TABLE 7—FEE SCHEDULE FOR FY 2026

Fee category	Fee rates for FY 2026
Initial BPD	$10,000
Annual BPD	10,000
Reactivation	20,000
Applications:	
Requiring Clinical Data	1,200,794
Not Requiring Clinical Data	600,397
Program Fee	209,097

V. Fee Payment Options and Procedures

A. Initial BPD, Reactivation, and Application Fees

The fees established in the new fee schedule apply to FY 2026, *i.e.,* the period from October 1, 2025, through September 30, 2026. The initial BPD fee for a product is due when the sponsor submits an IND that FDA determines is intended to support a biosimilar biological product application for the product or within 7 calendar days after FDA grants the first BPD meeting for the product, whichever occurs first. Sponsors who have discontinued participation in the BPD program for a product or have been administratively removed from the BPD program for a product, and seek to resume participation in the BPD program for the product must pay all annual BPD fees previously assessed for such product and still owed and the reactivation fee by the earlier of the following dates: no later than 7 calendar days after FDA grants the sponsor's request for a BPD meeting for that product, or upon the date of submission by the sponsor of an IND describing an investigation that FDA determines is intended to support a biosimilar biological product application for that product.

The application fee for a biosimilar biological product is due upon submission of the application (see section 744H(a)(2)(C) of the FD&C Act).

To make a payment of the initial BPD, reactivation, or application fee, complete the Biosimilar User Fee Cover Sheet, available on FDA's website (*https://www.fda.gov/bsufa*) and *https://userfees.fda.gov/OA_HTML/bsufaCAcdLogin.jsp,* and generate a user fee identification (ID) number. Payment must be made in U.S. currency by electronic check or wire transfer.[3] The preferred payment method is online using electronic check (Automated Clearing House (ACH) also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). FDA has partnered with the U.S. Department of the Treasury to use *www.pay.gov,* a web-based payment application, for online electronic payment. The *www.pay.gov* feature is available on the FDA website after the user fee ID number is generated. Secure electronic payments can be submitted using the User Fees Payment Portal at *https://userfees.fda.gov/pay* (*Note:* only full payments are accepted. No partial payments can be made online). Once you search for your invoice, click ''Pay Now'' to be redirected to *www.pay.gov.* Electronic payment options are based on the balance due. Payment by credit card is available for balances that are less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S. bank accounts as well as U.S. credit cards.

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 2026 annual BPD and program fees under the new fee schedule in August 2025. 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, 2025.

If sponsors join the BPD program after the annual BPD invoices have been issued in August 2025, FDA will issue invoices in December 2025 to sponsors subject to fees for FY 2026 that qualify for the annual BPD fee after the August 2025 billing. FDA will issue invoices in December 2026 for any products that qualify for the annual program fee after the August 2025 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 25, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–14416 Filed 7–29–25; 8:45 am]

BILLING CODE 4164–01–P

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–0008]

Arthritis Advisory Committee; Termination

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the termination of the Agency's Arthritis Advisory Committee (Committee) by the Commissioner of Food and Drugs (Commissioner). The Commissioner has determined that it is not necessary to continue to maintain this Committee.

DATES: This Committee will terminate on the date of publication of this notice.

FOR FURTHER INFORMATION CONTACT: Emily Helms Williams, Director, Advisory Committee Oversight and Management Staff, Office of the Chief Scientist, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 3240, Silver Spring, MD 20993, 301–796–3381, *Emily.HelmsWilliams@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Arthritis Advisory Committee was established on April 5, 1974 (39 FR 14737–14738), to advise the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use in arthritic conditions, and as required, any other product for which FDA has regulatory responsibility. This Committee has met infrequently in recent years, and FDA has determined that the effort and expense of

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]

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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