

Dated: July 30, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–17103 Filed 8–1–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–0008]

Advisory Committee; Psychopharmacologic Drugs Advisory Committee; Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of Federal advisory committee.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the renewal of the Psychopharmacologic Drugs Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Psychopharmacologic Drugs Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the June 4, 2026, expiration date.

DATES: Authority for the Psychopharmacologic Drugs Advisory Committee will expire on June 4, 2026, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Joyce Frimpong, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–7973, email: PDAC@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102–3.65 and approval by the Department of Health and Human Services and by the General Services Administration, FDA is announcing the renewal of the Psychopharmacologic Drugs Advisory Committee (the Committee). The Committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which FDA has regulatory responsibility.

The Committee reviews and evaluates data concerning the safety and effectiveness of marketed and

investigational human drug products for use in the practice of psychiatry and related fields and makes appropriate recommendations to the Commissioner of Food and Drugs.

Pursuant to its Charter, the Committee shall consist of a core of nine voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of psychopharmacology, psychiatry, epidemiology or statistics, and related specialties. Members will be invited to serve for overlapping terms of up to 4 years. Non-Federal members of this committee will serve as Special Government Employees or representatives. Federal members will serve as Regular Government Employees or Ex-Officios. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting representative member who is identified with industry interests. There may also be an alternate industry representative.

The Commissioner or designee shall have the authority to select members of other scientific and technical FDA advisory committees (normally not to exceed 10 members) to serve temporarily as voting members and to designate consultants to serve temporarily as voting members when: (1) expertise is required that is not available among current voting standing members of the Committee (when additional voting members are added to the Committee to provide needed expertise, a quorum will be based on the combined total of regular and added members), or (2) to comprise a quorum when, because of unforeseen circumstances, a quorum is or will be lacking. Because of the size of the Committee and the variety in the types of issues that it will consider, FDA may, in connection with a particular committee meeting, specify a quorum that is less than a majority of the current voting members. The Agency's regulations (21 CFR 14.22(d)) authorize a committee charter to specify quorum requirements.

If functioning as a medical device panel, an additional non-voting representative member of consumer interests and an additional non-voting representative member of industry interests will be included in addition to the voting members.

Further information regarding the most recent charter and other information can be found at <https://www.fda.gov/advisory-committees/human-drug-advisory-committees/psychopharmacologic-drugs-advisory-committee> or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*). For general information related to FDA advisory committees, please visit us at <http://www.fda.gov/AdvisoryCommittees/default.htm>.

Dated: July 30, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–17089 Filed 8–1–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Scientific Advisory Committee on Alternative Toxicological Methods; Notice of Public Meeting; Request for Public Input

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This notice announces the next meeting of the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM). SACATM is a federally chartered external advisory group of scientists from the public and private sectors, including representatives of regulated industry and national animal protection organizations. SACATM advises the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), the National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM), and the Director of the National Institute of Environmental Health Sciences (NIEHS) and NTP regarding statutorily mandated duties of ICCVAM and activities of NICEATM.

DATES:

Meeting: September 17, 2024, 10 a.m. to approximately 4 p.m. EDT; September 18, 2024, 9:30 a.m. to approximately 4 p.m. EDT.

Registration for Onsite Meeting:
Deadline is September 11, 2024, 5 p.m. EDT.

Registration for Webcast Viewing:
Deadline is September 18, 2024, 4 p.m. EDT.

Registration for Oral Statements:
Deadline is September 11, 2024, 5 p.m. EDT.

Registration to attend in person, view the webcast, and present oral public statements is required.

ADDRESSES: Interested individuals may attend the meeting in person or view the meeting webcast. Registration is required to attend in person, view the webcast, and/or present oral comments. Written public comments will be accepted. Information about the meeting and registration are available at <https://ntp.niehs.nih.gov/go/32822>.

Meeting Location: Building 35A, Room 620/630, National Institutes of Health (NIH), 35 Convent Dr., Bethesda, MD 20892.

Meeting Web Page: The preliminary agenda, registration, and other meeting materials will be available at <https://ntp.niehs.nih.gov/go/32822>.

Virtual Meeting: A link to access the meeting webcast will be emailed to registrants with their registration confirmation.

FOR FURTHER INFORMATION CONTACT: Dr. Milene Brownlow, Designated Federal Officer for SACATM, Office of Policy, Review, and Outreach, Division of Translational Toxicology, NIEHS. Phone: 984-287-3364, Email: milene.brownlow@nih.gov.

SUPPLEMENTARY INFORMATION:

Meeting and Registration: SACATM will provide input to ICCVAM, NICEATM, and NIEHS on programmatic activities and issues. Preliminary agenda items for the upcoming meeting include: (1) a review of the 2022–2023 ICCVAM Biennial Progress Report with a focus on activity gaps and future directions; (2) updates on validation and consideration of the new approach methodologies pipeline; (3) ICCVAM agency activities in the area of developmental neurotoxicity; and (4) update on NICEATM computational resources.

The preliminary agenda, roster of SACATM members, background materials, public comments, and any additional information will be posted when available on the SACATM meeting web page (<https://ntp.niehs.nih.gov/go/32822>) or may be requested from the Designated Federal Officer for SACATM. Individuals are encouraged to visit this web page often to stay abreast of the most current information regarding the meeting. Following the

meeting, summary minutes will be prepared and made available on the SACATM meeting web page. Slides and video from the meeting will also be posted on this page once they have been formatted to meet government accessibility standards.

This meeting is open to the public. The public may attend the meeting at NIH, where attendance is limited only by the space available, or view remotely by webcast. Those planning to attend the meeting in person are encouraged to register at <https://ntp.niehs.nih.gov/go/32822> by September 11, 2024, to facilitate planning for appropriate meeting space. Those planning to view the webcast may register at <https://ntp.niehs.nih.gov/go/32822> any time before the meeting ends on September 18, 2024. A link to access the meeting webcast will be provided to registrants in a confirmation email.

NIH visitor and security information is available at <https://www.nih.gov/about-nih/visitor-information>. Individuals with disabilities who need accommodation to participate in this event should contact Robbin Guy at phone: 984-287-3136 or email: robbin.guy@nih.gov. TTY users should contact the Federal TTY Relay Service at 800-877-8339. Requests should be made at least five business days in advance of the event.

Request for Public Comments: The preliminary agenda allows for several public comment periods, each allowing up to six commenters a maximum of five minutes per speaker. Registration for those wishing to provide oral public comments is required and is open through September 11, 2024, 5 p.m. EDT, at <https://ntp.niehs.nih.gov/go/32822>. Registration is on a first-come, first-served basis. If the maximum number of speakers per comment period is exceeded, individuals registering to submit an oral comment for the topic will be placed on a wait list and notified should an opening become available. Commenters will be notified after September 11, 2024, to provide logistical information for their presentations. Submitters will be identified by their name and affiliation and/or sponsoring organization, if applicable. If possible, oral public commenters should send a copy of their slides and/or statement or talking points to Robbin Guy by email: robbin.guy@nih.gov by September 11, 2024, 5 p.m. EDT.

Written statements on topics relevant to ICCVAM's mission may be submitted to support an oral public comment or as standalone documents. These should be emailed to Robbin Guy at robbin.guy@nih.gov by September 11, 2024, 5 p.m.

EDT. Materials submitted to accompany oral public statements or standalone written statements should include the submitter's name, affiliation (if any), mailing address, telephone, email, and sponsoring organization (if any) with the document. Guidelines for public statements are at http://ntp.niehs.nih.gov/ntp/about_ntp/guidelines_public_comments_508.pdf.

Responses to this notice are voluntary. No proprietary, classified, confidential, or sensitive information should be included in statements submitted in response to this notice or presented during the meeting. This request for input is for planning purposes only and is not a solicitation for applications or an obligation on the part of the U.S. Government to provide support for any ideas identified in response to the request. Please note that the U.S. Government will not pay for the preparation of any information submitted or for its use of that information.

Background Information on ICCVAM, NICEATM, and SACATM: ICCVAM is an interagency committee composed of representatives from 18 federal regulatory and research agencies that require, use, generate, or disseminate toxicological and safety testing information. ICCVAM conducts technical evaluations of new, revised, and alternative safety testing methods and integrated testing strategies with regulatory applicability. ICCVAM also promotes the scientific validation and regulatory acceptance of testing methods that more accurately assess the safety and hazards of chemicals and products and replace, reduce, or refine animal use.

The ICCVAM Authorization Act of 2000 (42 U.S.C. 285l-3) establishes ICCVAM as a permanent interagency committee of the National Institute of Environmental Health Sciences and provides the authority for ICCVAM involvement in activities relevant to the development of alternative test methods. Additional information about ICCVAM can be found at <https://ntp.niehs.nih.gov/go/iccvam>.

NICEATM administers ICCVAM, provides scientific and operational support for ICCVAM-related activities, and conducts and publishes analyses and evaluations of data from new, revised, and alternative testing approaches. NICEATM and ICCVAM work collaboratively to evaluate new and improved testing approaches applicable to the needs of U.S. federal agencies. NICEATM and ICCVAM welcome the public nomination of new, revised, and alternative test methods and strategies for validation studies and

technical evaluations. Additional information about NICEATM can be found at <https://ntp.niehs.nih.gov/go/niceatm>.

SACATM, established by the ICCVAM Authorization Act [Section 285I-3(d)], provides advice on priorities and activities related to the development, validation, scientific review, regulatory acceptance, implementation, and national and international harmonization of new, revised, and alternative toxicological test methods to ICCVAM, NICEATM, and Director of NIEHS and NTP. SACATM is governed by the provisions of the Federal Advisory Committee Act, as amended (5 U.S.C. ch.10), which sets forth standards for the formation and use of advisory committees.

Additional information about SACATM, including link to the charter, roster, and records of past meetings, can be found at <http://ntp.niehs.nih.gov/go/167>.

Dated: July 30, 2024.

Richard P. Woychik,

Director, National Institute of Environmental Health Sciences and National Toxicology Program, National Institutes of Health.

[FR Doc. 2024-17099 Filed 8-1-24; 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: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Clinical Trial Implementation Cooperative Agreement (U01 Clinical Trial Required).

Date: August 29, 2024.

Time: 10:00 a.m. to 1:00 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 3E71, Rockville, MD 20892 (Video Assisted Meeting).

Contact Person: Samita S. Andreansky, 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 3E71, Rockville, MD 20852, 240-669-2915, samita.andreansky@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: July 29, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024-17048 Filed 8-1-24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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: Center for Scientific Review Special Emphasis Panel; Biomedical Technology Optimization and Dissemination Center (BTOD).

Date: September 26, 2024.

Time: 10:00 a.m. to 8:30 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Joseph Thomas Peterson, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4118, MSC 7814, Bethesda, MD 20892, 301-408-9694, petersonjt@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844,

93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: July 29, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024-17049 Filed 8-1-24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Collaboration Opportunity for Combination of Vaccine With Adoptive Cell Therapies Made at NCI for the Treatment of Solid Cancers

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The Surgery Branch (SB) at the National Cancer Institute (NCI), is seeking a partner in the private sector to provide Good Manufacturing Practice-grade vaccine directed against cancer neo-antigens with the goal of conducting a Phase-I human clinical trial for solid cancers.

FOR FURTHER INFORMATION CONTACT:

Inquiries relating to this collaboration opportunity should be directed to: Aida Cremesti, Ph.D., Senior Technology Transfer Manager, NCI Technology Transfer Center, Telephone: (240) 276-5530; Email: aida.cremesti@mail.nih.gov. Inquiries related to licensing the related technology E-046-2022 should be directed to: Andrew Burke, Ph.D., Senior Technology Transfer Manager, NCI Technology Transfer Center, Telephone: (240)-276-5484; Email: andy.burke@nih.gov.

SUPPLEMENTARY INFORMATION:

Collaboration Opportunity Summary

The Surgery Branch (SB) at the National Cancer Institute (NCI), under the direction of Dr. Steven Rosenberg, is seeking a partner in the private sector to provide a GMP-grade vaccine directed against cancer neo-antigens, either private (patient-specific neo-antigens) or shared common tumor antigens (such as KRAS or P-53), with the goal of conducting a Phase-I human clinical trial for solid cancers. The trial would involve the combination of NCI-engineered cell therapies with a vaccine to be provided by the partner. The NCI SB has extensive expertise in the latest technology of tumor infiltrating lymphocyte (TIL) development, as well as T-Cell Receptor (TCR)-transduced Peripheral Blood Lymphocytes (PBL) development using NCI proprietary