

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.

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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.

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