4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-6896]

Over-the-Counter Monograph Drug User Fee Amendments--OTC Monograph Order Request 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 (OMOR)s for fiscal years 2026 through 2030. In this notice, FDA is announcing the OMOR fee rates for fiscal year (FY) 2026. FDA plans to announce the FY 2026 OMUFA facility fee rates, i.e., monograph drug facility (MDF) and contract manufacturing organization (CMO) facility fee rates, in a subsequent *Federal Register* notice (and anticipates its issuance will generally align with the timing of the OMUFA facility fee rate publication for prior FYs).

DATES: These OMOR 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 fees from qualifying owners of OTC MDFs and (2) fees from submitters of qualifying OTC OMORs. 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 regulating OTC monograph drugs.[2]

For OMUFA purposes, an OMOR is a request for an administrative order, with respect to an OTC monograph drug, which is submitted under section 505G(b)(5) of the FD&C Act (see section 744L(7) of the FD&C Act).

Under section 744M(a)(2)(A) of the FD&C Act, the Agency is authorized to assess and collect fees from submitters of OMORs, except for OMORs that request certain safety-related changes (as discussed below). There are two levels of OMOR fees, based on whether the OMOR at issue is a Tier 1 or Tier 2 OMOR.[2]

For FY 2026, the OMUFA fee rates for OMORs are: Tier 1 OMOR fees ($587,529) and Tier 2 OMOR fees ($117,505). These fees are effective for the period from October 1, 2025, through September 30, 2026. This document is issued pursuant to section 744M(a)(2) and (c)(5) of the FD&C Act and describes the calculations used to set the OMUFA OMOR fees for FY 2026 in accordance with the directives in the statute.

II. Determination of FY 2026 OMOR Fees

For FY 2026, the Tier 1 OMOR fee is $587,529 and the Tier 2 OMOR fee is $117,505, including an adjustment for inflation (see sections 744M(a)(2)(A)(i) and (ii) of the FD&C Act,

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[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 (PL 119-37).

[2] 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);

[2] Under OMUFA, a Tier 1 OMOR is defined as any OMOR that is not a Tier 2 OMOR (see section 744L(8) of the FD&C Act). Tier 2 OMORs are detailed in section 744L(9) of the FD&C Act.

respectively). OMOR fees are not included in the OMUFA target revenue calculation, which is based on the facility fees (see section 744M(b) of the FD&C Act).

An OMOR fee is generally assessed to each person who submits an OMOR (see section 744M(a)(2)(A) of the FD&C Act). OMOR fees are due on the date of the submission of the OMOR (see section 744M(a)(2)(B) of the FD&C Act). The payor should submit the OMOR fee that applies to the type of OMOR they are submitting (i.e., Tier 1 or Tier 2). FDA will determine whether the appropriate OMOR fee has been submitted following receipt of the OMOR and the fee.

An OMOR fee will not be assessed if the OMOR seeks to make certain safety changes with respect to an OTC monograph drug. Specifically, no fee will be assessed if FDA finds that the OMOR seeks to change the drug facts labeling of an OTC monograph drug in a way that would add to or strengthen: (1) a contraindication, warning, or precaution; (2) a statement about risk associated with misuse or abuse; or (3) an instruction about dosage and administration that is intended to increase the safe use of the OTC monograph drug (see section 744M(a)(2)(C) of the FD&C Act).

III. OMOR Fee Adjustment for Inflation

The dollar amount of the inflation adjustment to the fee for OMORs for FY 2026 is equal to the product of the applicable fee for FY 2025 and the inflation adjustment percentage.[3] For FY 2026, the inflation adjustment percentage is equal to the sum of:

- The average annual percent change in the cost, per full-time equivalent (FTE) position at 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 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); and

[3] See section 744M(c)(1)(B) of the FD&C Act.

- 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 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 FTEs	18,474	18,729	19,687	
PC&B per FTE	$171,348	$183,486	192,601	
Percent Change from Previous Year	4.2967%	7.0838%	4.9677%	5.4494%

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

	2022	2023	2024	3-Year Average
Total PC&B	$25,415,237	$39,133,075	$41,579,890	
Total Costs	$49,644,273	$68,480,052	$68,176,240	
PC&B Percent	51.1947%	57.1452%	60.9888%	56.4429%

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.[4]

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

Year	2022	2023	2024	3-Year Average
Annual CPI	296.12	305.32	315.19	
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 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.

IV. OMOR Fee Calculations

Under section 744M(a)(2)(A) of the FD&C Act, each person that submits a qualifying OMOR shall be subject to a fee for an OMOR. The amount of such fee shall be:

(1) For a Tier 1 OMOR, $500,000, adjusted for inflation for the FY (see section 744M(a)(2)(A)(i) of the FD&C Act); and

(2) For a Tier 2 OMOR, $100,000, adjusted for inflation for the FY (see section 744M(a)(2)(A)(ii) of the FD&C Act).

In addition, under section 744M(c)(1)(B)(i) of the FD&C Act and for purposes of section 744M(a)(2) of the FD&C Act, the inflation adjustment for the FY 2026 OMOR fee shall be equal to the product of:

[4] The 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.

(1) the fee for FY 2025 under section 744M(a)(2) of the FD&C (as in effect during OMUFA I); and

(2) the inflation adjustment percentage under subparagraph (C) of section 744M(c)(1) of the FD&C Act.

Therefore, for FY 2026, the base of OMOR fees taken from the preceding FY (i.e., FY 2025) are: Tier 1: $559,777 and Tier 2: $111,955. The FY 2026 inflation adjustment percentage is: 4.9576 percent.

V. 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
OMOR:	
Tier 1	$587,529
Tier 2	$117,505

VI. Fee Payment Options and Procedures

The new OMOR fee rates are for the period from October 1, 2025, through September 30, 2026. To pay the OMOR fees, complete an OTC Monograph User Fee Cover Sheet, available at: https://userfees.fda.gov/OA_HTML/omufaCAcdLogin.jsp, and generate a user fee identification (ID) number. Payment must be made in U.S. currency drawn on a U.S. bank by electronic check or wire transfer, payable to the order of the Food and Drug Administration. The preferred payment method is online using electronic check (Automated Clearing House (ACH) also known as eCheck). FDA has partnered with the U.S. Department of the Treasury to utilize Pay.gov, a web-based payment application, for online electronic payment. The Pay.gov feature is available on the FDA website after completing the OTC Monograph User Fee Cover Sheet and generating the user fee ID number.

Secure electronic payments can be submitted using the User Fees Payment Portal at https://userfees.fda.gov/pay. (Note: Only full payments are accepted; no partial payments can

be made online). Once an invoice is located, "Pay Now" should be selected to be redirected to Pay.gov. Electronic payment options are based on the balance due.[5]

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, which could result in FDA not filing an OMOR request, or other consequences of nonpayment. 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.

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Acting Deputy Commissioner for Policy, Legislation, and International Affairs.

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[5] Payment by credit card is available for balances that are less than $25,000 (Discover, VISA, MasterCard, American Express). 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.