

MD 20993-0002, letise.williams@fda.hhs.gov, 301-796-8398, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last-minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at <https://www.fda.gov/advisory-committees> and scroll down to the appropriate advisory committee meeting link or call the advisory committee information line to learn about possible modifications before the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. On September 6, 2023, the Committee will discuss and make recommendations on the topic of "Advancing Health Equity in Medical Devices." FDA CDRH is committed to working toward ensuring that all patients have access to high-quality, safe, and effective medical devices. This includes ensuring devices are designed to be safe and effective when used by various populations, are evaluated in the diverse populations for which they are intended, and that patients and consumers have the information they need to make decisions about their health, care and quality of life. Technology, including digital health technology, may help bridge gaps in health equity by extending access and bringing healthcare to patients at home, at work, and in their communities. The recommendations provided by the committee will address considerations for FDA and industry on these topics. The Committee will consider ways to advance access to devices that allow for care outside a hospital or clinical care setting—for example, in the home setting. The Committee will also discuss considerations for improving reach and comprehension of FDA's patient and caregiver communications across diverse demographic groups. Additionally, the Committee will discuss patient-focused considerations for when a device should be evaluated in diverse populations to support marketing authorization.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's

website at the time of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background materials and the link to the online teleconference meeting room will be available at <https://www.fda.gov/advisory-committees/committees-and-meeting-materials/patient-engagement-advisory-committee>. Select the link for the 2023 Meeting Materials. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person (see **FOR FURTHER INFORMATION CONTACT**) on or before August 10, 2023. Oral presentations from the public will be scheduled on September 6, 2023, between approximately 2:15 p.m. to 3:15 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person on or before August 2, 2023. The notification should include a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by August 3, 2023.

For press inquiries, please contact the Office of Media Affairs at fdaoma@fda.hhs.gov or 301-796-4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact AnnMarie Williams at Annmarie.Williams@fda.hhs.gov, or 240-507-6496 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/advisory-committees/about-advisory-committees/public-conduct-during-fda-advisory-committee-meetings> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: May 15, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023-10609 Filed 5-17-23; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the National Vaccine Advisory Committee

AGENCY: Office of Infectious Disease and HIV/AIDS Policy, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that the National Vaccine Advisory Committee (NVAC) will hold an in-person meeting. The meeting will be open to the public and public comment will be heard during the meeting.

DATES: The meeting will be held June 15-16, 2023. The confirmed meeting times and agenda will be posted on the NVAC website at <http://www.hhs.gov/nvpo/nvac/meetings/index.html> as soon as they become available.

ADDRESSES: Instructions regarding attending this meeting will be posted online at: <http://www.hhs.gov/nvpo/nvac/meetings/index.html> at least one week prior to the meeting. Pre-registration is required for those who wish to attend the meeting virtually or participate in public comment. Please register at <http://www.hhs.gov/nvpo/nvac/meetings/index.html>.

FOR FURTHER INFORMATION CONTACT: Ann Aikin, Acting Designated Federal Officer, Office of Infectious Disease and HIV/AIDS Policy, U.S. Department of Health and Human Services, Tower Building, Room, 1101 Wootton Parkway, Rockville, MD 20852. Email: nvac@hhs.gov. Phone: 202-795-7697.

SUPPLEMENTARY INFORMATION: Pursuant to section 2101 of the Public Health Service Act (42 U.S.C. 300aa-1), the Secretary of HHS was mandated to establish the National Vaccine Program to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines. The NVAC was established to provide advice and make recommendations to the Director of the

National Vaccine Program on matters related to the Program's responsibilities. The Assistant Secretary for Health serves as Director of the National Vaccine Program.

During this meeting, NVAC will hear presentations to support the recent charges on innovation and safety from Admiral Rachel L. Levine, MD, the Assistant Secretary for Health and Director of the National Vaccine Program. NVAC will also hear presentations on vaccine safety, antimicrobial resistance, pandemic preparedness, and routine immunization. Please note that agenda items are subject to change, as priorities dictate. Information on the final meeting agenda will be posted prior to the meeting on the NVAC website: <http://www.hhs.gov/nvpo/nvac/index.html>.

Members of the public will have the opportunity to provide comment at the NVAC meeting during the public comment period designated on the agenda. Public comments made during the meeting will be limited to three minutes per person to ensure time is allotted for all those wishing to speak. Individuals are welcome to submit written comments in advance. Written comments should not exceed three pages in length. Individuals submitting comments should email their written comments or their request to provide a comment during the meeting to nvac@hhs.gov at least five business days prior to the meeting.

Dated: May 10, 2023.

Ann Aikin,

Acting Designated Federal Official, Office of the Assistant Secretary for Health.

[FR Doc. 2023-10635 Filed 5-17-23; 8:45 am]

BILLING CODE 4150-44-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 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 on Alcohol Abuse and Alcoholism Special Emphasis Panel; NIAAA Member Conflict Applications.

Date: June 14, 2023.

Time: 1:00 p.m. to 4:00 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: 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, MSC 6902, Bethesda, MD 20892, (301) 443-0800, bbuzas@mail.nih.gov.

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

Dated: May 15, 2023.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023-10655 Filed 5-17-23; 8:45 am]

BILLING CODE 4140-01-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 Special Emphasis Panel; NIAID Investigator Initiated Program Project Applications (P01 Clinical Trial Not Allowed).

Date: June 14, 2023.

Time: 11:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F52, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Lindsey M. Pujanandez, Ph.D., 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 3F52, Rockville, MD 20852, (240) 627-3206, lindsey.pujanandez@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: May 12, 2023.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023-10615 Filed 5-17-23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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: Center for Scientific Review Special Emphasis Panel; Mechanisms of Cancer Therapeutics C.

Date: June 15-16, 2023.

Time: 8:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The Watergate, 2650 Virginia Avenue NW, Washington, DC 20037.

Contact Person: Gloria Huei-Ting Su, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301-496-0465, gloria.su@nih.gov.

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group; Neural Basis of Psychopathology, Addictions and Sleep Disorders Study Section.

Date: June 15-16, 2023.

Time: 9:00 a.m. to 7:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).