

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 2024, remain on the arrears list for failure to satisfy the FY 2022, FY 2023, or FY 2024 facility fee are likely to be placed on the FY 2025 arrears list as well.

In addition, the Agency made certain assumptions with respect to hand sanitizer manufacturers that remained registered after 12 a.m. Eastern Time on December 31, 2024, including that: (1) hand sanitizer manufacturers that have deregistered in eDRLS after December 31, 2024, have exited the market; (2) hand sanitizer manufacturers that did not actively update their registration in eDRLS during the FY 2025 fee liable period and let their registration lapse have likely exited the market; and (3) for the remaining hand sanitizer manufacturers that are newly fee liable, FDA estimated a portion will be in arrears based on a review of the prior 3-year average for newly registered facilities in arrears.

Based on the above-referenced factors and assumptions, FDA estimates there will be 1,134 OMUFA fee-paying units. The Agency estimates that 57 percent ( $1,134 \times 0.57 = 646$ , rounded) will incur the MDF fee and 43 percent ( $1,134 \times 0.43 = 488$ , 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 (646) and a value of  $\frac{2}{3}$  to each CMO ( $488 \times \frac{2}{3} = 325$ ) for a full facility equivalent of 971 (rounded). The target fee revenue of \$36,467,000 is then divided by 971 for an MDF fee of \$37,556 and a CMO fee of \$25,037.

#### IV. Fee Schedule for FY 2025

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

TABLE 4—FEE SCHEDULE FOR FY 2025

Fee category	FY 2025 fee rates
MDF .....	\$37,556
CMO .....	25,037

#### V. Fee Payment Options and Procedures

The new facility fee rates are for the period from October 1, 2024, through September 30, 2025. To pay the MDF and CMO fees, complete an OTC Monograph User Fee Cover Sheet, available at: [https://userfees.fda.gov/OA\\_HTML/omufacAcidLogin.jsp](https://userfees.fda.gov/OA_HTML/omufacAcidLogin.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.<sup>20</sup>

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 consequences of nonpayment per section 744M(e)(1) of the FD&C Act. 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.

If you are assessed an FY 2025 OMUFA facility fee and believe your facility is not an OTC monograph drug

<sup>20</sup> 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.

facility as described in this notice, please contact [CDERCollections@fda.hhs.gov](mailto:CDERCollections@fda.hhs.gov).

Dated: March 18, 2025.

**P. Ritu Nalubola,**

*Associate Commissioner for Policy.*

[FR Doc. 2025–04860 Filed 3–20–25; 8:45 am]

BILLING CODE 4164–01–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

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

The meeting 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 of Allergy and Infectious Diseases Allergy, Immunology, and Transplantation Research Committee (AITC) Special Emphasis Panel.

*Date:* April 18, 2025.

*Time:* 2:00 p.m. to 3:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, 3G47, Rockville, MD 20892.

*Meeting Format:* Video Assisted Meeting.

*Contact Person:* Vanitha S. Raman, Ph.D., Scientific Review Officer, Scientific Review Program, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, 3G47, Rockville, MD 20892, 301–761–7949, [vanitha.raman@nih.gov](mailto:vanitha.raman@nih.gov).

*Name of Committee:* National Institute of Allergy and Infectious Diseases Competitive Revision Supplements to Existing T32 Programs to Include Institutional Research Training in Data Science for Infectious and Immune Mediated Diseases Special Emphasis Panel.

*Date:* April 28, 2025.

*Time:* 10:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, 3G47, Rockville, MD 20892.

*Meeting Format:* Video Assisted Meeting.

*Contact Person:* Vanitha S. Raman, Ph.D., Scientific Review Officer, Scientific Review Program, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, 3G47, Rockville, MD 20892, 301-761-7949, [vanitha.raman@nih.gov](mailto:vanitha.raman@nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: March 17, 2025.

**Melanie J. Pantoja,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2025-04817 Filed 3-20-25; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

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

The meeting 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:* Microbiology, Infectious Diseases and AIDS Initial Review Group; Acquired Immunodeficiency Syndrome Research Study Section Acquired Immunodeficiency Syndrome Research Study Section (AIDS).

*Date:* April 23-24, 2025.

*Time:* 11:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3D32, Rockville, MD 20892 (Video Assisted Meeting).

*Contact Person:* Kristina Wickham, Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3D32, Rockville, MD 20892, 301-761-5390, [kristina.wickham@nih.gov](mailto:kristina.wickham@nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856,

Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: March 17, 2025.

**Melanie J. Pantoja,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

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**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

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

The meeting 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 of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; NIDDK RC2 REVIEW.

*Date:* April 15, 2025.

*Time:* 11:00 a.m. to 1:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Democracy II, Suite 7000A, 6707 Democracy Boulevard, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Elena Sanovich, Ph.D., Scientific Review Officer, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, 6707 Democracy Boulevard, Rm. 7351, Bethesda, MD 20892-2542, 301-594-8886, [sanoviche@mail.nih.gov](mailto:sanoviche@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: March 17, 2025.

**David W. Freeman,**

*Supervisory Program Analyst, Office of Federal Advisory Committee Policy.*

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**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

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

The meeting 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 of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Metabolic Dysregulation in Diabetes.

*Date:* April 28, 2025.

*Time:* 11:00 a.m. to 1:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Democracy II, Suite 7000A, 6707 Democracy Boulevard, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Elena Sanovich, Ph.D., Scientific Review Officer, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, 6707 Democracy Boulevard, Rm. 7351, Bethesda, MD 20892-2542, 301-594-8886, [sanoviche@mail.nih.gov](mailto:sanoviche@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: March 17, 2025.

**David W. Freeman,**

*Supervisory Program Analyst, Office of Federal Advisory Committee Policy.*

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**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Eye Institute; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as