drug or JINAD file submission. Once you are satisfied that the data on the cover sheet is accurate and you have finalized the cover sheet, you will be able to transmit it electronically to FDA and you will be able to print a copy of your cover sheet showing your unique PIN.

Step Three: Send the payment for your application or JINAD file submission as described in section VIII.A.

Step Four: Submit your application or JINAD file submission.

C. Product and Sponsor Fees

By December 31, 2026, FDA will issue invoices and payment instructions for product and sponsor fees for FY 2027 using this fee schedule. Payment will be due by January 31, 2027. FDA will issue invoices in November 2027 for any products and sponsors subject to fees for FY 2027 that qualify for fees after the December 2026 billing.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–7398]

Generic Drug User Fee Rates for Fiscal Year 2027

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) 2027 rates for GDUFA III fees.

DATES: These fees are effective on October 1, 2026, and will remain in effect through September 30, 2027.

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, 301–796–7900; or *FDAUserFees@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 2027, the generic drug user fee rates are ANDA ($375,684), DMF ($109,899), domestic API facility ($39,680), foreign API facility ($54,680), domestic FDF facility ($230,033), foreign FDF facility ($245,033), domestic CMO facility ($55,208), foreign CMO facility ($70,208), large size operation generic drug applicant program ($1,927,291), medium size operation generic drug applicant program ($770,916), and small business generic drug applicant program ($192,729). These fees are effective on October 1, 2026, and will remain in effect through September 30, 2027. The fee rates for FY 2027 are set out in table 1.

TABLE 1—FEE SCHEDULE FOR FY 2027

Fee category	Fee rates for FY 2027
Applications:	
Abbreviated New Drug Application (ANDA)	$375,684
Drug Master File (DMF)	109,899
Facilities:	
Active Pharmaceutical Ingredient (API)—Domestic	39,680
API—Foreign	54,680
Finished Dosage Form (FDF)—Domestic	230,033
FDF—Foreign	245,033
Contract Manufacturing Organization (CMO)—Domestic	55,208
CMO—Foreign	70,208
GDUFA Program:	
Large size operation generic drug applicant	1,927,291
Medium size operation generic drug applicant	770,916
Small business generic drug applicant	192,729

II. Fee Revenue Amount for FY 2027

Under section 744B(b)(1)(B)(ii) of the FD&C Act, the base revenue amount for FY 2027 for GDUFA III is $670,899,031. 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 2027, 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 2027, 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 10 weeks (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 2027 is $670,899,031. This is the total revenue amount specified for the prior fiscal year, FY 2026, pursuant to the statute (see section 744B(b)(1)(B) of the FD&C Act).[1] GDUFA III specifies that the $670,899,031 is to be adjusted for inflation for FY 2027 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)[2] 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 2027. The 3-year average is 5.7330 percent.

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

Fiscal year	2023	2024	2025	3-Year average
Total PC&B	$3,436,513,000	$3,791,729,000	$3,875,940,000	
Total FTEs	18,729	19,687	19,139	
PC&B per FTE	$183,486	$192,601	$202,515	
Percent Change from Previous Year	7.0838%	4.9677%	5.1474%	5.7330%

The statute specifies that this 5.7330 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 2023 through FY 2025.

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

Fiscal year	2023	2024	2025	3-Year average
PC&B	$441,930,068	$479,495,256	$485,081,368	
Non-PC&B	$301,930,017	$278,861,828	$248,716,445	
Total Costs	$743,860,085	$758,357,084	$733,797,813	
PC&B Percent	59.4104%	63.2282%	66.1056%	62.9147%
Non-PC&B Percent	40.5896%	36.7718%	33.8944%	37.0853%

The payroll adjustment is 5.7330 percent multiplied by 62.9147 percent (or 3.6069 percent).

The statute specifies that the portion of the inflation adjustment for non-PC&B costs for FY 2027 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.[3]

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

Year	2023	2024	2025	3-Year average
Annual CPI	305.317	315.186	321.993	
Annual Percent Change	3.1069%	3.2324%	2.1597%	2.8330%

To calculate the inflation adjustment for non-pay costs, we multiply the 3-year average percent change in the CPI (2.8330 percent) by the proportion of all costs other than PC&B to total costs of human generic drug activities obligated. Because 62.9147 percent was obligated for PC&B as shown in table 3, 37.0853 percent is the portion of costs other than PC&B. The non-pay adjustment is 2.8330 percent times 37.0853 percent, or 1.0506 percent.

To complete the inflation adjustment for FY 2027, we add the PC&B component (3.6069 percent) to the non-PC&B component (1.0506 percent) for a total inflation adjustment of 4.6575 percent (rounded), and then add 1,

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

[3] 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.*

making an inflation adjustment multiple of 1.046575. We then multiply the base revenue amount for FY 2027 ($670,899,031) by 1.046575, yielding an inflation-adjusted amount of $702,146,153.

B. FY 2027 Statutory Fee Revenue Adjustments for Capacity Planning

The statute specifies that after the base revenue amount for FY 2027 of $670,899,031 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).[4] This methodology includes a continuous, iterative improvement approach, under which the Agency intends to refine its data and estimates for the core review activities to improve their accuracy over time.

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 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 such 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 2027 based on predictive models, as well as historical actuals from FY 2025 for comparison.

TABLE 5—CDER ACTUAL FY 2025 WORKLOAD VOLUMES AND PREDICTED FY 2027 WORKLOAD VOLUMES

Workload driver category	FY 2025 actuals	FY 2027 predictions
ANDA Originals [1]	580	586
ANDA Supplements [2]	11,383	11,916
Pre-ANDA Meetings	114	106
Controlled Correspondences [3]	3,722	3,655
Suitability Petitions	95	100
ANDA Annual Reports [4]	14,223	14,655
Active REMS Programs [4 5]	52	52

[1] Excludes response to refused to receive (RTR) and Orig-2+. ANDA Original and Resubmissions/Amendments captured in time reporting data. The prediction consists of 122.3 complex ANDAs and 463.5 non-complex ANDAs.

[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 2027 collections amount without further adjustment from the CPA. As such, FDA determined that in FY 2027 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)	$670,899,031
Inflation Adjustment (section 744B(c)(1) of the FD&C Act)	31,247,122
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	702,146,153

[4] 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*.

C. FY 2027 Statutory Fee Revenue Adjustments for Operating Reserve

Under section 744B(c)(3) of the FD&C Act, for FY 2027, 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 2027, 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 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 2027 operating reserve adjustment, the FY 2027 adjusted revenue amount, $702,146,153 is divided by 52, resulting in a $13,502,811 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 2027 of $135,028,106. The 1-week value is multiplied by 12 to generate the 12-week operating reserve threshold amount for FY 2027 of $162,033,728.

To determine the FY 2026 end-of-year operating reserves of carryover user fees, the Agency assessed the operating reserve of carryover user fees at the end of June 2026 and forecast collections and obligations in the fourth quarter of FY 2026 combined. This provides an estimated end-of-year FY 2026 operating reserve of carryover user fees of $198,194,080 which equates to 14.68 weeks of operations. As the estimated end-of-year FY 2026 operating reserve of carryover user fees exceeds the 12-week threshold of $162,033,728, FDA will apply an operating reserve adjustment of -$36,160,352 to reduce the FY 2027 fee revenue and fees under the statutory provision for operating reserve adjustments.

Table 7 below summarizes FY 2027 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)	$670,899,031
Inflation Adjustment (section 744B(c)(1) of the FD&C Act)	31,247,122
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)	−36,160,352
Total Revenue Amount (sections 744B(b)(1), 744B(c)(1), 744B(c)(2) and 744B(c)(3) of the FD&C Act)	665,985,801
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)	665,986,000

III. ANDA Filing Fee

Under GDUFA III, the FY 2027 ANDA filing fee is owed by each applicant that submits an ANDA on or after October 1, 2026.[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 $665,986,000, which is $219,775,380.

To calculate the ANDA fee, FDA estimated the number of full application equivalents (FAEs) that will be submitted in FY 2027. 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 586 new original ANDAs will be submitted and incur filing fees in FY 2027. 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 585.28, rounded to 585 for FY 2027.

The FY 2027 ANDA filing fee is estimated by dividing the number of FAEs that will incur the fee in FY 2027 (585) into the fee revenue amount to be derived from ANDA filing fees in FY 2027 ($219,775,380). The result, rounded to the nearest dollar, is a fee of $375,684 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, subject to certain conditions (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.

[5] Section 744B(a)(3) of the FD&C Act. The FY 2027 ANDA filing fee is owed for each ANDA submitted during FY 2027.

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

To calculate the DMF fee, FDA assessed the volume of DMF submissions over time. FDA assessed DMFs from October 1, 2023, to April 30, 2026, and concluded that averaging the number of fee-paying DMFs provided the most accurate model for predicting fee-paying DMFs for FY 2027. The monthly average of paid DMF submissions FDA received from FY 2024 through April 2026 is 25.23. To determine the FY 2027 projected number of fee-paying DMFs, the average of 25.23 DMF submissions is multiplied by 12 months, which results in 303 estimated FY 2027 fee-paying DMFs. FDA is estimating 303 fee-paying DMFs for FY 2027.

The FY 2027 DMF fee is determined by dividing the DMF target revenue by the estimated number of fee-paying DMFs in FY 2027. Section 744B(b)(2)(A) of the FD&C Act specifies that the DMF fees will make up 5 percent of the $665,986,000, which is $33,299,300. Dividing the DMF revenue amount ($33,299,300) by the estimated fee-paying DMFs (303), and rounding to the nearest dollar, yields a DMF fee of $109,899 for FY 2027.

V. Foreign Facility Fee Differential

Under GDUFA III, the annual fee (as discussed below) for a generic drug or API 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 $665,986,000, which is $133,197,200.

To calculate the fees, data from FDA's Integrity Services were utilized as the primary source of facility information for determining the denominators of each facility fee type. Integrity Services 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 156 FDF domestic, 332 FDF foreign, 92 CMO domestic, and 155 CMO foreign facilities for FY 2027.

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 ($133,197,200), FDA must weight a CMO facility as 24 percent of an FDF facility. FDA set fees based on the estimate of 156 FDF domestic, 332 FDF foreign, 22.08 CMO domestic (92 multiplied by 24 percent), and 37.20 CMO foreign facilities (155 multiplied by 24 percent), which equals 547.28 total weighted FDF and CMO facilities for FY 2027.

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 ($133,197,200) as follows: the foreign facility fee differential revenue equals the foreign facility fee differential ($15,000) multiplied by the number of FDF foreign facilities (332) plus the foreign facility fee differential ($15,000) multiplied by the number of CMO foreign facilities (155), totaling $7,305,000. This results in foreign fee differential revenue of $7,305,000 from the total FDF and CMO facility fee target collection revenue.

Subtracting the foreign facility differential fee revenue ($7,305,000) from the total FDF and CMO facility target collection revenue ($133,197,200) results in a remaining facility fee revenue balance of $125,892,200. To determine the domestic FDF facility fee, FDA divides the $125,892,200 by the total weighted number of FDF and CMO facilities (547.28), which results in a domestic FDF facility fee of $230,033. The foreign FDF facility fee is $15,000 more than the domestic FDF facility fee, or $245,033.

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 $55,208, 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 $70,208.

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 $665,986,000 in fee revenue, which is $39,959,160.

To calculate the API facility fee, data from FDA's Integrity Services were utilized as the primary source of facility information for determining the denominator. As stated above, Integrity Services 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 753; of that number, 81 were domestic and 672 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 (672) 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 $10,080,000 of the total API fee revenue. Subtracting

[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.

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

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

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

the foreign facility differential fee revenue ($10,080,000) from the total API facility target revenue ($39,959,160) results in a remaining balance of $29,879,160. To determine the domestic API facility fee, we divide the $29,879,160 by the total number of facilities (753), which gives us a domestic API facility fee of $39,680. The foreign API facility fee is $15,000 more than the domestic API facility fee, or $54,680.

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, 2026, 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 $665,986,000 in fee revenue, which is $239,754,960.

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, 2026, in addition to CBER's database, shows 229 applicants in the small business tier, 70 applicants in the medium size tier, and 85 applicants in the large size tier. Factoring in all the variables, we estimate there will be 196 applicants in the small business tier, 67 applicants in the medium size tier, and 78 applicants in the large size tier for FY 2027.

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 ($239,754,960), 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 19.6 applicants in the small business tier (196 multiplied by 10 percent), 26.8 applicants in the medium size tier (67 multiplied by 40 percent), and 78 applicants in the large size tier, arriving at 124.4 total weighted applicants for FY 2027.

To generate the large size operation GDUFA program fee, FDA divides the target revenue amount of $239,754,960 by 124.4, which equals $1,927,291. The medium size operation GDUFA program fee is 40 percent of the full fee ($770,916), and the small business GDUFA program fee is 10 percent of the full fee ($192,729).

IX. Fee Schedule for FY 2027

The fee rates for FY 2027 are displayed in table 8.

TABLE 8—FEE SCHEDULE FOR FY 2027

Fee category	Fee rates for FY 2027
Applications:	
Abbreviated New Drug Application (ANDA)	$375,684
Drug Master File (DMF)	109,899
Facilities:	
Active Pharmaceutical Ingredient (API)—Domestic	39,680
API—Foreign	54,680
Finished Dosage Form (FDF)—Domestic	230,033
FDF—Foreign	245,033
Contract Manufacturing Organization (CMO)—Domestic	55,208
CMO—Foreign	70,208
GDUFA Program:	
Large size operation generic drug applicant	1,927,291
Medium size operation generic drug applicant	770,916
Small business generic drug applicant	192,729

X. Fee Payment Options and Procedures

The new fee rates are effective on October 1, 2026, and will remain in effect through September 30, 2027. 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

[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.

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

https://www.fda.gov/gdufa and *https://userfees.fda.gov/OA_HTML/gdufaCAcdLogin.jsp,* and generate a user fee identification (ID) number.

Payments made to FDA must be made in U.S. currency drawn on a U.S. bank by electronic check, credit card, or wire transfer. The preferred method for payments to FDA 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 upon receipt of an invoice or after completing the User Fee Cover Sheet and generating the user fee ID number.

Secure electronic payments to FDA 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 or cover sheet 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 or invoice number to ensure that the payment is applied to the correct fee(s). Without the unique user fee ID or invoice 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, Account No: 75060099, Routing No: 021030004, SWIFT: FRNYUS33.

FDA's tax identification number is 53–0196965. If a fee is not paid in full, the fee will be treated as a claim of the U.S. Government (see section 744B(j) of the FD&C Act and 45 CFR part 30), meaning the invoice balance due amount is referred to collections.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–0007]

Prescription Drug User Fee Rates for Fiscal Year 2027

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the rates for prescription drug user fees for fiscal year (FY) 2027. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Prescription Drug User Fee Amendments of 2022 (PDUFA VII), authorizes FDA to collect application fees for certain applications for the review of human drug and biological products and prescription drug program fees for certain approved products. This notice establishes the fee rates for FY 2027.

DATES: These fees apply to the period from October 1, 2026, through September 30, 2027.

FOR FURTHER INFORMATION CONTACT: For more information on prescription drug fees, visit FDA's website at: *https://www.fda.gov/industry/fda-user-fee-programs/prescription-drug-user-fee-amendments. For questions relating to this notice:* Olufunmilayo Ariyo, Office of Financial Management, Food and Drug Administration, 301–796–7900; or *FDAUserFees@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Sections 735 and 736 of the FD&C Act (21 U.S.C. 379g and 379h) establish two different kinds of user fees. Fees are assessed as follows: (1) application fees are assessed on certain types of applications for the review of human drug and biological products and (2) prescription drug program fees are assessed on certain approved products (section 736(a) of the FD&C Act). The statute also includes conditions under which such fees may be waived or reduced (section 736(d) of the FD&C Act), or under which fee exceptions, refunds, or exemptions apply (sections 736(a)(1)(C) through (H), 736(a)(2)(B) through (C), and 736(k) of the FD&C Act).

For FY 2023 through FY 2027, the base revenue amounts for the total revenues from all PDUFA fees are established by PDUFA VII. The base revenue amount for FY 2027 is $1,515,410,160. The FY 2027 base revenue amount is adjusted for (1) inflation, (2) strategic hiring and retention, and for (3) the resource capacity needs for the process for the review of human drug applications (the capacity planning adjustment (CPA)). This amount is further adjusted to include the additional dollar amount as specified in the statute (see section 736(b)(1)(G) of the FD&C Act) to provide for additional full-time equivalent (FTE) [1] positions to support PDUFA VII initiatives. If applicable, an operating reserve adjustment is added to provide sufficient operating reserves of carryover user fees. The amount from the preceding adjustments is then adjusted to provide for additional direct costs to fund PDUFA VII initiatives. Fee amounts are to be established each year so that revenues from application fees provide 20 percent of the total revenue, and prescription drug program fees provide 80 percent of the total revenue (see section 736(b)(2) of the FD&C Act).

This document provides fee rates for FY 2027 for an application requiring covered clinical data [2] ($4,600,753), for an application not requiring covered clinical data ($2,300,376), and for the prescription drug program fee ($416,857). These fees are effective on October 1, 2026, and will remain in effect through September 30, 2027. For applications that are submitted on or after October 1, 2026, the new fee schedule must be used.

II. Fee Revenue Amount for FY 2027

The base revenue amount for FY 2027 is $1,515,410,160 (see section 736(b)(1)(A) and (b)(3) of the FD&C Act). This amount is prior to any adjustments made for inflation, the strategic hiring and retention adjustment, CPA, additional dollar amount, operating reserve adjustment (if applicable), and additional direct costs (see section 736(b)(1) of the FD&C Act).

A. FY 2027 Statutory Fee Revenue Adjustments for Inflation

PDUFA VII specifies that the $1,515,410,160 is to be adjusted for inflation increases for FY 2027 using two separate adjustments: one for personnel compensation and benefits (PC&B) and one for non-PC&B costs (see section 736(c)(1) of the FD&C Act).

The component of the inflation adjustment for payroll costs is the average annual percent change in the

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

[2] As used herein, ''covered clinical data'' is ''clinical data (other than bioavailability or bioequivalence studies) with respect to safety or effectiveness [that] are required for approval'' (see section 736(a)(1)(A) of the FD&C Act).