maintaining the Committee is no longer justified. This Committee is therefore terminated, effective on July 30, 2025, in accordance with 21 CFR 14.55. This notice is issued under the Federal Advisory Committee Act of October 6, 1972 (Pub. L. 92–463) (5 U.S.C. 1001 *et seq.*). Elsewhere in this issue of the **Federal Register,** FDA is publishing a final rule announcing the removal of the Arthritis Advisory Committee from the Agency's list of standing advisory committees.

Dated: July 25, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–14345 Filed 7–29–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–2248]

Generic Drug User Fee Rates for Fiscal Year 2026

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) 2026 rates for GDUFA III fees.

DATES: These fees are effective on October 1, 2025, and will remain in effect through September 30, 2026.

FOR FURTHER INFORMATION CONTACT: For more information on human generic drug fees, visit FDA's website at: *https://www.fda.gov/industry/fda-user-fee-programs/generic-drug-user-fee-amendments. For questions relating to this notice:* Olufunmilayo Ariyo, Office of Financial Management, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20903, 240–402–4989; or the User Fees Support Staff at *UFSS@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 2026, the generic drug user fee rates are ANDA ($358,247), DMF ($102,584), domestic API facility ($43,549), foreign API facility ($58,549), domestic FDF facility ($238,943), foreign FDF facility ($253,943), domestic CMO facility ($57,346), foreign CMO facility ($72,346), large size operation generic drug applicant program ($1,918,377), medium size operation generic drug applicant program ($767,351), and small business generic drug applicant program ($191,838). These fees are effective on October 1, 2025, and will remain in effect through September 30, 2026. The fee rates for FY 2026 are set out in table 1.

TABLE 1—FEE SCHEDULE FOR FY 2026

Fee category	Fee rates for FY 2026
Applications:	
Abbreviated New Drug Application (ANDA)	$358,247
Drug Master File (DMF)	102,584
Facilities:	
Active Pharmaceutical Ingredient (API)—Domestic	43,549
API—Foreign	58,549
Finished Dosage Form (FDF)—Domestic	238,943
FDF—Foreign	253,943
Contract Manufacturing Organization (CMO)—Domestic	57,346
CMO—Foreign	72,346
GDUFA Program:	
Large size operation generic drug applicant	1,918,377
Medium size operation generic drug applicant	767,351
Small business generic drug applicant	191,838

II. Fee Revenue Amount for FY 2026

Under section 744B(b)(1)(B)(ii) of the FD&C Act, the base revenue amount for FY 2026 for GDUFA III is $638,961,803. 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 2026, 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 2026, 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 2026 is $638,961,803. This is the total revenue amount specified for the prior fiscal year, FY

2025, pursuant to the statute (see section 744B(b)(1)(A) of the FD&C Act).[1] GDUFA III specifies that the $638,961,803 is to be adjusted for inflation for FY 2026 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 2026. The 3-year average is 5.4494 percent.

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

Fiscal year	2022	2023	2024	3-Year average
Total PC&B	$3,165,477,000	$3,436,513,000	$3,791,729,000	
Total FTEs	18,474	18,729	19,687	
PC&B per FTE	$171,348	$183,486	$192,601	
Percent Change from Previous Year	4.2967%	7.0838%	4.9677%	5.4494%

The statute specifies that this 5.4494 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 2022 through FY 2024.

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

Fiscal year	2022	2023	2024	3-Year average
PC&B	$391,922,747	$441,930,068	$479,495,256	
Non-PC&B	$289,479,265	$301,930,017	$278,861,828	
Total Costs	$681,402,012	$743,860,085	$758,357,084	
PC&B Percent	57.5171%	59.4104%	63.2282%	60.0519%
Non-PC&B Percent	42.4829%	40.5896%	36.7718%	39.9481%

The payroll adjustment is 5.4494 percent multiplied by 60.0519 percent (or 3.2725 percent).

The statute specifies that the portion of the inflation adjustment for non-PC&B costs for FY 2026 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.[2]

TABLE 4—ANNUAL AND 3-YEAR AVERAGE PERCENT CHANGE IN CPI FOR WASHINGTON-ARLINGTON-ALEXANDRIA AREA

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

To calculate the inflation adjustment for non-pay costs, we multiply the 3-year average percent change in the CPI (4.3202 percent) by the proportion of all costs other than PC&B to total costs of human generic drug activities obligated. Because 60.0519 percent was obligated for PC&B as shown in table 3, 39.9481 percent is the portion of costs other than PC&B. The non-pay adjustment is 4.3202 percent times 39.9481 percent, or 1.7258 percent.

To complete the inflation adjustment for FY 2026, we add the PC&B component (3.2725 percent) to the non-PC&B component (1.7258 percent) for a total inflation adjustment of 4.9983 percent (rounded), and then add 1, making an inflation adjustment multiple of 1.049983. We then multiply the base revenue amount for FY 2026 ($638,961,803) by 1.049983, yielding an inflation-adjusted amount of $670,899,031.

B. FY 2026 Statutory Fee Revenue Adjustments for Capacity Planning

The statute specifies that after the base revenue amount for FY 2026 of $638,961,803 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

[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).

[2] The data are published by the Bureau of Labor Statistics and can be found on its website at: *https://data.bls.gov/pdq/SurveyOutputServlet?data_tool=dropmap&series_id=CUURS35ASA0, CUUSS35ASA0.*

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).[3] 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.[4]

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

3. *A managerial adjustment to assess the resource forecast in the context of additional internal factors:* program leadership examines operational, financial, and resourcing data to assess whether FDA will be able to utilize additional funds during the 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 2026 based on predictive models, as well as historical actuals from FY 2024 for comparison.

TABLE 5—CDER ACTUAL FY 2024 WORKLOAD VOLUMES AND PREDICTED FY 2026 WORKLOAD VOLUMES

Workload driver category	FY 2024 actuals	FY 2026 predictions
ANDA Originals[1]	713	618
ANDA Supplements[2]	11,807	11,699
Pre-ANDA Meetings	95	91
Controlled Correspondences[3]	3,277	3,092
Suitability Petitions	111	52
ANDA Annual Reports[4]	13,395	14,499
Active REMS Programs[4 5]	53	53

[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.

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

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)	$638,961,803
Inflation Adjustment (section 744B(c)(1) of the FD&C Act)	31,937,228
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	670,899,031

C. FY 2026 Statutory Fee Revenue Adjustments for Operating Reserve

Under section 744B(c)(3) of the FD&C Act, for FY 2026, 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 2026, FDA may take an adjustment to provide for not more than 10 weeks of operating reserve. If carryover is more than 12 weeks of operating reserve, FDA

[3] 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*.

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

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

must decrease the fee revenues and fees to provide for not more than 12 weeks of operating reserve. To calculate the 10-week and 12-week threshold amounts for the FY 2026 operating reserve adjustment, the FY 2026 adjusted revenue amount, $670,899,031 is divided by 52, resulting in a $12,901,904 cost of operation for 1 week. The 1-week value is then multiplied by 10 weeks to generate the 10-week operating reserve threshold amount for FY 2026 of $129,019,040. The 1-week value is multiplied by 12 to generate the 12-week operating reserve threshold amount for FY 2026 of $154,822,848.

To determine the FY 2025 end-of-year operating reserves of carryover user fees, the Agency assessed the operating reserve of carryover user fees at the end of June 2025 and forecast collections and obligations in the fourth quarter of FY 2025 combined. This provides an estimated end-of-year FY 2025 operating reserve of carryover user fees of $126,429,724 which equates to 9.80 weeks of operations. As the estimated end-of-year FY 2025 operating reserve of carryover user fees is just below the 10-week discretionary increase threshold, there will not be an operating reserve adjustment.

Table 7 below summarizes FY 2026 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)	$638,961,803
Inflation Adjustment (section 744B(c)(1) of the FD&C Act)	31,937,228
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)	670,899,031
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)	670,899,000

III. ANDA Filing Fee

Under GDUFA III, the FY 2026 ANDA filing fee is owed by each applicant that submits an ANDA on or after October 1, 2025.[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 the $670,899,000, which is $221,396,670.

To calculate the ANDA fee, FDA estimated the number of full application equivalents (FAEs) that will be submitted in FY 2026. 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 618 new original ANDAs will be submitted and incur filing fees in FY 2026. 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. After accounting for these factors, FDA expects that the FAE count for ANDAs will be 617.66, rounded to 618 for FY 2026.

The FY 2026 ANDA filing fee is estimated by dividing the number of FAEs that will incur the fee in FY 2026 (618) into the fee revenue amount to be derived from ANDA filing fees in FY 2026 ($221,396,670). The result, rounded to the nearest dollar, is a fee of $358,247 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. FDA assessed DMFs from October 1, 2022, to April 30, 2025, and concluded that averaging the number of fee-paying DMFs provided the most accurate model for predicting fee-paying DMFs for FY 2026. The monthly average of paid DMF submissions FDA received from FY 2023 through April 2025 is 27.3. To determine the FY 2026 projected number of fee-paying DMFs, the average of 27.3 DMF submissions is multiplied by 12 months, which results in 327 estimated FY 2026 fee-paying DMFs. FDA is estimating 327 fee-paying DMFs for FY 2026.

The FY 2026 DMF fee is determined by dividing the DMF target revenue by the estimated number of fee-paying DMFs in FY 2026. Section 744B(b)(2)(A) of the FD&C Act specifies that the DMF fees will make up 5 percent of the $670,899,000, which is $33,544,950. Dividing the DMF revenue amount

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

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

($33,544,950) by the estimated fee-paying DMFs (327), and rounding to the nearest dollar, yields a DMF fee of $102,584 for FY 2026.

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 $670,899,000, which is $134,179,800.

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 of Inspections and Investigations (OII) to exclude facilities that are no longer operational.

Based on these data, the FDF and CMO facility denominators are 153 FDF domestic, 325 FDF foreign, 84 CMO domestic, and 142 CMO foreign facilities for FY 2026.

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 ($134,179,800), FDA must weight a CMO facility as 24 percent of an FDF facility. FDA set fees based on the estimate of 153 FDF domestic, 325 FDF foreign, 20.16 CMO domestic (84 multiplied by 24 percent), and 34.08 CMO foreign facilities (142 multiplied by 24 percent), which equals 532.24 total weighted FDF and CMO facilities for FY 2026.

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 ($134,179,800) as follows: the foreign facility fee differential revenue equals the foreign facility fee differential ($15,000) multiplied by the number of FDF foreign facilities (325) plus the foreign facility fee differential ($15,000) multiplied by the number of CMO foreign facilities (142), totaling $7,005,000. This results in foreign fee differential revenue of $7,005,000 from the total FDF and CMO facility fee target collection revenue.

Subtracting the foreign facility differential fee revenue ($7,005,000) from the total FDF and CMO facility target collection revenue ($134,179,800) results in a remaining facility fee revenue balance of $127,174,800. To determine the domestic FDF facility fee, FDA divides the $127,174,800 by the total weighted number of FDF and CMO facilities (532.24), which results in a domestic FDF facility fee of $238,943. The foreign FDF facility fee is $15,000 more than the domestic FDF facility fee, or $253,943.

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 $57,346, 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 $72,346.

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 $670,899,000 in fee revenue, which is $40,253,940.

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 OII to exclude facilities that are no longer operational.

Based on these data, the total number of API facilities identified was 707; of that number, 76 were domestic and 631 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 (631) 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 $9,465,000 of the total API fee revenue. Subtracting the foreign facility differential fee revenue ($9,465,000) from the total API facility target revenue ($40,253,940) results in a remaining balance of $30,788,940. To determine the domestic API facility fee, we divide the $30,788,940 by the total number of facilities (707), which gives us a domestic API facility fee of $43,549. The foreign API facility fee is $15,000 more than the domestic API facility fee, or $58,549.

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, 2025, 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

[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.

[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.

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 $670,899,000 in fee revenue, which is $241,523,640.

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;[17] (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, 2025, in addition to CBER's database, shows 259 applicants in the small business tier, 63 applicants in the medium size tier, and 88 applicants in the large size tier. Factoring in all the variables, we estimate there will be 221 applicants in the small business tier, 57 applicants in the medium size tier, and 81 applicants in the large size tier for FY 2026.

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.[18] To generate the target collection revenue amount from GDUFA program fees ($241,523,640), 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 22.1 applicants in the small business tier (221 multiplied by 10 percent), 22.8 applicants in the medium size tier (57 multiplied by 40 percent), and 81 applicants in the large size tier, arriving at 125.9 total weighted applicants for FY 2026.

To generate the large size operation GDUFA program fee, FDA divides the target revenue amount of $241,523,640 by 125.9, which equals $1,918,377. The medium size operation GDUFA program fee is 40 percent of the full fee ($767,351), and the small business GDUFA program fee is 10 percent of the full fee ($191,838).

IX. Fee Schedule for FY 2026

The fee rates for FY 2026 are displayed in table 8.

TABLE 8—FEE SCHEDULE FOR FY 2026

Fee category	Fee rates for FY 2026
Applications:	
Abbreviated New Drug Application (ANDA)	$358,247
Drug Master File (DMF)	102,584
Facilities:	
Active Pharmaceutical Ingredient (API)—Domestic	43,549
API—Foreign	58,549
Finished Dosage Form (FDF)—Domestic	238,943
FDF—Foreign	253,943
Contract Manufacturing Organization (CMO)—Domestic	57,346
CMO—Foreign	72,346
GDUFA Program:	
Large size operation generic drug applicant	1,918,377
Medium size operation generic drug applicant	767,351
Small business generic drug applicant	191,838

X. Fee Payment Options and Procedures

The new fee rates are effective on October 1, 2025, and will remain in effect through September 30, 2026. 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, credit card, or wire transfer.[19] 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;

[16] Id.

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

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

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

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.

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, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–14411 Filed 7–29–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–2488]

Animal Drug User Fee Rates and Payment Procedures for Fiscal Year 2026

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the fee rates and payment procedures for fiscal year (FY) 2026 animal drug user fees. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Animal Drug User Fee Amendments of 2023 (ADUFA V), authorizes FDA to collect user fees for certain animal drug applications and supplemental animal drug applications, for certain animal drug products, for certain establishments where such products are made, and for certain sponsors of such animal drug applications and/or investigational animal drug submissions. This notice establishes the fee rates for FY 2026.

DATES: The application fee rates apply to applications submitted on or after October 1, 2025, and will remain in effect through September 30, 2026.

FOR FURTHER INFORMATION CONTACT: Visit FDA's website at: *https://www.fda.gov/industry/fda-user-fee-programs/animal-drug-user-fee-act-adufa.* For general questions, you may also email FDA's Center for Veterinary Medicine (CVM) at: *cvmadufa@fda.hhs.gov. For questions relating to this notice:* UFFS, Office of Financial Management, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993; or email the User Fee Support Staff at *UFSS@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 740(a) of the FD&C Act (21 U.S.C. 379j–12), as amended by ADUFA V, establishes four different types of user fees: (1) fees for certain animal drug applications and supplemental animal drug applications; (2) annual fees for certain animal drug products; (3) annual fees for certain establishments where such products are made; and (4) annual fees for certain sponsors of animal drug applications and/or investigational animal drug submissions. When certain conditions are met, FDA will waive or reduce fees per section 740(d) of the FD&C Act.

For FYs 2024 through 2028, section 740(b)(1) of the FD&C Act establishes the base revenue amount for each fiscal year. Per section 740(c)(2) and (3) of the FD&C Act, the base revenue amounts established for fiscal years after FY 2024 are subject to adjustment for inflation and workload. Beginning in FY 2025, the annual fee revenue amount is also subject to an operating reserve adjustment to allow FDA to adjust the fee revenue amount to maintain a specified operating reserve of carryover user fees, per section 740(c)(4) of the FD&C Act. FDA may increase the fee revenue amount to maintain a 12-week minimum. If FDA has an excess operating reserve, FDA will decrease the fee revenue amount so that FDA has 22 weeks of operating reserve for FY 2025, 20 weeks for FY 2026, 18 weeks for FY 2027, and 16 weeks for FY 2028.

Per section 740(b)(2) of the FD&C Act, fees for applications, establishments, products, and sponsors are to be established each year by FDA so that the percentages of the total revenue that are derived from each type of user fee will be as follows: (1) revenue from application fees shall be 20 percent of total fee revenue; (2) revenue from product fees shall be 27 percent of total fee revenue; (3) revenue from establishment fees shall be 26 percent of total fee revenue; and (4) revenue from sponsor fees shall be 27 percent of total fee revenue. The target revenue amounts for each fee category for FY 2026 are as follows: for application fees, the target revenue amount is $7,230,400; for product fees, the target revenue amount is $9,761,040; for establishment fees, the target revenue amount is $9,399,520; and for sponsor fees, the target revenue amount is $9,761,010.

For FY 2026, the animal drug user fee rates are: (1) $708,863 for an animal drug application; (2) $354,431 for a supplemental animal drug application for which safety or effectiveness data are required, for an animal drug application subject to the criteria set forth in section 512(d)(4) of the FD&C Act (21 U.S.C. 360b), and for an application for conditional approval under section 571 of the FD&C Act (21 U.S.C. 360ccc) for which an animal drug application submitted under section 512(b)(1) of the FD&C Act has been previously approved under section 512(d)(1) of the FD&C Act for another intended use; (3) $13,463 for the annual product fee; (4) $200,000 for the annual establishment fee; and (5) $165,441 for the annual sponsor fee. FDA will issue invoices for FY 2026 product, establishment, and sponsor fees by December 31, 2025, and payment will be due by January 31, 2026. The application fee rates are effective for applications submitted on or after October 1, 2025, and will remain in effect through September 30, 2026. Applications will not be accepted for review until FDA has received full payment of application fees and any other animal drug user fees owed under the ADUFA program.

II. Fee Revenue Amount for FY 2026

A. Statutory Fee Revenue Amounts

Section 740(b)(1) of the FD&C Act specifies that the base fee revenue amount for FY 2026 for all animal drug user fee categories totals $33,500,000.

B. Inflation Adjustment to Fee Revenue Amount

Section 740(c)(2)(A)(ii) and (iii) of the FD&C Act specifies that the annual fee revenue amount is to be adjusted for inflation increases for FY 2025 and subsequent fiscal years using two separate adjustments: one for personnel compensation and benefits (PC&B) and one for non-PC&B costs. Section 740(c)(2)(A)(ii) of the FD&C Act