DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3001]

Over-the-Counter Monograph Drug User Fee Program—OTC Monograph Order Request Fee Rates for Fiscal Year 2025

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the over-the-counter (OTC) monograph order request (OMOR) fee rates under the OTC monograph drug user fee program (OMUFA) for fiscal year (FY) 2025. The Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes FDA to assess and collect user fees from qualifying manufacturers of OTC monograph drugs and submitters of OMORs. This notice publishes the OMOR fee rates under OMUFA for FY 2025. FDA plans to publish the FY 2025 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 OMUFA facility fee rate publication for prior fiscal years).

DATES: These OTC OMORs fees are effective on October 1, 2024, and will remain in effect through September 30, 2025.

FOR FURTHER INFORMATION CONTACT: 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 *OO-OFBAP-OFM-UFSS-Government@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Section 744M of the FD&C Act (21 U.S.C. 379j–72), authorizes FDA to assess and collect: (1) facility fees from qualifying owners of OTC monograph drug facilities and (2) fees from submitters of qualifying OTC monograph order requests. 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 various FDA activities associated with OTC monograph drugs.[1]

For OMUFA purposes, an OTC 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 2025, the OMUFA fee rates for OTC OMORs are: Tier 1 OMOR fees ($559,777), Tier 2 OMOR fees ($111,955). These fees are effective for the period from October 1, 2024, through September 30, 2025. This document is issued pursuant to section 744M(a)(2) and (c)(4)(B) of the FD&C Act and describes the calculations used to set the OMUFA OMOR fees for FY 2025 in accordance with the directives in the statute.

II. Determination of FY 2025 OMOR Fees

Under OMUFA, the FY 2025 Tier 1 OMOR fee is $559,777 and the Tier 2 OMOR fee is $111,955, including an adjustment for inflation (see sections 744M(a)(2)(A)(i) and (ii) 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

Under OMUFA, the OMOR fee is adjusted for inflation for FY 2022 and each subsequent FY (see section 744M(c)(1)(B) of the FD&C Act). That provision states that the dollar amount of the inflation adjustment to the fee for OMORs is equal to the product of the applicable fee for the preceding fiscal year and the inflation adjustment percentage.[3] For FY 2025, the inflation adjustment percentage is equal to the sum of:

- The average annual percent change in the cost, per full-time equivalent position of FDA, of all personnel compensation and benefits paid with respect to such positions for the first 3 years of the preceding 4 FYs, multiplied by the proportion of personnel compensation and benefits 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)(I) of the FD&C Act); and
- The average annual percent change that occurred in the Consumer Price Index for urban consumers (Washington-Baltimore, DC-MD-VA-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 personnel compensation and benefits 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)(II) of the FD&C Act).

As a result of a geographical revision made by the Bureau of Labor and Statistics in January 2018, the ''Washington, DC-Baltimore'' index was discontinued and replaced with two separate indices (*i.e.,* the ''Washington-Arlington-Alexandria'' and ''Baltimore-Columbia-Towson'' indices). To continue applying a CPI that best reflects the geographic region in which FDA is located and that provides the most current data available, the ''Washington-Arlington-Alexandria'' index is used in calculating the inflation adjustment percentage.

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

[1] 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.

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

percent changes over the first 3 of the 4 FYs preceding FY 2025. The 3-year average is 3.8539 percent.

TABLE 1—FDA PERSONNEL COMPENSATION AND BENEFITS (PC&B) EACH YEAR AND PERCENT CHANGES

	2021	2022	2023	3-Year average
Total PC&B	$3,039,513,000	$3,165,477,000	$3,436,513,000	.....
Total FTE	18,501	18,474	18,729	.....
PC&B per FTE	$164,289	$171,348	$183,486	.....
Percent Change from Previous Year	0.1811%	4.2967%	7.0838%	3.8539%

Under the statute, this 3.8539 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)(ii) 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

	2021	2022	2023	3-Year average
Total PC&B	$23,133,775	$25,415,237	$39,133,075	.....
Total Costs	$35,030,659	$49,644,273	$68,480,052	.....
PC&B Percent	66.0387%	51.1947%	57.1452%	58.1262%

The payroll adjustment is 3.8539 percent from table 1 multiplied by 58.1262 percent resulting in 2.2401 percent.

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

TABLE 3—ANNUAL AND 3-YEAR AVERAGE PERCENT CHANGE IN CPI FOR WASHINGTON-ARLINGTON-ALEXANDRIA, DC-VA-MD-WV AREA

Year	2021	2022	2023	3-Year average
Annual CPI	277.73	296.12	305.32	.....
Annual Percent Change	3.9568%	6.6212%	3.1069%	4.5616%

The statute specifies that this 4.5616 percent be multiplied by the proportion of all costs other than PC&B to total costs of OTC monograph drug activities. Because 58.1262 percent was obligated for PC&B (as shown in table 2), 41.8738 percent is the portion of costs other than PC&B (100 percent minus 58.1262 percent equals 41.8738 percent). The non-payroll adjustment is 4.5616 percent times 41.8738 percent, or 1.9101 percent.

Next, we add the payroll adjustment (2.2401 percent) to the non-payroll adjustment (1.9101 percent), for a total inflation adjustment of 4.1502 percent (rounded) for FY 2025.

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 OTC monograph order request, $500,000, adjusted for inflation for the FY (see section 744M(c)(1)(B) of the FD&C Act); and

(2) For a Tier 2 OTC monograph order request, $100,000, adjusted for inflation for the FY (see section 744M(c)(1)(B) of the FD&C Act).

In addition, under section 744M(c)(1)(B) of the FD&C Act and for purposes of section 744M(a)(2) of the FD&C Act, the dollar amount of the inflation adjustment to the fee for OMORs for FY 2022 and each subsequent FY shall be equal to the product of:

(1) The applicable fee under section 744M(a)(2) of the FD&C Act for the preceding FY; and

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

Thus, for FY 2025, the base of OMOR fees taken from the preceding FY (*i.e.,* FY 2024) are: Tier 1: $537,471 and Tier 2: $107,494. The FY 2025 inflation adjustment percentage is: 4.1502%.

V. Fee Schedule

The fee rates for FY 2025 are displayed in Table 4.

TABLE 4—FEE SCHEDULE FOR FY 2025

Fee category	FY 2025 fee rates
OMOR:	
Tier 1	$559,777
Tier 2	111,955

VI. Fee Payment Options and Procedures

The new OMOR fee rates are for the period from October 1, 2024, through September 30, 2025. To pay the OMOR fees, complete an OTC Monograph User Fee Cover Sheet, available at: *https://*

userfees.fda.gov/OA_HTML/omufaCAcdLogin.jsp.

A user fee identification (ID) number will be generated. Payment must be made in U.S. currency 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 use *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 through *https://userfees.fda.gov/pay.* 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. 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.

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. Applicable wire transfer fees must be included with payment to ensure fees are fully paid. Questions about wire transfer fees should be addressed to the financial institution. The account information for wire transfers is as follows: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No.: 75060099, Routing No.: 021030004, SWIFT: FRNYUS33. If needed, FDA's tax identification number is 53–0196965.

Dated: July 26, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3029]

Agency Information Collection Activities; Proposed Collection; Comment Request; FDA Food Safety and Nutrition Survey

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on a collection of information used to conduct a voluntary consumer survey entitled, ''FDA Food Safety and Nutrition Survey.''

DATES: Either electronic or written comments on the collection of information must be submitted by September 30, 2024.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 30, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2024–N–3029 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; FDA Food Safety and Nutrition Survey.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not