Submitted that are Complex Submitted between April 1, 2021 through March 31, 2023	16%

FDA determined that the criteria to increase the CPA cap was not, and therefore, the GDUFA CPA cap for FY 2024 is 3 percent of inflation-adjusted base revenue. FDA further determined that the 25 FTE delta when converted to dollars did not exceed 3 percent of FY 2024 inflation-adjusted base revenue, and therefore, this 25 FTE delta required no further adjustment.

The FY 2024 GDUFA CPA is therefore $8,406,725, as summarized in table 8.

TABLE 8—FY 2024 GDUFA CPA

Center	Additional FTEs for 2024	Cost for each additional FTE	CDER FY 2024 GDUFA CPA
CDER	25	$336,269	$8,406,725

TABLE 9—BASE REVENUE AMOUNT AND SECTION 744B(c)(1) AND (2) ADJUSTMENT AMOUNTS

Fee	Amount
Statutory Fee Revenue Base Amount (section 744B(b)(1) of the FD&C Act)	$582,500,000
Statutory Fee Revenue Adjustments for Inflation (section 744B(c)(1) of the FD&C Act)	22,631,290
Statutory Fee Revenue Adjustments for Capacity Planning (section 744B(c)(2) of the FD&C Act)	8,406,725
Cumulative Adjusted Revenue Amount (sections 744B(b)(1), 744B(c)(1), and 744B(c)(2) of the FD&C Act	613,538,015

C. FY 2024 Statutory Fee Revenue Adjustments for Operating Reserve

Under section 744B(c)(3) of the FD&C Act, beginning with FY 2024, FDA may, in addition to the inflation and capacity planning adjustments, apply an operating reserve adjustment to further increase the fee revenue and fees if necessary to provide operating reserves of carryover user fees for human generic drug activities for not more than the number of weeks specified in such section (or as applicable, shall apply such adjustment to decrease the fee revenues and fees to provide for not more than 12 weeks of such operating reserves).

The upward operating reserve adjustment is discretionary—for FY 2024, FDA may take an adjustment to provide for not more than 8 weeks of operating reserve. If carryover is more than 12 weeks of operating reserve, FDA must decrease the fee revenues and fees to provide for not more than 12 weeks of operating reserve. To calculate the 8-week and 12-week threshold amounts for the FY 2024 operating reserve adjustment, the FY 2024 estimated adjusted revenue amount, $613,538,015 is divided by 52, resulting in a $11,798,808 cost of operation for 1 week. The 1-week value is then multiplied by 8 weeks to generate the 8-week operating reserve threshold amount for FY 2024 of $94,390,464. The 1-week value is multiplied by 12 to generate the 12-week operating reserve threshold amount for FY 2024 of $141,585,696.

To determine the FY 2023 end-of-year operating reserves of carryover user fees, the Agency assessed the operating reserve of carryover fees at the end of June 2023 and forecast collections and obligations in the fourth quarter of FY 2023 combined. This provides an estimated end-of-year FY 2023 operating reserve of carryover user fees of $130,218,707 which equates to 11.04 weeks of operations.

The statutory criteria for an operating reserve adjustment were not met. Table 10 below summarizes FY 2024 fee revenue.

TABLE 10—TOTAL ESTIMATED ADJUSTED REVENUE AMOUNT

Fee	Amount
Statutory Fee Revenue Base Amount (section 744B(b)(1) of the FD&C Act)	$582,500,000
Statutory Fee Revenue Adjustments for Inflation (section 744B(c)(1) of the FD&C Act)	22,631,290
Statutory Fee Revenue Adjustments for Capacity Planning (section 744B(c)(2) of the FD&C Act)	8,406,725
Operating Reserve Adjustment (section 744B(c)(3) of the FD&C Act)	.....
Total Revenue Amount (rounded to the nearest thousand dollars) (sections 744B(b)(1), 744B(c)(1), 744B(c)(2) and 744B(c)(3) of the FD&C Act)	613,538,000

III. ANDA Filing Fee

Under GDUFA III, the FY 2024 ANDA filing fee is owed by each applicant that submits an ANDA on or after October 1, 2023.[6] This fee is due on the submission date of the ANDA. Section 744B(b)(2)(B) of the FD&C Act specifies that the ANDA fee will make up 33 percent of

[5] Definition of complex products in section XI of the GDUFA III Commitment Letter *https://www.fda.gov/media/153631/download*.

[6] Section 744B(a)(3) of the FD&C Act.

the $613,538,000, which is $202,467,540.

To calculate the ANDA fee, FDA estimated the number of full application equivalents (FAEs) that will be submitted in FY 2024. The submissions are broken down into three categories: new originals (submissions that have not been received by FDA previously), submissions that FDA RTR for reasons other than failure to pay fees, and applications that are resubmitted after an RTR decision for reasons other than failure to pay fees. An ANDA counts as one FAE; however, 75 percent of the fee paid for an ANDA that has been RTR shall be refunded according to GDUFA III if: (1) the ANDA is refused for a cause other than failure to pay fees or (2) the ANDA has been withdrawn prior to receipt (section 744B(a)(3)(D)(i) of the FD&C Act). Therefore, an ANDA that is considered not to have been received by FDA due to reasons other than failure to pay fees or withdrawn prior to receipt counts as one-fourth of an FAE. After an ANDA has been RTR, the applicant has the option of resubmitting. For user fee purposes, these resubmissions are equivalent to new original submissions: ANDA resubmissions are charged the full amount for an application (one FAE).

As shown in table 5, FDA estimates that 801 new original ANDAs will be submitted and incur filing fees in FY 2024. Not all of the new original ANDAs will be received by FDA and some of those not received will be resubmitted in the same fiscal year. Therefore, FDA expects that the FAE count for ANDAs will be 802 for FY 2024.

The FY 2024 ANDA filing fee is estimated by dividing the number of FAEs that will incur the fee in FY 2024 (802) into the fee revenue amount to be derived from ANDA filing fees in FY 2024 ($202,467,540). The result, rounded to the nearest dollar, is a fee of $252,453 per ANDA.

The statute provides that those ANDAs that include information about the production of APIs other than by reference to a DMF will pay an additional fee that is based on the number of such APIs and the number of facilities proposed to produce those ingredients (see section 744B(a)(3)(F) of the FD&C Act). FDA anticipates that this additional fee is unlikely to be assessed often; therefore, FDA has not included projections concerning the amount of this fee in calculating the fees for ANDAs.

IV. DMF Fee

Under GDUFA III, the DMF fee is owed by each person that owns a type II API DMF that is referenced, on or after October 1, 2012, in a generic drug submission by an initial letter of authorization.[7] This is a one-time fee for each DMF. This fee is due on the earlier of the date on which the first generic drug submission is submitted that references the associated DMF or the date on which the DMF holder requests the initial completeness assessment. Under section 744B(a)(2)(D)(iii) of the FD&C Act, if a DMF has successfully undergone an initial completeness assessment and the fee is paid, the DMF will be placed on a publicly available list documenting DMFs available for reference.

To calculate the DMF fee, FDA assessed the volume of DMF submissions over time. We assessed DMFs from October 1, 2021, to April 30, 2023, and concluded that averaging the number of fee-paying DMFs provided the most accurate model for predicting fee-paying DMFs for FY 2024. The monthly average of paid DMF submissions FDA received during FY 2022 and FY 2023 is 27. To determine the FY 2024 projected number of fee-paying DMFs, the average of 27 DMF submissions is multiplied by 12 months, which results in 324 estimated FY 2024 fee-paying DMFs. FDA is estimating 324 fee-paying DMFs for FY 2024.

The FY 2024 DMF fee is determined by dividing the DMF target revenue by the estimated number of fee-paying DMFs in FY 2024. Section 744B(b)(2)(A) of the FD&C Act specifies that the DMF fees will make up 5 percent of the $613,538,000, which is $30,676,900. Dividing the DMF revenue amount ($30,676,900) by the estimated fee-paying DMFs (324), and rounding to the nearest dollar, yields a DMF fee of $94,682 for FY 2024.

V. Foreign Facility Fee Differential

Under GDUFA III, the fee for a facility located outside the United States and its territories and possessions shall be $15,000 higher than the amount of the fee for a facility located in the United States and its territories and possessions.[8] The basis for this differential is the extra cost incurred by conducting an inspection outside the United States and its territories and possessions.

VI. FDF and CMO Facility Fees

Under GDUFA III, the annual FDF facility fee is owed by each person who owns an FDF facility that is identified in at least one approved generic drug submission owned by that person or its affiliates.[9] The CMO facility fee is owed by each person who owns an FDF facility that is identified in at least one approved ANDA but is not identified in an approved ANDA held by the owner of that facility or its affiliates.[10] Section 744B(b)(2)(C) of the FD&C Act specifies that the FDF and CMO facility fee revenue will make up 20 percent of the $613,538,000, which is $122,707,600.

To calculate the fees, data from FDA's Integrity Services (IS) were utilized as the primary source of facility information for determining the denominators of each facility fee type. IS is the master data steward for all facility information provided in generic drug submissions received by FDA. A facility's reference status in an approved generic drug submission is extracted directly from submission data rather than relying on data from self-identification. This information provided the number of facilities referenced as FDF manufacturers in at least one approved generic drug submission. Based on FDA's IS data, the FDF and CMO facility denominators are 173 FDF domestic, 307 FDF foreign, 81 CMO domestic, and 118 CMO foreign facilities for FY 2024.

GDUFA III specifies that the CMO facility fee is to be equal to 24 percent of the FDF facility fee.[11] Therefore, to generate the target collection revenue amount from FDF and CMO facility fees ($122,707,600), FDA must weight a CMO facility as 24 percent of an FDF facility. FDA set fees based on the estimate of 173 FDF domestic, 307 FDF foreign, 19.44 CMO domestic (81 multiplied by 24 percent), and 28.32 CMO foreign facilities (118 multiplied by 24 percent), which equals 528 total weighted FDF and CMO facilities for FY 2024.

To calculate the fee for domestic facilities, FDA first determines the total fee revenue that will result from the foreign facility differential by subtracting the fee revenue resulting from the foreign facility fee differential from the target collection revenue amount ($122,707,600) as follows: the foreign facility fee differential revenue equals the foreign facility fee differential ($15,000) multiplied by the number of FDF foreign facilities (307) plus the foreign facility fee differential ($15,000) multiplied by the number of CMO foreign facilities (118), totaling $6,375,000. This results in foreign fee differential revenue of $6,375,000 from

[7] Section 744B(a)(2) of the FD&C Act.

[8] Section 744B(b)(2)(C) and (D) of the FD&C Act.

[9] Section 744B(a)(4)(A) of the FD&C Act.

[10] Section 744A(5) and 744B(b)(2)(C) of the FD&C Act.

[11] Section 744B(b)(2)(C) of the FD&C Act.

the total FDF and CMO facility fee target collection revenue.

Subtracting the foreign facility differential fee revenue ($6,375,000) from the total FDF and CMO facility target collection revenue ($122,707,600) results in a remaining facility fee revenue balance of $116,332,600. To determine the domestic FDF facility fee, FDA divides the $116,332,600 by the total weighted number of FDF and CMO facilities (527.76), which results in a domestic FDF facility fee of $220,427. The foreign FDF facility fee is $15,000 more than the domestic FDF facility fee, or $235,427.

According to GDUFA III, the domestic CMO fee is calculated as 24 percent of the amount of the domestic FDF facility fee.[12] Therefore, the domestic CMO fee is $52,902, rounded to the nearest dollar. The foreign CMO fee is calculated as the domestic CMO fee plus the foreign fee differential of $15,000. Therefore, the foreign CMO fee is $67,902.

VII. API Facility Fee

Under GDUFA III, the annual API facility fee is owed by each person who owns a facility that is identified in at least one approved generic drug submission in which the facility is approved to produce one or more API or in a Type II API DMF referenced in at least one approved generic drug submission.[13] Section 744B(b)(2)(D) of the FD&C Act specifies the API facility fee will make up 6 percent of $613,538,000 in fee revenue, which is $36,812,280.

To calculate the API facility fee, data from FDA's IS were utilized as the primary source of facility information for determining the denominator. As stated above, IS is the master data steward for all facility information provided in generic drug submissions received by FDA. A facility's reference status in an approved generic drug submission is extracted directly from submission data rather than relying on data from self-identification. This information provided the number of facilities referenced as API manufacturers in at least one approved generic drug submission.

The total number of API facilities identified was 684; of that number, 75 were domestic and 609 were foreign facilities. The foreign facility differential is $15,000. To calculate the fee for domestic facilities, FDA must first subtract the fee revenue that will result from the foreign facility fee differential. FDA takes the foreign facility differential ($15,000) and multiplies it by the number of foreign facilities (609) to determine the total fee revenue that will result from the foreign facility differential. As a result of this calculation, the foreign fee differential revenue will make up $9,135,000 of the total API fee revenue. Subtracting the foreign facility differential fee revenue ($9,135,000) from the total API facility target revenue ($36,812,280) results in a remaining balance of $27,677,280. To determine the domestic API facility fee, we divide the $27,677,280 by the total number of facilities (684), which gives us a domestic API facility fee of $40,464. The foreign API facility fee is $15,000 more than the domestic API facility fee, or $55,464.

VIII. Generic Drug Applicant Program Fee

Under GDUFA III, if a person and its affiliates own at least one but not more than five approved ANDAs on October 1, 2023, the person and its affiliates shall owe a small business generic drug applicant program fee.[14] If a person and its affiliates own at least 6 but not more than 19 approved ANDAs, the person and its affiliates shall owe a medium size operation generic drug applicant program fee.[15] If a person and its affiliates own at least 20 approved ANDAs, the person and its affiliates shall owe a large size operation generic drug applicant program fee.[16] Section 744B(b)(2)(E) of the FD&C Act specifies the GDUFA program fee will make up 36 percent of $613,538,000 in fee revenue, which is $220,873,680.

To determine the appropriate number of parent companies for each tier, FDA asked companies to claim their ANDAs and affiliates in the CDER NextGen Portal. The companies were able to confirm relationships currently present in FDA's records, while also reporting newly approved ANDAs, newly acquired ANDAs, and new affiliations.

In determining the appropriate number of approved ANDAs, FDA has factored in a number of variables that could affect the collection of the target revenue: (1) inactive ANDAs: applicants who have not submitted an annual report for one or more of their approved applications within the past 2 years; (2) Program Fee Arrears List: parent companies that are on the arrears list for any fiscal year; (3) Large and Medium Tier Adjustment: the frequency of large-tiered companies dropping to the medium tier and medium-tiered companies moving to the small tier after the completion of the program fee methodology and tier determination; (4) CBER-approved ANDAs: applicants and their affiliates with CBER-approved ANDAs in addition to CDER's approved ANDAs; and (5) withdrawals of approved ANDAs by April 1: applicants who have submitted a written request for withdrawal of approval by April 1 of the previous fiscal year.

The list of original approved ANDAs from the Generic Drug Review Platform as of April 30, 2023, in addition to CBER's database, shows 248 applicants in the small business tier, 71 applicants in the medium size tier, and 82 applicants in the large size tier. Factoring in all the variables, we estimate there will be 205 applicants in the small business tier, 68 applicants in the medium size tier, and 80 applicants in the large size tier for FY 2024.

To calculate the GDUFA program fee, GDUFA III provides that large size operation generic drug applicants pay the full fee, medium size operation applicants pay two-fifths of the full fee, and small business applicants pay one-tenth of the full fee.[17] To generate the target collection revenue amount from GDUFA program fees ($220,873,680), we must weigh medium and small tiered applicants as a subset of a large size operation generic drug applicant. FDA will set fees based on the weighted estimate of 20.5 applicants in the small business tier (205 multiplied by 10 percent), 27.2 applicants in the medium size tier (68 multiplied by 40 percent), and 80 applicants in the large size tier, arriving at 127.7 total weighted applicants for FY 2024.

To generate the large size operation GDUFA program fee, FDA divides the target revenue amount of $220,873,680 by 127.7, which equals $1,729,629. The medium size operation GDUFA program fee is 40 percent of the full fee ($691,852), and the small business GDUFA program fee is 10 percent of the full fee ($172,963).

IX. Fee Schedule For FY 2024

The fee rates for FY 2024 are set out in table 11.

TABLE 11—FEE SCHEDULE FOR FY 2024

Generic drug fee category	Fees rates for FY 2024
Applications	
Abbreviated New Drug Application (ANDA)	$252,453
Drug Master File (DMF)	94,682
Facilities	

[12] Section 744B(b)(2)(C) of the FD&C Act.

[13] Section 744B(a)(4)(A)(ii) of the FD&C Act.

[14] Sections 744B(a)(5)(A) and 744B(b)(2)(E)(i) of the FD&C Act.

[15] Id.

[16] Id.

[17] Section 744B(b)(2)(E)(i) of the FD&C Act.

TABLE 11—FEE SCHEDULE FOR FY 2024—Continued

Generic drug fee category	Fees rates for FY 2024
Active Pharmaceutical Ingredient (API)—Domestic	40,464
API—Foreign	55,464
Finished Dosage Form (FDF)—Domestic	220,427
FDF—Foreign	235,427
Contract Manufacturing Organization (CMO)—Domestic	52,902
CMO—Foreign	67,902
GDUFA Program	
Large size operation generic drug applicant	1,729,629
Medium size operation generic drug applicant	691,852
Small business generic drug applicant	172,963

X. Fee Payment Options and Procedures

The new fee rates are effective on October 1, 2023, and will remain in effect through September 30, 2024. Under sections 744B(a)(4) and (5) of the FD&C Act, respectively, facility and program fees are generally due on the later of the first business day on or after October 1 of each fiscal year or the first business day after the enactment of an appropriations act providing for the collection and obligation of GDUFA fees for the fiscal year.

To pay the ANDA, DMF, API facility, FDF facility, CMO facility, and GDUFA program fees, complete the Generic Drug User Fee Cover Sheet, available at *https://www.fda.gov/gdufa and https://userfees.fda.gov/OA_HTML/gdufaCAcdLogin.jsp,* and generate a user fee identification (ID) number. Payment must be made in U.S. currency drawn on a U.S. bank by electronic check, check, bank draft, U.S. postal money order, credit card, 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 utilize *Pay.gov,* a web-based payment application, for online electronic payment. The *Pay.gov* feature is available on the FDA website after completing the Generic 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 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 checks are to be sent by a courier that requests a street address, the courier can deliver checks 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. For questions concerning courier delivery, U.S. Bank can be contacted at 314–418–4013. This telephone number is only for questions about courier delivery.) The FDA post office box number (P.O. Box 979108) must be 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. If the payment amount is not applied, the invoice amount will be referred to collections. The originating financial institution may charge a wire transfer fee. 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, account number: 75060099, routing number: 021030004, SWIFT: FRNYUS33. FDA's tax identification number is 53–0196965.

Dated: July 25, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–2965]

Medical Device User Fee Rates for Fiscal Year 2024

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the fee rates and payment procedures for medical device user fees for fiscal year (FY) 2024. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Medical Device User Fee Amendments of 2022 (MDUFA V), authorizes FDA to collect user fees for certain medical device submissions and annual fees both for certain periodic reports and for establishments subject to registration. This notice establishes the fee rates for FY 2024, which apply from October 1, 2023, through September 30, 2024, and provides information on how the fees for FY 2024 were determined, the payment procedures you should follow, and how you may qualify for reduced small business fees.

FOR FURTHER INFORMATION CONTACT:

For information on Medical Device User Fees: https://www.fda.gov/industry/fda-user-fee-programs/medical-device-user-fee-amendments-mdufa.

For questions relating to the MDUFA Small Business Program, please visit the Center for Devices and Radiological Health's website: https://www.fda.gov/medical-devices/premarket-submissions/reduced-medical-device-user-fees-small-business-determination-sbd-program.

For questions relating to this notice: Olufunmilayo Ariyo, Office of Financial Management, Food and Drug Administration, 4041 Powder Mill Rd., Beltsville, MD 20705–4304, 240–402–4989; or the User Fee Support Staff at *OO-OFBAP-OFM-UFFS-Government@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The FD&C Act, as amended by MDUFA V, authorizes FDA to collect user fees for certain medical device submissions and annual fees both for certain periodic reports and for establishments subject to registration. Section 738 of the FD&C Act (21 U.S.C. 379j) establishes fees for certain medical device applications, submissions, supplements, notices, and requests (for