4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2026-N-2362]

Over-the-Counter Monograph Drug Facility 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), as amended by the Over-the-Counter Monograph Drug User Fee Amendments (herein referred to as "OMUFA II"), authorizes the Food and Drug Administration (FDA, the Agency, or we) to assess and collect user fees from qualifying manufacturers of over-the-counter (OTC) monograph drugs and submitters of OTC monograph order requests (OMORs) for fiscal years 2026 through 2030. This notice publishes the OTC monograph drug facility (MDF) fee rates for fiscal year (FY) 2026.

DATES: These facility fees are effective on October 1, 2025, and will remain in effect 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; or the User Fees Support Staff at OO-OFBA-OFM-UFSS-Government@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 744M of the FD&C Act (21 U.S.C. 379j-72), as amended by OMUFA II,[1] authorizes FDA to assess and collect, for each of fiscal years 2026 through 2030: (1) facility

[1] Over-the-Counter Monograph Drug User Fee Amendments, title V of Division F of the Continuing Appropriations, Agriculture, Legislative Branch, Military Construction and Veterans Affairs, and Extensions Act, 2026 (Pub. L. 119-37).

fees from qualifying owners of OTC MDFs and (2) fees from submitters of qualifying OMORs. The OMOR fee rates for FY 2026 were published on December 29, 2025.[2] These fees are to support FDA's OTC monograph drug activities, which are detailed in section 744L(6) of the FD&C Act (21 U.S.C. 379j-71(6)) and include specified FDA activities associated with OTC monograph drugs. For OMUFA purposes:

- An OTC monograph drug is a nonprescription drug without an approved new drug application that is governed by the provisions of section 505G of the FD&C Act (21 U.S.C. 355h) (see section 744L(5) of the FD&C Act);
- An OTC MDF is a foreign or domestic business or other entity that, in addition to meeting other criteria, is engaged in manufacturing or processing the finished dosage form of an OTC monograph drug (see section 744L(10) of the FD&C Act); and
- A contract manufacturing organization (CMO) facility is an OTC monograph drug facility where neither the owner nor any affiliate of the owner or facility sells the OTC monograph drug produced at such facility directly to wholesalers, retailers, or consumers in the United States (see section 744L(2) of the FD&C Act).

Under section 744M(a)(1)(A) of the FD&C Act, a facility fee for FY 2026 shall be assessed with respect to each facility that is identified as an OTC monograph drug facility during the fee-liable period from January 1, 2025, through December 31, 2025.[3] Consistent with the statute, FDA will assess and collect facility fees with respect to the two types of OTC monograph drug facilities—MDF and CMO facilities. A full facility fee will be assessed to each qualifying person that owns a facility identified as an MDF (see section 744M(a)(1)(A) of the FD&C Act), and a reduced facility fee of two-thirds will be assessed to each qualifying person that owns a facility identified as a CMO facility (see section 744M(a)(1)(B)(ii) of the FD&C

[2] https://www.federalregister.gov/documents/2025/12/29/2025-23852/over-the-counter-monograph-drug-user-fee-amendments-otc-monograph-order-request-fee-rates-for-fiscal.

[3] Under section 744M(a)(1)(A)(i) of the FD&C Act, "Each person that owns a facility identified as an OTC monograph drug facility at any time during the applicable period… for a fiscal year shall be assessed an annual fee for each such facility". The applicable period for FY 2026 is the 12-month period ending December 31, 2025.

Act). The facility fees for FY 2026 are due on June 1, 2026 (see section 744M(a)(1)(D)(i)(I) of the FD&C Act).[4]

As discussed in greater detail below, OTC monograph drug facilities are exempt from FY 2026 facility fees if they had ceased OTC monograph drug activities, and updated their registration with FDA to that effect, prior to January 1, 2025 (see section 744M(a)(1)(B)(i)(I)(aa) of the FD&C Act).

For FY 2026, the OMUFA facility fee rates are: MDF facility fees ($19,188) and CMO facility fees ($12,792). These fees are effective for the period from October 1, 2025, through September 30, 2026.[5] This document is issued pursuant to section 744M(a)(4) and 744M(c)(5)(B) of the FD&C Act and describes the calculations used to set the OMUFA facility fees for FY 2026 in accordance with the directives in the statute.

II. Facility Fee Revenue Amount for FY 2026

A. Base Fee Revenue Amount

Under OMUFA, FDA sets annual facility fees to generate the total facility fee revenues for each fiscal year established by section 744M(b) of the FD&C Act. The yearly base revenue amount is the starting point for setting annual facility fee rates. The base revenue for FY 2026 is the dollar amount of the total revenue amount for the previous fiscal year, without certain adjustments made for that previous year, and is $36,467,438 (see section 744M(b)(2)(A) of the FD&C Act).

B. Fee Revenue Adjustment for Inflation

Under OMUFA, the annual base revenue amount for facility fees is adjusted for inflation for FY 2026, per section 744M(c)(1) of the FD&C Act. That provision states that the dollar amount of the inflation adjustment is equal to the product of the annual base revenue for the

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[4] Assuming that, as we anticipate, the FY 2026 fee appropriation will occur prior to June 1, 2026. Under section 744M(a)(1)(D)(i), the FY 2026 facility fees are due on the later of: (1) the first business day of June 2026 (i.e., June 1, 2026) or (2) the first business day after the enactment of an appropriations Act providing for the collection and obligation of FY 2026 OMUFA fees.

[5] These OMUFA facility fees are for FY 2026, per section 744M(a) of the FD&C Act.

fiscal year and the inflation adjustment percentage. For FY 2026, the inflation adjustment percentage is equal to the sum of:

- The average annual percent change in cost, per full-time equivalent (FTE) position of the FDA, of all personnel compensation and benefits (PC&B) paid with respect to such positions for the first 3 years of the preceding 4 FYs, multiplied by the proportion of PC&B costs to total costs of the OTC monograph drug activities for the first 3 years of the preceding 4 FYs (see section 744M(c)(1)(C)(i) of the FD&C Act); and
- 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 OTC monograph drug activities for the first 3 years of the preceding 4 FYs (see section 744M(c)(1)(C)(ii) of the FD&C Act).

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

Table 1.--FDA Personnel Compensation and Benefits (PC&B) Each Fiscal Year and Percent Changes

Fiscal Year	2022	2023	2024	3-Year Average
Total PC&B	3,165,477,000	3,436,513,000	3,791,729,000	5.4494%
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%	

Under the statute, this 5.4494 percent is multiplied by the proportion of PC&B costs to the total FDA costs of OTC monograph drug activities for the first 3 years of the preceding 4 FYs (see section 744M(c)(1)(C)(i) of the FD&C Act).

Table 2 shows the PC&B and the total obligations for OTC monograph drug activities for the first 3 of the preceding 4 FYs.

Table 2.-- PC&B as a Percent of Total Cost of OTC Monograph Drug Activities

Fiscal Year	2022	2023	2024	3-Year Average

Total PC&B	25,415,237	39,133,075	41,579,890	56.4429%
Total Costs	49,644,273	68,480,052	68,176,240	
PC&B Percent	51.1947%	57.1452%	60.9888%	

The payroll adjustment is 5.4494 percent from table 1 multiplied by 56.4429 percent from table 2, resulting in 3.0758 percent.

Table 3 provides the summary data for the percent changes in the specified CPI for the Washington-Arlington-Alexandria, DC-VA-MD-WV area.[6]

Table 3.--Annual and 3-Year Average Percent Change in CPI for Washington-Arlington-Alexandria, DC-VA-MD-WV Area

Fiscal Year	2022	2023	2024	3-Year Average
Annual CPI	296.12	305.32	315.186	4.3202%
Annual Percent Change	6.6212%	3.1069%	3.2324%	

The statute specifies that this 4.3202 percent be multiplied by the proportion of all costs other than PC&B to total costs of OTC monograph drug activities (see section 744M(c)(1)(C)(ii) of the FD&C Act). Because 56.4429 percent was obligated for PC&B (as shown in table 2), 43.5571 percent is the portion of costs other than PC&B (100 percent-56.4429 percent = 43.5571 percent). The non-payroll adjustment is 4.3202 percent x 43.5571 percent, or 1.8818 percent.

Next, we add the payroll adjustment (3.0758 percent) to the non-payroll adjustment (1.8818 percent), for a total inflation adjustment of 4.9576 percent (rounded) for FY 2026.

Pursuant to the statute, the FY 2026 base revenue of $36,467,438 is increased by the total inflation adjustment of 4.9576 percent, yielding an inflation adjusted base revenue amount of $38,275,348 for FY 2026 (see section 744M(c)(1)(A)).

C. Additional Dollar Amounts

OMUFA II requires that the facility fee revenue be increased by an additional dollar amount for each of fiscal years 2026-2028. For FY 2026, the inflation adjusted revenue amount

[6] These data are published by the Bureau of Labor Statistics on its website: https://data.bls.gov/pdq/SurveyOutputServlet?data_tool=dropmap&series_id=CUURS35ASA0,CUUSS35ASA0.

of $38,275,348 is increased by an additional dollar amount of $2,373,000 as specified in the statute (see section 744M(b)(1)(E)(i) of the FD&C Act). This yields an adjusted fee revenue subtotal of $40,648,348.

D. Fee Revenue Adjustment for Additional Direct Cost

Fee revenue is further adjusted for additional direct costs as specified in the statute. In FY 2026, $135,000 is added to the facility fee revenues to account for additional direct costs (see section 744M(c)(3)(A) of the FD&C Act). Adding the additional direct costs amount of $135,000 to $40,648,348 yields an additional direct cost adjusted fee revenue of $40,783,348.

E. Fee Revenue Adjustment for Operating Reserve

Under OMUFA, FDA may further increase the FY 2026 facility fee revenue and fees if such an adjustment is necessary to provide up to 10 weeks of operating reserves of carryover user fees for OTC monograph drug activities (see section 744M(c)(2)(A) of the FD&C Act). Accordingly, in setting fees for FY 2026, the Agency must estimate its carryover for FY 2026 to ensure the Agency has sufficient operating reserves of carryover user fees to mitigate certain financial risks, such as under collections, unanticipated surges in program costs, or a lapse in appropriations. Under the statute, if FDA has carryover for OTC monograph drug activities that would exceed 10 weeks of such operating reserves, FDA is required to decrease FY 2026 fee revenues and fees to provide for not more than 10 weeks of operating reserves of carryover user fees (see section 744M(c)(2)(B) of the FD&C Act).

Under OMUFA II, OMUFA facility fees will transition to being due the first business day in October, instead of the third quarter of each fiscal year (i.e., the first business day in June) (see section 744M(a)(1)(D)).[7] For FY 2027, OMUFA facility fees will be due in two equal installments, due the first business day of October and the first business day of February,

[7] Assuming that, as we anticipate, the annual fiscal year OMUFA fee appropriation will be enacted by October 1 of the fiscal year. Otherwise, the transitioned due date would be the first business day after the enactment of an appropriations Act providing for the collection and obligation of OMUFA fees for the fiscal year, per section 744M(a)(1)(D).

respectively.[8] With this transition, FDA will no longer need to retain sufficient carryover to sustain its statutorily-required OTC monograph drug activities until receipt of annual facility fee funding in the 3rd fiscal quarter. Accordingly, the additional 35-week continuity set-aside utilized under OMUFA I is no longer necessary and has been eliminated from fee calculations for FY 2026 and subsequent fiscal years under OMUFA II.

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 January 2026 and forecast collections and obligations for the remainder of FY 2026. FDA estimates the FY 2026 operating reserve of carryover user fees to be $31,741,457.

To determine whether the carryover is within the 10-week limit for the operating reserve, the Agency starts with the additional direct cost adjusted fee revenue of 40,783,348 (calculated in section D), divides it by 52 to yield a weekly operating amount of $784,295, and then multiplies the weekly operating reserve amount ($784,295) by 10, resulting in an operating reserve limit of $7,842,951. Because the estimated FY 2026 carryover is above the 10-week threshold, FDA is applying a downward operating reserve adjustment of $23,898,506, equivalent to approximately 30 weeks, to bring the operating reserve of carryover user fees to the statutory limit for such operating reserves (see section 744M(c)(2)(B) of the FD&C Act). The final FY 2026 OMUFA target facility fee revenue is $16,885,000 (rounded to the nearest thousand dollars).

III. Facility Fee Calculations

A. Facility Fee Revenues and Fees

For FY 2026, facility fee rates are being established to generate a total target revenue amount, as determined under the statute, equal to $16,885,000 (rounded to the nearest thousand

[8] See section 744M(a)(1)(D)(ii) of the FD&C Act. For fiscal year 2028 and subsequent fiscal years, OMUFA facility fees will be due the first business day of October (or if later, the first business day after enactment of an appropriations Act providing for the collection and obligation of OMUFA fees for the fiscal year), per section 744M(a)(1)(D)(iii) of the FD&C Act.

dollars). FDA used the methodology described below to determine the appropriate number of MDF and CMO facilities to be used in setting the OMUFA facility fees for FY 2026. FDA took into consideration that the CMO facility fee is equal to two-thirds of the amount of the MDF facility fee (see section 744M(a)(1)(B)(ii) of the FD&C Act).

B. Calculating the Number of Qualifying Facilities and Setting the Facility Fees

For FY 2026, FDA utilized data consisting of the number of facilities that were registered in FDA's Electronic Drug Registration and Listing System (eDRLS) to manufacture human OTC drug products produced under a monograph[9] during the FY 2026 fee-liable period (i.e., January 1, 2025, through December 31, 2025, and that paid prior FY OMUFA facility fees, as the primary sources for estimating the number of each facility fee type (i.e., MDF and CMO). In addition, the Agency considered data provided by firms regarding their operation as MDFs and CMOs during FY 2025 (i.e., October 1, 2024, through September 30, 2025) when they were submitting OTC Monograph User Fee Cover Sheets to pay the FY 2025 fee. This data supported FDA's estimate of the number of firms operating as MDF and CMO facilities during the FY 2026 fee-liable period (i.e., January 1, 2025, through December 31, 2025),[10] and informed FDA's calculation of the number and ratio of MDF and CMO facilities used in determining the FY 2026 fee rates. FDA's review of data also reflected input received during the FY 2026 fee-liable period from facilities whose manufacturing or processing practices meet the definition of fee-

[9] See section 744M(d) of the FD&C Act. OTC monograph drug facilities had selected in the eDRLS the business operation qualifiers of "manufactures human over-the-counter drug products produced under a monograph" or "contract manufacturing for human over-the-counter drug products produced under a monograph" and indicated at least one of the following business operations: finished dosage form manufacture, label, manufacture, pack, relabel, or repack.

[10] FDA considers relabelers and repackagers to be a category of OTC monograph drug facilities subject to OMUFA facility fees. See section 744L(10)(A); see also section 744L(10)(A)(iii) of the FD&C Act, excluding from the definition of "OTC monograph drug facility" those facilities whose manufacturing or processing consists solely of a narrow range of specified activities (e.g., placement of outer overpackaging on products already in final packaged form); *cf* section 744A(6)(A)(ii) of the FD&C Act (which expressly excludes from the definition of "facility", for purposes of Generic Drug User Fee Amendments facility fees, a business or other entity whose only manufacturing or processing activities are repackaging, relabeling, or testing). See also 21 CFR 207.1 (addressing drug establishment registration), stating that "[m]anufacture means each step in the manufacture, preparation, propagation, compounding, or processing of a drug," and indicating that "the term 'manufacture, preparation, propagation, compounding, or processing,' as used in section 510 of the Federal Food, Drug, and Cosmetic Act, includes relabeling, repackaging, and salvaging activities."

eligible OTC monograph drug facilities, to help capture those facilities that are in the market and intend to remain in the market for FY 2026.

Those facilities that only manufacture the active pharmaceutical ingredient of an OTC monograph drug do not meet the definition of an OTC monograph drug facility (see section 744L(10)(A)(i)(II)) of the FD&C Act). Likewise, a facility is not an OTC monograph drug facility if its only manufacturing or processing activities are one or more of the following: (1) production of clinical research supplies; (2) testing; or (3) placement of outer packaging on packages containing multiple products, for such purposes as creating multipacks, when each monograph drug product contained within the overpackaging is already in a final packaged form prior to placement in the outer overpackaging (see section 744L(10)(A)(iii) of the FD&C Act).

In undertaking the statutorily directed fee calculations for FY 2026 fees, the Agency also made certain assumptions, including that: (1) facilities using expired Structured Product Labeling codes in eDRLS that have not reregistered, were no longer manufacturing and marketing OTC monograph drugs; (2) facilities that have deregistered in eDRLS have exited the market; (3) facilities that FDA believes registered incorrectly as OTC monograph drug facilities (for example, because the associated drug listings for these facilities did not include OTC monograph drugs but instead indicated such products as nonprescription drug products marketed under an approved drug application or nonprescription animal drug products) were not engaged in manufacturing or processing the finished dosage form of an OTC monograph drug; (4) facilities that registered but did not have an active OTC monograph drug product listing associated in their registration profile were not manufacturing or processing such drug products; (5) a portion of facilities that newly registered during the fee liable period are estimated to be in arrears based on a review of the prior 3-year average of newly registered facilities in arrears; and (6) facilities that, at the close of FY 2025, remain on the arrears list for failure to satisfy the FY 2023, FY 2024, or FY 2025 facility fee are likely to be placed on the FY 2026 arrears list as well.

Based on the above-referenced factors and assumptions, FDA estimates there will be 1,039 OMUFA fee-paying units. The Agency estimates that 54 percent (1,039 × 0.54 = 561, rounded) will incur the MDF fee and 46 percent (1,039 × 0.46 = 478, rounded) will incur the CMO fee.

To determine the number of full fee-paying equivalents (the denominator) to be used in setting the OMUFA fees, FDA assigns a value of 1 to each MDF (561) and a value of 2/3 to each CMO (478 × 2/3 = 319) for a full facility equivalent of 880 (rounded). The target fee revenue of $16,885,000 is then divided by 880 for an MDF fee of $19,188 and a CMO fee of $12,792.

IV. Fee Schedule for FY 2026

The fee rates for FY 2026 are displayed in table 4.

Table 4.--Fee Schedule for FY 2026

Fee Category	FY 2026 Fee Rates
MDF	$19,188
CMO	$12,792

V. Electronic Federal Payment Methods

The new facility fee rates are for the period from October 1, 2025, through September 30, 2026. To pay the MDF and CMO fees, complete an OTC Monograph User Fee Cover Sheet, available at: https://userfees.fda.gov/OA_HTML/omufaCAcdLogin.jsp, and generate a unique user fee identification (ID) number or use the OMUFA FY 2026 Facility Fee Invoice that is issued by the Agency in April 2026.[11]

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.

[11] The unique user fee identification (ID) number is also referred to as Payment Identification Number (PIN) in OMUFA coversheet creation instructions; these terms are used interchangeably. See https://userfees.fda.gov/OA_HTML/OMUFAFacilityFeeCoverSheetCreationProcess.pdf.

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 transfers: 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 744M(g) of the FD&C Act and 45 CFR Part 30), meaning the invoice balance due amount is referred to collection.

If you are assessed an FY 2026 OMUFA facility fee and believe your facility is not an OTC monograph drug facility as described in this notice, please contact CDERCollections@fda.hhs.gov.

Grace Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026-05276 Filed: 3/17/2026 8:45 am; Publication Date: 3/18/2026]