accept or review any abbreviated new drug application from Ms. Tatsene during her period of debarment, other than in connection with an audit under section 306 of the FD&C Act. Note that, for purposes of sections 306 and 307 of the FD&C Act, a ''drug product'' is defined as a ''drug subject to regulation under section 505, 512, or 802 of this Act [(21 U.S.C. 355, 360b, 382)] or under section 351 of the Public Health Service Act [(42 U.S.C. 262)]'' (section 201(dd) of the FD&C Act (21 U.S.C. 321(dd))).

Dated: September 7, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–19672 Filed 9–11–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–3573]

Over-the-Counter Monograph Drug User Fee Program—OTC Monograph Order Requests Fee Rates for Fiscal Year 2024

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) 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) 2024. 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 2024. FDA plans to publish the FY 2024 OMUFA 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 fees are effective on October 1, 2023, and will remain in effect through September 30, 2024.

FOR FURTHER INFORMATION CONTACT: Olufunmilayo Ariyo, Office of Financial Management, Food and Drug Administration, 4041 Powder Mill Rd., 6th Floor, Beltsville, MD 20705–4304, 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 monograph order request (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). Given that OMOR fees are due on the date of submission of the OMOR,[2] the Agency is publishing the OMOR fee rates for FY 2024 in advance of the fiscal year to ensure that applicable OMOR fee rates are available in the event that OMORs are submitted early in the fiscal year.[3]

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.[4]

For FY 2024, the OMUFA fee rates are: Tier 1 OMOR fees ($537,471), Tier 2 OMOR fees ($107,494). These fees are effective for the period from October 1, 2023, through September 30, 2024. This document is issued pursuant to sections 744M(a)(4) and 744M(c)(4)(B) of the FD&C Act and describes the calculations used to set the OMUFA OMOR fees for FY 2024 in accordance with the directives in the statute.

II. Determination of FY 2024 OMOR Fees

Under OMUFA, the FY 2024 Tier 1 OMOR fee is $537,471 and the Tier 2 OMOR fee is $107,494, 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 fiscal year (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.[5] For FY 2024, the inflation adjustment percentage is equal to the sum of

- (1) the average annual percent change in the cost, per full-time equivalent position of the FDA, of all personnel compensation and benefits paid with respect to such positions for the first 3 years of the preceding 4 fiscal years, 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 fiscal years (see section 744M(c)(1)(C)(ii)(I) of the FD&C Act); and
- (2) 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

[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] Section 744M(a)(2)(B) of the FD&C Act.

[3] The Agency anticipates a greater likelihood of OMOR submissions in FY 2024 compared to prior fiscal years.

[4] 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.

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

other than personnel compensation and benefits costs to total costs of OTC monograph drug activities for the first 3 years of the preceding 4 fiscal years (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 fiscal years, provides the percent changes from the previous fiscal years, and provides the average percent changes over the first 3 of the 4 fiscal years preceding FY 2024. The 3-year average is 3.9280 percent.

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

	2020	2021	2022	3-year average
Total PC&B	$2,875,592,000	$3,039,513,000	$3,165,477,000	
Total FTE	17,535	18,501	18,474	
PC&B per FTE	163,992	164,289	171,348	
Percent Change From Previous Year	7.3063	0.1811	4.2967	3.9280

Under the statute, this 3.9280 percent would be 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 fiscal years (see section 744M(c)(1)(C)(ii) of the FD&C Act). Because OMUFA was first authorized beginning with FY 2021, FDA used cost data of OTC monograph drug activities for the preceding 3 fiscal years (*i.e.,* FYs 2021–2023) to align with OMUFA's authorization. Because final FY 2023 spending data (total FDA PC&B costs and OTC monograph drug activities cost) were unavailable at the time of this fee rate notice, the Agency estimated final FY 2023 costs by using actual plus planned FY 2023 spending on PC&B costs and actual plus planned FY 2023 spending on OTC monograph drug activities cost. The above approach reflects FDA's application of the OMUFA inflation adjustment in a manner that aligns with initiation of the OMUFA user fee program and the need to make FY 2024 OMOR fee rates available in a timely manner, so that these fees can be assessed to support OTC monograph drug activities pursuant to the statute.[6]

Table 2 shows the PC&B and the total obligations for OTC monograph drug activities for the last 3 fiscal years.

TABLE 2—PC&B AS A PERCENT OF TOTAL COST OF OTC MONOGRAPH DRUG ACTIVITIES

	2021	2022	2023*	3-year average
Total PC&B	$23,133,775.00	$25,415,237.00	$28,622,100.47	
Total Costs	35,030,659.00	49,644,273.00	56,038,274.22	
PC&B Percent	66.0387	51.1947	51.0760	56.1031

*FY 2023 actual plus planned FY 2023 spending on PC&B costs to the actual plus planned FY 2023 spending on OTC monograph drug activities cost.

The payroll adjustment is 3.9280 percent from table 1 multiplied by 56.1031 percent resulting in 2.2037 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	2020	2021	2022	3-year average
Annual CPI	267.16	277.73	296.12	
Annual Percent Change	0.8989	3.9568	6.6212	3.8256

The statute specifies that this 3.8256 percent be multiplied by the proportion of all costs other than PC&B to total costs of OTC monograph drug activities. Because 56.1031 percent was obligated for PC&B (as shown in table 2), 43.8969 percent is the portion of costs other than PC&B (100 percent minus 56.1031 percent equals 43.8969 percent). The non-payroll adjustment is 3.8256 percent times 43.8969 percent, or 1.6793 percent.

Next, we add the payroll adjustment (2.2037 percent) to the non-payroll adjustment (1.6793 percent), for a total inflation adjustment of 3.8830 percent (rounded) for FY 2024.

IV. OMOR Fee Calculations

Under section 744M(a)(2)(A) of the FD&C Act, each person that submits a

[6] Under section 744M(f)(1) of the FD&C Act, OMUFA fees are authorized to support OTC monograph drug activities. Although authority for OMUFA fees (and the accompanying OMUFA definition of ''OTC monograph drug activities'') was enacted on March 27, 2020, under the CARES Act, OMUFA's first authorized program year was FY 2021.

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 fiscal year (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 fiscal year (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 fiscal year shall be equal to the product of:

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

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

Thus, for FY 2024, the base of OMOR fees taken from the preceding fiscal year (*i.e.,* FY 2023) are: Tier 1: $517,381 and Tier 2: $103,476. The FY 2024 inflation adjustment percentage is: 3.8830%.

V. Fee Schedule

The fee rates for FY 2024 are displayed in Table 4.

TABLE 4—FEE SCHEDULE FOR FY 2024

Fee category	FY 2024 fee rates
OMOR:	
Tier 1	$537,471
Tier 2	107,494

VI. Fee Payment Options and Procedures

The new OMOR fee rates are for the period from October 1, 2023, through September 30, 2024. 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) or credit card for payments under $25,000 (Discover, VISA, MasterCard, American Express).

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. 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: September 6, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–19609 Filed 9–11–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Initial Review Group; Clinical, Treatment and Health Services Research Study Section.

Date: October 4, 2023.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Health, National Institute on Alcohol Abuse and Alcoholism, 6700B Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Luis Espinoza, Ph.D., Scientific Review Officer, Extramural Project Review Branch, National Institute on Alcohol Abuse and Alcoholism, 6700B Rockledge Drive, Room 2109, Bethesda, MD 20817, (301) 443–8599, *espinozala@mail.nih.gov*.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel; NIAAA Fellowship Review Panel.

Date: October 24, 2023.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Health, National Institute on Alcohol Abuse and Alcoholism, 6700B Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Luis Espinoza, Ph.D., Scientific Review Officer, Extramural Project Review Branch, National Institute on Alcohol Abuse and Alcoholism, 6700B Rockledge Drive, Room 2109, Bethesda, MD 20817, (301) 443–8599, *espinozala@mail.nih.gov*.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel; NIAAA Special Emphasis Panel for Member Conflict Applications.

Date: October 31, 2023.

Time: 11:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Health, National Institute on Alcohol Abuse and Alcoholism, 6700B Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Luis Espinoza, Ph.D., Scientific Review Officer, Extramural Project Review Branch, National Institute on Alcohol Abuse and Alcoholism, 6700B Rockledge Drive, Room 2109, Bethesda, MD 20817, (301) 443–8599, *espinozala@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.273, Alcohol Research Programs, National Institutes of Health, HHS)

Dated: September 6, 2023.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–19564 Filed 9–11–23; 8:45 am]

BILLING CODE 4140–01–P