2021 and FY 2022 OMUFA fees (respectively),[10] [11] facilities are not identified as an ''OTC monograph drug facility'' and will not be assessed a FY 2023 OMUFA facility fee if they: (1) were not registered with FDA as OTC drug manufacturers prior to the HHS declaration of the COVID–19 public health emergency on January 27, 2020; [12] (2) registered with FDA on or after the declaration of the COVID–19 public health emergency; and (3) registered for the sole purpose of producing hand sanitizer products during the COVID–19 public health emergency. We note, however, that under the FD&C Act, whether an entity is subject to OMUFA fees has no bearing on whether the entity or the entity's products are subject to other requirements under the FD&C Act. FDA will continue to use its regulatory compliance and enforcement tools to protect consumers, including from potentially dangerous or subpotent hand sanitizers.

In undertaking the statutorily directed fee calculations, the Agency also made certain assumptions, including that: (1) facilities using expired Structured Product Labeling (SPL) codes in eDRLS, that did not reregister for calendar year 2023, were no longer manufacturing and marketing OTC monograph drugs; (2) facilities that have deregistered in eDRLS have exited the market; (3) facilities that FDA believes registered incorrectly as OTC monograph drug facilities (for example, because the associated drug listings for these facilities did not include OTC monograph drugs but instead indicated such products as OTC drug products under an approved drug application or OTC animal drug products) were not engaged in manufacturing or processing 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; and (5) facilities that, at the close of FY 2022, remain on the arrears list for failure to satisfy the FY 2021 or FY 2022 facility fee are likely to be placed on the FY 2023 arrears list as well.

Based on the above-referenced factors and assumptions, FDA estimates there will be 1,122 OMUFA fee-paying units. The Agency estimates that 60 percent ($1,122 \times 0.60 = 673$, rounded) will incur the MDF fee and 40 percent ($1,122 \times 0.40 = 449$, 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 (673) and a value of ⅔ to each CMO ($449 \times ⅔ = 299$) for a full facility equivalent of 972 (rounded). The target fee revenue of $25,421,000 is then divided by 972 for an MDF fee of $26,153 and a CMO fee of $17,435.

V. Fee Schedule for FY 2023

The fee rates for FY 2023 are displayed in table 2.

TABLE 2—FEE SCHEDULE FOR FY 2023

Fee category	FY 2023 fee rates
OMOR:	
Tier 1	$517,381
Tier 2	103,476
Facility Fees:	
MDF	26,153
CMO	17,435

VI. Fee Payment Options and Procedures

The new fee rates are for the period from October 1, 2022, through September 30, 2023. To pay the OMOR, MDF, and CMO 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.

If you are assessed an FY 2023 OMUFA facility fee and believe your facility is not an OTC monograph drug facility as described in this notice, please contact *CDERCollections@fda.hhs.gov.*

Dated: March 22, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–06299 Filed 3–24–23; 8:45 am]

BILLING CODE 4164–01–P

[11] See 87 FR 14888, *https://www.federalregister.gov/documents/2022/03/16/2022-05542/over-the-counter-monograph-drug-user-fee-rates-for-fiscal-year-2022.*

[12] See *https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health and Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting of the National Institute of Child Health and Human Development Special Emphasis Panel.

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 Child Health and Human Development Special Emphasis Panel; Prevention and Treatment through a Comprehensive Care Continuum for HIV-affected Adolescents in Resource Constrained Settings Implementation Science Network (PATC[3]H–IN) Clinical Research Centers.

Date: May 1, 2023.

Closed: 9:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Room 2131B, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Luis E. Dettin, Ph.D., MS, MA, Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute, of Child Health and Human Development, National Institutes of Health ,6710B Rockledge Drive, Room 2131B, Bethesda, MD 20892, 301–827–8231, *luis_dettin@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.865, Research for Mothers and Children, National Institutes of Health, HHS)

Dated: March 21, 2023.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–06232 Filed 3–24–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

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

Pursuant to section 10(d) 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 on Alcohol Abuse and Alcoholism Initial Review Group; Neuroscience and Behavior Study Section.

Date: June 13, 2023.

Time: 9:00 a.m. to 5:00 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.

Contact Person: Beata Buzas, Ph.D., Scientific Review Officer, Extramural Project Review Branch, Office of Extramural Activities, National Institute on Alcohol Abuse and Alcoholism, 6700B Rockledge Drive, Room 2116, Bethesda, MD 20892, 301–443–0800, *bbuzas@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research and Research Support Awards., National Institutes of Health, HHS)

Dated: March 21, 2023.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–06238 Filed 3–24–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Meeting

Notice is hereby given of a change in the meeting of the Sleep Disorders Research Advisory Board, April 6, 2023, 12 p.m. to 5 p.m., and April 7, 2023, 9 a.m. to 2 p.m., National Institutes of Health, Two Rockledge Centre, Rockledge I, 6705 Rockledge Drive, Bethesda, MD 20892 which was published in the **Federal Register** on March 16, 2023, 88 FRN 16275.

This notice is being amended to change the meeting start time for April 6, 2023 from 12:00 p.m. to 1:00 p.m. Also, the in person location is amended for both days to Two Rockledge Centre, 6701 Rockledge Drive, Suite 260, Bethesda, MD 20817.

Dated: March 20, 2023.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–06085 Filed 3–24–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2023–0179]

National Towing Safety Advisory Committee; April 2023 Meeting

AGENCY: U.S. Coast Guard, Department of Homeland Security.

ACTION: Notice of Federal Advisory Committee meeting.

SUMMARY: The National Towing Safety Advisory Committee (Committee) will meet to review and discuss matters relating to shallow-draft inland navigation, coastal waterway navigation, and towing safety. The meeting will be open to the public.

DATES:

Meeting: The Committee will hold a meeting on Wednesday, April 12, 2023, from 8 a.m. until 5 p.m. Eastern Daylight Time (EDT). Please note the meeting may close early if the Committee has completed its business.

Comments and supporting documentation: To ensure your comments are received by Committee members before the meeting, submit your written comments no later than March 29, 2023.

ADDRESSES: The meeting will be held at the Crowley Maritime Corporation Headquarters located at 9487 Regency Square Boulevard, Jacksonville, FL 32225 *(https://www.crowley.com/?utm_source=gmb&utm_medium=jacksonville&utm_campaign=corporate&utm_content=office).*

The National Towing Safety Advisory Committee is committed to ensuring all participants have equal access regardless of disability status. If you require reasonable accommodation due to a disability to fully participate, please email Mr. Matthew D. Layman at *Matthew.D.Layman@uscg.mil* or call at 202–372–1421 as soon as possible.

Instructions: You are free to submit comments at any time, including orally at the meeting as time permits, but if you want Committee members to review your comment before the meeting, please submit your comments no later than March 29, 2023. We are particularly interested in comments regarding the topics in the ''Agenda'' section below. We encourage you to submit comments through Federal eRulemaking Portal at *https://www.regulations.gov.* If your material cannot be submitted using *https://www.regulations.gov,* call or email the individual in the **FOR FURTHER**