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.

TABLE 1—FEE SCHEDULE FOR FY 2025

Generic drug fee category	Fees rates for FY 2025
Applications:	
Abbreviated New Drug Application (ANDA)	$321,920
Drug Master File (DMF)	95,084
Facilities:	
Active Pharmaceutical Ingredient (API)—Domestic	41,580
API—Foreign	56,580
Finished Dosage Form (FDF)—Domestic	231,952
FDF—Foreign	246,952
Contract Manufacturing Organization (CMO)—Domestic	55,668
CMO—Foreign	70,668
GDUFA Program:	
Large size operation generic drug applicant	1,891,664
Medium size operation generic drug applicant	756,666
Small business generic drug applicant	189,166

II. Fee Revenue Amount for FY 2025

Under section 744B(b)(1)(B)(ii) of the FD&C Act, the base revenue amount for FY 2025 for GDUFA III is $613,538,015. 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, for FY 2025, 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, for FY 2025, 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 2025 is $613,538,015. This is the total revenue amount specified for the prior fiscal year, FY 2024, pursuant to the statute (see section 744B(b)(1)(A) of the FD&C Act).[1] GDUFA III specifies that the $613,538,015 is to be adjusted for inflation for FY 2025 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) positions 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 2025. The 3-year average is 3.8539 percent.

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

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

The statute specifies that this 3.8539 percent 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 2021 through FY 2023.

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

Fiscal year	2021	2022	2023	3-Year average
PC&B	$410,587,565	$391,922,747	$441,930,068	.....
Non-PC&B	$271,328,560	$289,479,265	$301,930,017	.....
Total Costs	$681,916,125	$681,402,012	$743,860,085	.....
PC&B Percent	60.2109%	57.5171%	59.4104%	59.0461%

[1] Under section 744B(b)(1)(B)(ii) of the FD&C Act, 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).

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

Fiscal year	2021	2022	2023	3-Year average
Non-PC&B Percent	39.7891%	42.4829%	40.5896%	40.9539%

The payroll adjustment is 3.8539 percent multiplied by 59.0461 percent (or 2.2756 percent).

The statute specifies that the portion of the inflation adjustment for non-PC&B costs for FY 2025 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	2021	2022	2023	3-Year average
Annual CPI	277.73	296.12	305.32	.....
Annual Percent Change	3.9568%	6.6212%	3.1069%	4.5616%

To calculate the inflation adjustment for non-pay costs, we multiply the 3-year average percent change in the CPI (4.5616 percent) by the proportion of all costs other than PC&B to total costs of human generic drug activities obligated. Because 59.0461 percent was obligated for PC&B as shown in table 3, 40.9539 percent is the portion of costs other than PC&B. The non-pay adjustment is 4.5616 percent times 40.9539 percent, or 1.8682 percent.

To complete the inflation adjustment for FY 2025, we add the PC&B component (2.2756 percent) to the non-PC&B component (1.8682 percent) for a total inflation adjustment of 4.1438 percent (rounded), and then add 1, making an inflation adjustment multiple of 1.041438. We then multiply the base revenue amount for FY 2025 ($613,538,015) by 1.041438, yielding an inflation-adjusted amount of $638,961,803.

B. FY 2025 Statutory Fee Revenue Adjustments for Capacity Planning

The statute specifies that after the base revenue amount for FY 2025 of $613,538,015 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] Improvements adopted for the FY2025 CPA include the incorporation of hiring plans and attrition estimates within the capacity calculation. In calculation of GDUFA fees for the prior fiscal year (FY 2024), the impacts of expected hiring on the review capacity of the program were considered within the managerial adjustment process (described below).

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. The current available resources for the direct review related workload are a measure of the percentage of time onboard staff report to direct review workload activities, plus a percentage of the additional positions that are targeted to be hired within the remainder of FY 2024.

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 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)

[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, 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.

for FY 2025 based on predictive models, as well as historical actuals from FY 2023 for comparison.

TABLE 5—CDER ACTUAL FY 2023 WORKLOAD VOLUMES AND PREDICTED FY 2025 WORKLOAD VOLUMES

Workload driver category	FY 2023 actuals	FY 2025 predictions
ANDA Originals [1]	685	651
ANDA Supplements [2]	10,237	12,045
Pre-ANDA Meetings	114	106
Controlled Correspondences [3]	3,580	3,156
Suitability Petitions	14	32
ANDA Annual Reports [4]	12,162	13,230
Active REMS Programs [4 5]	49	49

[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 (CBE) and prior approval supplement (PAS) 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] Data represents workload related to resource needs for post-marketing safety activities (developed in alignment with the methodology used in fee-setting under PDUFA (section 736 of the FD&C Act) (21 U.S.C. 379h) and BsUFA (section 744H of the FD&C Act) (21 U.S.C. 379j–52)), 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 2025 were then converted into estimated FTE needs for FDA's GDUFA direct review-related work. The resulting expected FY 2025 FTE need for GDUFA was compared to current onboard capacity for GDUFA direct review-related work. Based on this comparison, FDA determined that the GDUFA program had sufficient resources to perform expected workload. Therefore, no CPA is applicable for FY 2025 fee setting.

TABLE 6—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)	$613,538,015
Inflation Adjustment (section 744B(c)(1) of the FD&C Act)	25,423,788
Capacity Planning Adjustment (section 744B(c)(2) of the FD&C Act)	0
Revenue Amount after Adjustments in sections 744B(b)(1), 744B(c)(1), and 744B(c)(2) of the FD&C Act	638,961,803

C. FY 2025 Statutory Fee Revenue Adjustments for Operating Reserve

Under section 744B(c)(3) of the FD&C Act, for FY 2025, 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 2025, FDA may take an adjustment to provide for not more than 9 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 9-week and 12-week threshold amounts for the FY 2025 operating reserve adjustment, the FY 2025 adjusted revenue amount, $638,961,803 is divided by 52, resulting in a $12,287,727 cost of operation for 1 week. The 1-week value is then multiplied by 9 weeks to generate the 9-week operating reserve threshold amount for FY 2025 of $110,589,543. The 1-week value is multiplied by 12 to generate the 12-week operating reserve threshold amount for FY 2025 of $147,452,724.

To determine the FY 2024 end-of-year operating reserves of carryover user fees, the Agency assessed the operating reserve of carryover fees at the end of June 2024 and forecast collections and obligations in the fourth quarter of FY 2024 combined. This provides an estimated end-of-year FY 2024 operating reserve of carryover user fees of $110,920,103 which equates to 9.03 weeks of operations. As the estimated end-of-year FY 2024 operating reserve is within the thresholds, there will not be an operating reserve adjustment.

Table 7 below summarizes FY 2025 fee revenue.

TABLE 7—TOTAL ESTIMATED ADJUSTED REVENUE AMOUNT

Fee	Amount
Statutory Fee Revenue Base Amount (section 744B(b)(1) of the FD&C Act)	$613,538,015
Inflation Adjustment (section 744B(c)(1) of the FD&C Act)	25,423,788
Capacity Planning Adjustment (section 744B(c)(2) of the FD&C Act)	0
Operating Reserve Adjustment (section (744B(c)(3) of the FD&C Act)	0
Total Revenue Amount (sections 744B(b)(1), 744B(c)(1), 744B(c)(2) and 744B(c)(3) of the FD&C Act)	638,961,803

TABLE 7—TOTAL ESTIMATED ADJUSTED REVENUE AMOUNT—Continued

Fee	Amount
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) (rounded to the nearest thousand)	638,962,000

III. ANDA Filing Fee

Under GDUFA III, the FY 2025 ANDA filing fee is owed by each applicant that submits an ANDA on or after October 1, 2024.[5] 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 the $638,962,000, which is $210,857,460.

To calculate the ANDA fee, FDA estimated the number of full application equivalents (FAEs) that will be submitted in FY 2025. 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 651 new original ANDAs will be submitted and incur filing fees in FY 2025. Not all 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 655 for FY 2025.

The FY 2025 ANDA filing fee is estimated by dividing the number of FAEs that will incur the fee in FY 2025 (655) into the fee revenue amount to be derived from ANDA filing fees in FY 2025 ($210,857,460). The result, rounded to the nearest dollar, is a fee of $321,920 per ANDA.

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

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.[6] 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. FDA assessed DMFs from October 1, 2022, to April 30, 2024, and concluded that averaging the number of fee-paying DMFs provided the most accurate model for predicting fee-paying DMFs for FY 2025. The monthly average of paid DMF submissions FDA received during FY 2023 and FY 2024 is 28. To determine the FY 2025 projected number of fee-paying DMFs, the average of 28 DMF submissions is multiplied by 12 months, which results in 336 estimated FY 2025 fee-paying DMFs. FDA is estimating 336 fee-paying DMFs for FY 2025.

The FY 2025 DMF fee is determined by dividing the DMF target revenue by the estimated number of fee-paying DMFs in FY 2025. Section 744B(b)(2)(A) of the FD&C Act specifies that the DMF fees will make up 5 percent of the $638,962,000, which is $31,948,100. Dividing the DMF revenue amount ($31,948,100) by the estimated fee-paying DMFs (336), and rounding to the nearest dollar, yields a DMF fee of $95,084 for FY 2025.

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

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.[7] 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.[8] 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.[9] 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 $638,962,000, which is $127,792,400.

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. These findings were compared against facility statuses from FDA's Office Regulatory Affairs (ORA) to exclude facilities that are no longer operational.

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

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

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

Based on these data, the FDF and CMO facility denominators are 160 FDF domestic, 311 FDF foreign, 83 CMO domestic, and 131 CMO foreign facilities for FY 2025.

GDUFA III specifies that the CMO facility fee is to be equal to 24 percent of the FDF facility fee.[10] Therefore, to generate the target collection revenue amount from FDF and CMO facility fees ($127,792,400), FDA must weight a CMO facility as 24 percent of an FDF facility. FDA set fees based on the estimate of 160 FDF domestic, 311 FDF foreign, 19.92 CMO domestic (83 multiplied by 24 percent), and 31.44 CMO foreign facilities (131 multiplied by 24 percent), which equals 522.36 total weighted FDF and CMO facilities for FY 2025.

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 ($127,792,400) as follows: the foreign facility fee differential revenue equals the foreign facility fee differential ($15,000) multiplied by the number of FDF foreign facilities (311) plus the foreign facility fee differential ($15,000) multiplied by the number of CMO foreign facilities (131), totaling $6,630,000. This results in foreign fee differential revenue of $6,630,000 from the total FDF and CMO facility fee target collection revenue.

Subtracting the foreign facility differential fee revenue ($6,630,000) from the total FDF and CMO facility target collection revenue ($127,792,400) results in a remaining facility fee revenue balance of $121,162,400. To determine the domestic FDF facility fee, FDA divides the $121,162,400 by the total weighted number of FDF and CMO facilities (522.36), which results in a domestic FDF facility fee of $231,952. The foreign FDF facility fee is $15,000 more than the domestic FDF facility fee, or $246,952.

According to GDUFA III, the domestic CMO fee is calculated as 24 percent of the amount of the domestic FDF facility fee.[11] Therefore, the domestic CMO fee is $55,668, 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 $70,668.

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

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

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.[12] Section 744B(b)(2)(D) of the FD&C Act specifies the API facility fee will make up 6 percent of $638,962,000 in fee revenue, which is $38,337,720.

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. These findings were compared against facility statuses from FDA's ORA to exclude facilities that are no longer operational.

Based on these data, the total number of API facilities identified was 698; of that number, 77 were domestic and 621 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 (621) 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 $9,315,000 of the total API fee revenue. Subtracting the foreign facility differential fee revenue ($9,315,000) from the total API facility target revenue ($38,337,720) results in a remaining balance of $29,022,720. To determine the domestic API facility fee, we divide the $29,022,720 by the total number of facilities (698), which gives us a domestic API facility fee of $41,580. The foreign API facility fee is $15,000 more than the domestic API facility fee, or $56,580.

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, 2024, the person and its affiliates shall owe a small business generic drug applicant program fee.[13] 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.[14] 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.[15] Section 744B(b)(2)(E) of the FD&C Act specifies the GDUFA program fee will make up 36 percent of $638,962,000 in fee revenue, which is $230,026,320.

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) 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;[16] (2) inactive ANDAs: applicants who have not submitted an annual report for one or more of their approved applications within the past 2 years; (3) CBER-approved ANDAs: applicants and their affiliates with CBER-approved ANDAs are added to CDER's population of approved ANDAs; (4) Program Fee Arrears List: parent companies that are on the arrears list for any fiscal year; (5) Out of Business companies: parent companies that are no longer in operation; and (6) Tier Adjustment: the frequency of large-tier, medium-tier, and small-tier companies moving to different tiers (or as applicable, dropping out of any tier) after the completion of the program fee methodology and tier determination.

The list of original approved ANDAs from the Generic Drug Review Platform as of April 30, 2024, in addition to CBER's database, shows 241 applicants in the small business tier, 74 applicants in the medium size tier, and 81 applicants in the large size tier. Factoring in all the variables, we estimate there will be 194 applicants in

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

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

[14] Id.

[15] Id.

[16] See section 744B(b)(2)(E)(ii) of the FD&C Act.

the small business tier, 68 applicants in the medium size tier, and 75 applicants in the large size tier for FY 2025.

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 ($230,026,320), 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 19.40 applicants in the small business tier (194 multiplied by 10 percent), 27.2 applicants in the medium size tier (68 multiplied by 40 percent), and 75 applicants in the large size tier, arriving at 121.60 total weighted applicants for FY 2025.

To generate the large size operation GDUFA program fee, FDA divides the target revenue amount of $230,026,320 by 121.60, which equals $1,891,664. The medium size operation GDUFA program fee is 40 percent of the full fee ($756,666), and the small business GDUFA program fee is 10 percent of the full fee ($189,166).

IX. Fee Schedule for FY 2025

The fee rates for FY 2025 are set out in table 8.

TABLE 8—FEE SCHEDULE FOR FY 2025

Generic drug fee category	Fees rates for FY 2025
Applications:	
Abbreviated New Drug Application (ANDA)	$321,920
Drug Master File (DMF)	95,084
Facilities:	
Active Pharmaceutical Ingredient (API)—Domestic	41,580
API—Foreign	56,580
Finished Dosage Form (FDF)—Domestic	231,952
FDF—Foreign	246,952
Contract Manufacturing Organization (CMO)—Domestic	55,668
CMO—Foreign	70,668
GDUFA Program:	
Large size operation generic drug applicant	1,891,664
Medium size operation generic drug applicant	756,666
Small business generic drug applicant	189,166

X. Fee Payment Options and Procedures

The new fee rates are effective on October 1, 2024, and will remain in effect through September 30, 2025. 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, 3180 Rider Trail S, Earth City, MO 63045. (*Note:* This U.S. Bank address is for courier delivery only). For questions concerning courier delivery, U.S. Bank can be contacted at 800–495–4981. 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:

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

FRNYUS33. FDA's tax identification number is 53–0196965.

Dated: July 26, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–16896 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–2865]

Agency Information Collection Activities; Proposed Collection; Comment Request; Generic Clearance for Quantitative Testing for the Development of Food and Drug Administration Communications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on generic clearance for quantitative testing for the development of FDA communications, which collects individual generic quantitative information (*e.g.,* surveys, experimental studies) to test communications or educational messages on FDA-regulated food and cosmetic products, dietary supplements, and animal food and feed while they are being developed or are in review.

DATES: Either electronic or written comments on the collection of information must be submitted by September 30, 2024.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 30, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2024–N–2865 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Generic Clearance for Quantitative Testing for the Development of Food and Drug Administration Communications.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an