advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. The committee will discuss supplemental new drug applications 210793–s008 and 207318–s011, efficacy supplement resubmission for NUPLAZID (pimavanserin) tablets, submitted by Acadia Pharmaceuticals Inc., for the proposed treatment of hallucinations and delusions associated with Alzheimer's disease psychosis.

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. Background material and the link to the online teleconference meeting room will be available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link. 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. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before June 3, 2022, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 2 p.m. and 3 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person and submit 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 on or before May 25, 2022. 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 May 26, 2022.

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 Joyce Frimpong (see **FOR FURTHER INFORMATION CONTACT**) 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/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* 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: April 27, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–09433 Filed 5–2–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Substance Abuse and Mental Health Services Administration (SAMHSA)

Statement of Organization, Functions, and Delegations of Authority

AGENCY: SAMHSA, HHS.

ACTION: Notice.

SUMMARY: The Substance Abuse and Mental Health Services Administration has modified its structure. This new organizational structure was approved by the Deputy Secretary of Health and Human Services and effective on April 14, 2022.

FOR FURTHER INFORMATION CONTACT: Robert T. Atanda, Ph.D., Director, Division of Management Services, Office of Management, Technology, and Operations, Substance Abuse and Mental Health Services Administration, Parklawn Building, Room 12E49, 5600 Fishers Lane, Rockville, MD 20857, Phone: 240–276–2826.

Part M of the Substance Abuse and Mental Health Services Administration (SAMHSA) Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (DHHS) at 73, Number 147, pages 44274–44275, July 30, 2008, is amended to reflect the new functional statement for the Office of the Assistant Secretary for Mental Health and Substance Use (OAS). This notice identifies a new Office of 988 and Behavioral Health Crisis Coordination (988) and Office of Recovery (OR). This change allows innovative prevention implementation. The changes are as follows:

Section M.20, Functions is amended as follows:

The functional statement for the Office of the Assistant Secretary is amended to name a new Office of 988 and Behavioral Health Crisis Coordination (988) and Office of Recovery (OR). The functional statement for each office is as follows:

Office of 988 and Behavioral Health Crisis Coordination

(1) 988 (988 is the dialing code for the National Suicide Prevention Lifeline) provides leadership in planning, implementing, and evaluating the office's goals, priorities, policies, and programs, and is the focal point for the Department's efforts on 988 and Behavioral Health Crisis Coordination; (2) plans, directs, and provides overall administration of the programs of the office; (3) conducts and coordinates office interagency, interdepartmental, and intergovernmental activities; (4) provides information to the public and constituent organizations on 988 and Behavioral Health Crisis Coordination activities; (5) maintains liaison with national organizations, other Federal departments/agencies, and with other SAMHSA Centers and Offices; (6) administers internal and external committee management (7) conducts services quality and financing activities and coordinates these activities with other components in SAMHSA; and (8) works with SAMHSA's Labor and Employee Relation staff to monitor the conduct of equal employment opportunity activities of the Office of 988 and Behavioral Health Crisis Coordination.

Office of Recovery

Recovery from substance use and/or mental health disorders is a life journey that allows individuals to change by improving their health and wellness. The Office of Recovery (OR): (1) Provides leadership in the identification of new and emerging issues related to recovery support services in major SAMHSA programs (2) provides leadership, coordination, and direction in the development and implementation of the Office of Recovery goals and priorities, and serves as the focal point for the Department's efforts on recovery support services; (3) plans, directs, and provides overall administration of the programs and activities of the Office of Recovery; (4) manages special projects

and external liaison activities; and (5) directs Office of Recovery's overall human resource activities and works with SAMHSA's Labor and Employee Relations staff to monitor the conduct of equal employment opportunity activities for the Office of Recovery.

Office of the Assistant Secretary for Mental Health and Substance Use (MA)

The Office of the Assistant Secretary for Mental Health and Substance Use (OAS): (1) Maintains a system to disseminate research findings and evidence-based practices to service providers to improve treatment and prevention services and incorporate these findings into SAMHSA programs; (2) ensures that grants are subject to performance and outcome evaluations and that center directors consistently document the grant process and conduct ongoing oversight of grantees; (3) consults with stakeholders to improve community-based and other mental health services, including adults with a serious mental illness (SMI), and children with a serious emotional disturbance (SED); (4) collaborates with other federal departments, including the Departments of Defense (DOD), Veterans Affairs (VA), Housing and Urban Development (HUD), and Labor (DOL) to improve care for veterans and service members, and support programs to address chronic homelessness; and (5) works with stakeholders to improve the recruitment and retention of mental health and substance use disorder professionals. In addition, the OAS provides leadership in the development of agency policies and programs, and maintains a close working relationship and coordination with Congress, other operating and staff divisions within the Department of Health and Human Services, and external Federal and private sector entities.

The OAS consists of the Office of Intergovernmental and External Affairs, the Office of Behavioral Health Equity and Justice-Involved, the Office of Tribal Affairs and Policy/Office of Indian Alcohol and Substance Abuse, and the Office of the Chief Medical Officer.

Office of Intergovernmental and External Affairs (MAC)

The Office of Intergovernmental and External Affairs (OIEA) serves as the central point for providing leadership and coordination in establishing and maintaining a collaborative effort between SAMHSA, other government agencies, and service providers in order to improve behavioral health outcomes. The Office is SAMHSA's lead for institutional and intergovernmental communication and coordination. As such, the Office: (1) Ensures that critical information from the field is incorporated into all policy activities and shared broadly across SAMHSA to support program development and implementation; (2) establishes and sustains relationships between SAMHSA and key stakeholders in other government agencies and institutions; (3) ensures that SAMHSA's policies are effectively communicated to Regional and National stakeholders; and, (4) meets routinely with staff from Centers and Offices to discuss program policy issues, seek input, and review progress.

Office of Behavioral Health Equity and Justice-Involved (MACA)

The Office of Behavioral Health Equity and the Justice-Involved (OBHEJI) coordinates agency efforts to ensure that racial and ethnic minority, underserved, and criminal justice-involved populations have equitable access to high quality behavioral health care. Functions of the office include: (1) Strengthening SAMHSA's capacity, through its grant programs and technical assistance efforts, to address the behavioral health needs of minority, underserved and justice involved populations; (2) enhancing measurement and data strategies to identify, assess and respond to the behavioral health challenges for these populations; (3) promoting policy initiatives that strengthen SAMHSA's programs and the broader field in improving the behavioral health of the underserved and the justice-involved; and, (4) expanding the behavioral health workforce capacity to improve outreach, engagement and quality of care.

Office of Tribal Affairs and Policy/ Office of Indian Alcohol and Substance Abuse (MACB)

The Office of Tribal Affairs and Policy (OTAP)/Office of Indian Alcohol and Substance Abuse (OIASA) coordinates federal partners and provides tribes with technical assistance and resources to develop and enhance prevention and treatment programs for substance use disorders, including the misuse of alcohol. The Office serves as the agency's primary point of contact for tribal governments, tribal organizations, and federal agencies on behavioral health issues that impact tribal communities.

OTAP/OIASA is charged with aligning, leveraging, and coordinating federal agencies and departments in carrying out SAMHSA's responsibilities delineated in the Tribal Law and Order Act (TLOA). This effort is overseen through the Indian Alcohol and Substance Abuse (IASA) Interdepartmental Coordinating Committee, which is comprised of more than 60 members representing a range of federal agencies and departments.

Health Financing and Policy Branch (MACC)

Leads the Health Financing and Policy efforts on behalf of the Agency. Maintains relationships with the Centers for Medicare & Medicaid Services (CMS), Public, and Commercial insurance sector to ensure Agency influence and support for behavioral health services within Medicare, Medicaid, and private insurance plans. Oversees Agency role in CMS Medicaid waiver programs. Maintains Agency voice on mental health and substance use parity laws. Agency Regulatory Officer.

Executive Correspondence and Support Branch (MACD)

The Executive Correspondence and Support Branch: (1) Receives, analyzes, assigns, distributes and tracks executive correspondence and maintains files; (2) ensuring responsiveness, quality and timeliness of executive correspondence; (3) issues guidance and establishes administrative processes to ensure that executive correspondence complies with all DHHS requirements and reflects positively on the reputation of SAMHSA; and, (4) responds to Freedom of Information Act requests.

Office of the Chief Medical Officer (MAD)

The Office of the Chief Medical Officer (OCMO) provides assistance to the Assistant Secretary in evaluating and organizing programs within the Agency, and to promote evidence-based and promising best practices emphasizing clinical focus. The OCMO has in-depth experience providing mental health care or substance use disorder treatment services. Furthermore, the OCMO coordinates with the Assistant Secretary for Planning and Evaluation (ASPE) to assess the use of performance metrics to evaluate SAMHSA programs, and to coordinate with the Assistant Secretary to ensure consistent utilization of appropriate performance metrics and evaluation designs.

Delegation of Authority

All delegations and re-delegations of authority made to SAMHSA officials that were in effect immediately prior to this reorganization, and that are consistent with this reorganization, shall continue in effect pending further re-delegation.

Dated: April 27, 2022.

Xavier Becerra,

Secretary.

[FR Doc. 2022–09404 Filed 5–2–22; 8:45 am]

BILLING CODE 4162–20–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 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 of Diabetes and Digestive and Kidney Diseases Initial Review Group; Diabetes, Endocrinology and Metabolic Diseases B Study Section.

Date: May 31–June 2, 2022.

Time: 10:00 a.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Democracy Two, 6707 Democracy Blvd., Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Charlene J. Repique, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7347, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7791, *charlene.repique@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: April 27, 2022.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–09395 Filed 5–2–22; 8:45 am]

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 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 of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; NIDDK SBIR Applications Developing New Technologies for Development and Integration of Novel Components for Open and Closed Loop Hormone Replacement Platforms for T1D Therapy.

Date: May 27, 2022.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Democracy II, 6707 Democracy Blvd., Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Ryan G. Morris, Ph.D., Scientific Review Officer, Review Branch, Division of Extramural Activities, NIDDK, National Institutes of Health, Room 7015, 6707 Democracy Boulevard, Bethesda, MD 20892–2542, 301–594–4721, *ryan.morris@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: April 27, 2022.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–09403 Filed 5–2–22; 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 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 of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Resource Related Research Projects (R24 Clinical Trial Not Allowed).

Date: May 20, 2022.

Time: 10:00 a.m. to 12:00 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 3G42, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Sandip Bhattacharyya, 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 3G42, Rockville, MD 20852, (240) 292–0189, *sandip.bhattacharyya@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: April 27, 2022.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–09432 Filed 5–2–22; 8:45 am]

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 10(d) of the Federal Advisory Committee Act, as