reduction, exemption or return not later than 180 days after such fee is due (section 736(i) of the FD&C Act). A request submitted under this paragraph must include any legal authorities under which the request is made.

Dated: July 25, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–14413 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–2273]

Biosimilar User Fee Rates for Fiscal Year 2026

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the rates for biosimilar user fees for fiscal year (FY) 2026. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Biosimilar User Fee Amendments of 2022 (BsUFA III), authorizes FDA to assess and collect user fees for certain activities in connection with biosimilar biological product development; review of certain applications for approval of biosimilar biological products; and each biosimilar biological product approved in a biosimilar biological product application. BsUFA III directs FDA to establish, before the beginning of each fiscal year, the amount of initial and annual biosimilar biological product development (BPD) fees, the reactivation fee, and the biosimilar biological product application and program fees for such year.

DATES: These fees apply to the period from October 1, 2025, through September 30, 2026.

FOR FURTHER INFORMATION CONTACT: Olufunmilayo Ariyo, Office of Financial Management, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 240–402–4989, and the User Fees Support Staff at *UFSS@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Sections 744G, 744H, and 744I of the FD&C Act (21 U.S.C. 379j–51, 379j–52, and 379j–53), as amended by BsUFA III, authorize the collection of fees for biosimilar biological products. Under section 744H(a)(1)(A) of the FD&C Act, the initial BPD fee for a product is due when the sponsor submits an investigational new drug (IND) application that FDA determines is intended to support a biosimilar biological product application or within 7 calendar days after FDA grants the first BPD meeting, whichever occurs first. A sponsor who has paid the initial BPD fee is considered to be participating in FDA's BPD program for that product.

Under section 744H(a)(1)(B) of the FD&C Act, once a sponsor has paid the initial BPD fee for a product, the annual BPD fee is assessed beginning with the next fiscal year. The annual BPD fee is assessed for the product each fiscal year until the sponsor submits a marketing application for the product that is accepted for filing, the sponsor discontinues participation in FDA's BPD program for the product, or the sponsor has been administratively removed from the BPD program for the product.

Under section 744H(a)(1)(D) of the FD&C Act, if a sponsor has discontinued participation in FDA's BPD program or has been administratively removed from the BPD program for a product and wants to reengage with FDA on development of the product, the sponsor must pay all annual BPD fees previously assessed for such product and still owed, and a reactivation fee to resume participation in the program. The sponsor must pay the reactivation fee by the earlier of the following dates: (1) no later than 7 calendar days after FDA grants the sponsor's request for a BPD meeting for that product or (2) 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 sponsor will be assessed an annual BPD fee beginning in the next fiscal year after payment of the reactivation fee.

BsUFA III also authorizes fees for certain biosimilar biological product applications and for each biosimilar biological product identified in an approved biosimilar biological product application (section 744H(a)(2) and (3) of the FD&C Act). Under certain conditions, FDA will grant a small business a waiver of the biosimilar biological product application fee (section 744H(d)(1) of the FD&C Act).

For FY 2023 through FY 2027, the base revenue amounts for the total revenues from all BsUFA fees are established by BsUFA III. For FY 2026, the base revenue amount is the FY 2025 total revenue amount excluding any operating reserve adjustment, which equates to the amount of $56,011,943. The FY 2026 base revenue amount is to be adjusted by the inflation adjustment, strategic hiring and retention adjustment, capacity planning adjustment (CPA), operating reserve adjustment, and the additional dollar amount. Each of these adjustments will be discussed in the sections below.

This document provides fee rates for FY 2026 for the initial and annual BPD fee ($10,000), for the reactivation fee ($20,000), for an application requiring clinical data ($1,200,794) for an application not requiring clinical data ($600,397) and for the program fee ($209,097). These fees are effective on October 1, 2025, and will remain in effect through September 30, 2026. For applications that are submitted on or after October 1, 2025, the new fee schedule must be used.

II. Fee Revenue Amount for FY 2026

The base revenue amount for FY 2026 is $56,011,943 prior to adjustments for inflation, strategic hiring and retention, capacity planning, operating reserves, and the additional dollar amount (see section 744H(b) and (c) of the FD&C Act).

A. FY 2026 Statutory Fee Revenue Adjustments for Inflation

BsUFA III specifies that the $56,011,943 is to be adjusted for inflation increases for FY 2026 using two separate adjustments: one for personnel compensation and benefits (PC&B) and one for non-PC&B costs (see section 744H(c)(1) of the FD&C Act).

The component of the inflation adjustment for payroll costs shall be the average annual percent change in the cost of all PC&B paid per full-time equivalent (FTE [1]) positions at FDA for the first 3 of the preceding 4 fiscal years, multiplied by the proportion of PC&B costs to total FDA costs of the process for the review of biosimilar biological product applications for the first 3 of the preceding 4 fiscal years (see section 744H(c)(1)(B) of the FD&C Act).

Table 1 summarizes the actual cost and FTE data for the specified fiscal years and provides the percent changes from the previous fiscal years and the average percent changes over the first 3 of the 4 fiscal years preceding FY 2026. The 3-year average is 5.4494 percent.

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

TABLE 1—FDA PC&B EACH YEAR AND PERCENT CHANGES

	2022	2023	2024	3-Year average
Total PC&B	$3,165,477,000	$3,436,513,000	$3,791,729,000	
Total FTE	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 be multiplied by the proportion of PC&B costs to the total FDA costs of the process for the review of biosimilar biological product applications. Table 2 shows the PC&B and the total obligations for the process for the review of biosimilar biological product applications for the first 3 of the preceding 4 fiscal years.

TABLE 2—PC&B AS A PERCENT OF TOTAL COST OF THE PROCESS FOR THE REVIEW OF BIOSIMILAR BIOLOGICAL PRODUCT APPLICATIONS

	2022	2023	2024	3-Year average
Total PC&B (proportion of costs)	$34,065,826	$45,893,774	$55,198,837	
Total Costs	68,521,689	86,101,288	91,066,972	
PC&B percent	49.7154%	53.3021%	60.6135%	54.5437%

The payroll adjustment is 5.4494 percent from table 1 multiplied by 54.5437 percent (or 2.9723 percent).

The statute specifies that the portion of the inflation adjustment for nonpayroll costs is the average annual percent change that occurred in the Consumer Price Index (CPI) for urban consumers (Washington-Arlington-Alexandria, DC–VA–MD–WV; not seasonally adjusted; all items; annual index) for the first 3 years of the preceding 4 years of available data multiplied by the proportion of all costs other than PC&B costs to total costs of the process for the review of biosimilar biological product applications for the first 3 years of the preceding 4 fiscal years (see section 744H(c)(1)(B) of the FD&C Act). Table 3 provides the summary data for the percent changes in the specified CPI for the Washington-Arlington-Alexandria area.[2]

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

Fiscal 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%

The statute specifies that this 4.3202 percent be multiplied by the proportion of all costs other than PC&B to total costs of the process for the review of biosimilar biological product applications obligated. Since 54.5437 percent was obligated for PC&B (as shown in table 2), 45.4563 percent is the portion of costs other than PC&B (100 percent minus 54.5437 percent equals 45.4563 percent). The non-payroll adjustment is 4.3202 percent times 45.4563 percent, 1.9638 percent.

Next, we add the payroll adjustment (2.9723 percent) to the nonpayroll adjustment (1.9638 percent), for a total inflation adjustment of 4.9361 percent (rounded) for FY 2026.

We then multiply the base revenue amount for FY 2026 ($56,011,943) by the inflation adjustment percentage (4.9361 percent), yielding an inflation adjustment of $2,764,806. Adding this amount yields an inflation-adjusted amount of $58,776,749.

B. Strategic Hiring and Retention Adjustment

The statute specifies that for each fiscal year, after the annual base revenue is adjusted for inflation, FDA shall further increase the fee revenue and fees by the strategic hiring and retention adjustment, which is $150,000 for FY 2026 (see section 744H(c)(2) of the FD&C Act).

C. FY 2026 Statutory Fee Revenue Adjustments for Capacity Planning

The statute specifies that the fee revenue and fees shall be further adjusted to reflect changes in the resource capacity needs for the process for the review of biosimilar biological product applications (see section 744H(c)(3) of the FD&C Act). Following a process agreed upon by FDA and industry during BsUFA II reauthorization discussions and subsequently required in statute, FDA established the capacity planning adjustment methodology and first applied it in the setting of FY 2021 fees. The establishment of this methodology is described in the **Federal Register** at 85 FR 47220. 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] 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.*

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 the 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 4 summarizes the forecasted workload volumes for BsUFA III in FY 2026 based on predictive models, as well as historical actuals from FY 2024 for comparison.

TABLE 4—BSUFA III ACTUAL FY 2024 WORKLOAD VOLUMES & PREDICTED FY 2026 WORKLOAD VOLUMES

Workload category	FY 2024 actuals	FY 2026 predictions
Original Biosimilar Supplements [1]	49	53
Manufacturing Supplements	128	123
Biosimilar Biological Product Applications	19	17
BsUFA Industry Meetings (BIA, BPD Type 1–4)	162	159
Participating BPD Programs	123	150
Annual Reports [2]	54	58
PMR/PMC-Related Documents [2]	38	23
Active REMS Programs [2 3]	1	1

[1] Includes Supplements with Clinical Data and Labeling Supplements.
[2] Represents activities related to the review of materials submitted to the application file after approval.
[3] Represents the number 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 BsUFA fee amounts do not need adjustment from the CPA to provide funds for the program.

D. FY 2026 Additional Dollar Amount

For FY 2023 and FY 2024, BsUFA III provided an additional dollar amount for additional FTE for the biosimilar biological product review program to support enhancements outlined in the BsUFA III Commitment Letter. For FY 2025, FY 2026, and FY 2027, no additional amount is specified in statute.

TABLE 5—BASE REVENUE AMOUNT AND ADJUSTMENTS PRIOR TO OPERATIVE RESERVE ADJUSTMENT

Fee	Amount
Base Revenue Amount (Section 744H(b)–(c) of the FD&C Act)	$56,011,943
Inflation Adjustment (Section 744H(c)(1) of the FD&C Act)	2,764,806
Strategic Hiring and Retention Adjustment (Section 744H(c)(2) of the FD&C Act)	150,000
Capacity Planning Adjustment (Section 744H(c)(3) of the FD&C Act)	0
Additional Dollar Amount	0
Cumulative Revenue Amount Prior to Operative Reserve Adjustment	58,926,749

E. FY 2026 Statutory Fee Revenue Adjustments for Operating Reserve

BsUFA III sets forth an operating reserve adjustment to the fee revenue and fees. Specifically, for FY 2026, the statute directs FDA: (1) to increase the fee revenue and fees if such an adjustment is necessary to provide for at least 10 weeks of operating reserves of carryover user fees for the process for the review of biosimilar biological product applications and (2) if FDA has carryover balances for such process in excess of 21 weeks of such operating reserves, to decrease such fee revenue and fees to provide for not more than 21 weeks of such operating reserves (see section 744H(c)(4) of the FD&C Act).

To calculate the 10-week and 21-week threshold amounts for the FY 2026 operating reserve adjustment, the estimated adjusted revenue amount (*i.e.,* the base revenue amount and adjustments prior to the operating reserve adjustment), $58,926,749 is divided by 52, resulting in a $1,133,207 cost of operation for 1 week (rounded to the nearest dollar). The 1-week value ($1,133,207) is then multiplied by 10 weeks to generate the 10-week operating reserve threshold amount for FY 2026 of $11,332,067. The 1-week value is multiplied by 21 to generate the 21-week operating reserve threshold amount for FY 2026 of $23,797,341.

To calculate the estimated operating reserve of carryover user fees at the end of FY 2025, FDA estimated the operating reserves of carryover fees at the end of June 2025. The balance of operating reserves of carryover fees at the end of June 2025 is combined with the forecasted collections and obligations for the remainder of FY 2025 to generate a full year estimate for FY 2025. The estimated operating reserve of carryover user fees at the end of FY 2025 is $26,883,182.

The estimated operating reserve of carryover user fees at the end of FY 2025 of $26,883,182 is above the 21-week threshold allowable operating reserve of carryover user fees for FY 2026 of $23,797,341. As such, FDA is applying a downward operating reserve adjustment of $3,085,841 (rounded to the nearest dollar), an amount equivalent to a reduction of approximately 2.72 weeks of operations, to bring the operating reserve of carryover user fees to $23,797,341 or 21 weeks of operations at the start of FY 2026. With this operating reserve

adjustment, the estimated adjusted revenue amount of $58,926,749 will be lowered by $3,085,841, yielding the FY 2026 target revenue amount of $55,841,000 (rounded to the nearest thousand), summarized below.

TABLE 6—TOTAL ESTIMATED ADJUSTED REVENUE AMOUNT

Fee	Amount
Base Revenue Amount (Section 744H(b)–(c) of the FD&C Act)	$56,011,943
Inflation Adjustment (Section 744H(c)(1) of the FD&C Act)	2,764,806
Strategic Hiring and Retention Adjustment (Section 744H(c)(2) of the FD&C Act)	150,000
Capacity Planning Adjustment (Section 744H(c)(3) of the FD&C Act)	0
Additional Dollar Amount	0
Operating Reserve Adjustment	(3,085,841)
Total Revenue Amount in sections 744H(b)–(c), 744H(c)(1), (2), (3) of the FD&C Act	55,840,908
Total Revenue Amount in sections 744H(b)–(c), 744H(c)(1), (2), (3) of the FD&C Act (rounded to the nearest thousand dollars)	55,841,000

III. Fee Amounts for FY 2026

Under section 744H(b)(2)(A) of the FD&C Act, FDA must determine the percentage of the total revenue amount for a fiscal year to be derived from: (1) initial and annual BPD fees, and reactivation fees; (2) biosimilar biological product application fees; and (3) biosimilar biological product program fees. As described above, a downward operating reserve adjustment is required for FY 2026. The operating reserve adjustment in subsequent years may not be as large. As such, the target revenue in FY 2026 may be lower than in prior or future years, and thereby the fee amounts may also be lower than in prior or future years.

A. Application Fees

To calculate the biosimilar biological product application fee, FDA estimated the number of full application equivalents (FAEs) that will be submitted in FY 2026. A filed original 351(k) BLA with clinical data counts as one FAE. A filed original 351(k) BLA without clinical data counts as one-half of an FAE. An original 351(k) BLA that is refused to file (RTF) or withdrawn before filing (WD), counts as one-fourth of an FAE if the application required clinical data, or one-eighth of an FAE if the application did not require clinical data. After an original 351(k) BLA has been RTF or WD, the applicant has the option of resubmitting. For user fee purposes, these resubmitted original 351(k) BLAs are equivalent to original 351(k) BLA submissions. Filed original 351(k) BLA resubmissions are charged the full amount for an application with clinical data (one FAE) or without clinical data (one-half FAE). Additionally, a filed original 351(k) BLA with or without clinical data that is granted a small business waiver (SBW) from the application fee counts as zero FAE.

As discussed in II.C above, FDA estimates that 17 original 351(k) BLAs will be submitted in FY 2026. Based on recent years' data regarding SBWs, original 351(k) BLAs with or without clinical data, original 351(k) BLAs that are RTF or WD, and considering that some of these applications may be resubmitted in the same fiscal year, it is assumed that the 17 submissions will equate to 16 FAEs.

For FY 2026 the biosimilar biological product application fee for applications requiring clinical data is $1,200,794. Applications not requiring clinical data pay half that fee, or $600,397. This is estimated to provide a total of $19,212,704 representing 34 percent (rounded to the nearest whole number) of the FY 2026 target revenue amount.

B. Biosimilar Biological Product Program Fee

Under BsUFA III, FDA assesses biosimilar biological product program fees (''program fees''). An applicant in a biosimilar biological product application shall not be assessed more than five program fees for a fiscal year for biosimilar biological products identified in a single biosimilar biological product application (see section 744H(a)(3)(D) of the FD&C Act). Applicants are assessed a program fee for a fiscal year for biosimilar biological products that are identified in a biosimilar biological product application approved as of October 1 of such fiscal year; that may be dispensed only under prescription pursuant to section 503(b) of the FD&C Act; and that, as of October 1 of such fiscal year, do not appear on a list developed and maintained by FDA of discontinued biosimilar biological products. An approved biosimilar biological product that appears on the list of discontinued biosimilar biological products as of October 1 of a fiscal year would also be assessed the program fee if it is removed from the discontinued list during the fiscal year and the other statutory criteria for fee assessment are satisfied (see section 744H(a)(3)(E)(iii) of the FD&C Act).

Based on available information, FDA estimates that 168 program fees will be invoiced for FY 2026. For products invoiced in the FY 2026 regular billing cycle, FDA anticipates that zero program fees will be refunded.

For FY 2026, the biosimilar biological product program fee is $209,097. This is estimated to provide a total of $35,128,296, representing 63 percent (rounded to the nearest whole number) of the FY 2026 target revenue amount.

C. Initial and Annual BPD Fees, and Reactivation Fees

To estimate the number of BPD fees to be paid in FY 2026, FDA must consider the number of new BPD programs, the number of current BPD programs, and the number of BPD programs that will be reactivated. These estimates provide information that, when aggregated, allows FDA to set BPD fees (initial BPD fees, annual BPD fees, reactivation fees).

FDA analyzed available data to estimate the total number of BPD programs for FY 2026. In FY 2026, FDA estimates approximately 30 new BPD programs, no reactivations (a single reactivation is weighted as two BPD fees), and approximately 120 BPD programs to pay the annual BPD fee, yielding a rounded total estimated equivalent of 150 BPD fees to be collected in FY 2026. The remainder of the target revenue of $1,500,000 or 3 percent is to be collected from the BPD fees. Dividing this amount by the estimated 150 BPD fees to be paid equals an initial BPD and annual BPD fee amount of $10,000 (rounded to the nearest dollar). The reactivation fee is set at twice the initial/annual BPD amount at $20,000 (rounded to the nearest dollar).

IV. Fee Schedule for FY 2026

The fee rates for FY 2026 are displayed in table 7.

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