4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Maria Clary, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4638, Silver Spring, MD 20993–0002, 240–402–8615.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry entitled ''Development of Monoclonal Antibody Products Targeting SARS–CoV–2 for Emergency Use Authorization.'' This guidance provides recommendations to sponsors on the development of monoclonal antibody products targeting SARS–CoV–2 intended for the prevention or treatment of COVID–19. The recommendations focus on the data and information that may be used to support a request for EUA under section 564 of the FD&C Act (21 U.S.C. 360bbb–3). Specifically, the guidance discusses the manufacturing, pharmacology/toxicology, virologic, and clinical considerations to support EUA.

This guidance supersedes the guidance for industry entitled ''Development of Monoclonal Antibody Products Targeting SARS–CoV–2, Including Addressing the Impact of Emerging Variants, During the COVID–19 Public Health Emergency,'' which was published in February 2021. FDA issued the guidance to communicate its policy for the duration of the COVID–19 public health emergency (PHE) declared by the Secretary of Health and Human Services (HHS) on January 31, 2020, including any renewals made by the HHS Secretary in accordance with section 319(a)(2) of the Public Health Service Act (42 U.S.C. 247d(a)(2)). In the **Federal Register** of March 13, 2023 (88 FR 15417), FDA listed certain guidance documents that FDA was revising to continue in effect for 180 days after the expiration of the COVID–19 PHE declaration, during which time FDA planned to further revise the guidances. The February 2021 guidance on development of monoclonal antibody products targeting SARS–CoV–2 is included in this list.

Although circumstances have improved, SARS–CoV–2 remains in broad circulation throughout the United States. The virus has and continues to evolve over time, and in certain instances, mutations in the virus have greatly reduced the activity of monoclonal antibody therapies available for the prevention or treatment of COVID–19, resulting in vulnerable populations having limited preventative and therapeutic options. FDA retains the ability to issue an EUA under section 564 of the FD&C Act for products to treat or prevent COVID–19, so the recommendations in this guidance are still pertinent (88 FR 16644). This guidance is intended to remain in effect only for the duration of the declaration by the Secretary of HHS under section 564 of the FD&C Act effective March 27, 2020, that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID–19 pandemic (85 FR 18250). In revising this guidance, FDA considered comments received on the 2021 guidance as well as the Agency's experience issuing COVID–19-related EUAs. In addition, editorial changes were made to improve clarity.

Given the need to ensure that sponsors are aware of our current recommendations to facilitate timely development of monoclonal antibody products targeting SARS–CoV–2, FDA is issuing this guidance for immediate implementation without initially seeking prior comment because the Agency has determined that prior public participation is not feasible or appropriate (see § 10.115(g)(2) and section 701(h)(1)(C)(i) of the FD&C Act (21 U.S.C. 371(h)(1)(C)(i))). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices (see § 10.115(g)(3)).

The guidance represents the current thinking of FDA on ''Development of Monoclonal Antibody Products Targeting SARS–CoV–2 for Emergency Use Authorization.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 314 pertaining to new drug applications have been approved under 0910–0001. The collections of information pertaining to EUA of medical products have been approved under OMB control number 0910–0595.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: December 15, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–28092 Filed 12–20–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Advisory Committee on Minority Health

AGENCY: Office of Minority Health, Office of the Secretary, U.S. Department of Health and Human Services.

ACTION: Notice of meeting.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Services (HHS) is hereby giving notice that the Advisory Committee on Minority Health (ACMH) will hold a meeting. This meeting will be open to the public. Preregistration is required for the public to attend the meeting, provide comments, and/or distribute printed material(s) to ACMH members. Information about the meeting is available from the designated contact person and will be posted on the HHS Office of Minority Health (OMH) website: *www.minorityhealth.hhs.gov.* Information about ACMH activities can be found on the OMH website under the heading *About OMH, Committees and Working Groups.*

DATES: The ACMH meeting will be held on February 13–14, 2024 from 8:30 a.m. to 5:30 p.m. EST each day. If the Committee completes its work before 5:30 p.m., the meeting will adjourn early.

ADDRESSES: The meeting will be held at the Tower Building at 1101 Wootton Parkway, Lower Level Conference Room, Rockville, Maryland 20852 and will be accessible by webcast. Members of the public must register for the meeting by 5:00 p.m. EST on January 30, 2024. Registered webcast participants will receive webcast access information prior to the meeting.

FOR FURTHER INFORMATION CONTACT: Violet Woo, Designated Federal Officer,

Advisory Committee on Minority Health, OMH, HHS, Tower Building, 1101 Wootton Parkway, Suite 100, Rockville, Maryland 20852. Phone: 240–453–6816; email: *OMH-ACMH@hhs.gov.*

SUPPLEMENTARY INFORMATION: In accordance with Public Law 105–392, the ACMH was established to provide advice to the Deputy Assistant Secretary for Minority Health on the development of goals and program activities related to OMH's duties. The topic to be discussed during the meeting is the implementation of the anticipated updates to the Office of Management and Budget (OMB) federal race and ethnicity data collection standards. The focus will be on opportunities for supporting community awareness of and engagement in future efforts to implement the revised race and ethnicity data collection standards, anticipated to be published by the OMB no later than Summer 2024. The recommendations will be given to the Deputy Assistant Secretary for Minority Health to inform efforts related to implementation of the revised OMB standards. Information on OMB's Interagency Technical Working Group on Race and Ethnicity Standards can be found on this website: *spd15revision.gov.*

The meeting is open to the public. Any individual who wishes to attend the meeting must register by sending an email to *OMH-ACMH@hhs.gov* by 5:00 p.m. EST on January 30, 2024. Each registrant should provide their name, affiliation, phone number, email address, days attending, and if participation is in-person or via webcast. Registrants will receive webcast access information via email. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact *OMH-ACMH@hhs.gov* and reference this meeting. Requests for special accommodation should be made during registration or at least ten (10) business days prior to the meeting.

Registered members of the public will have an opportunity to provide comments at the meeting. Public comments will be limited to two minutes per speaker during the time allotted. Individuals of the public may also submit and distribute electronic or printed statements or material(s) related to this meeting's topic. Written comments should not exceed two pages in length. Individuals planning to submit material should email the material to *OMH-ACMH@hhs.gov* at least five (5) business days prior to the meeting.

Violet Woo,

Designated Federal Officer, Advisory Committee on Minority Health.

[FR Doc. 2023–28101 Filed 12–20–23; 8:45 am]

BILLING CODE 4150–29–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; 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 Aging Special Emphasis Panel; Role of Tau Oligomer Polymorphism in Alzheimer's Disease and Related Disorders.

Date: March 6, 2024.

Time: 11:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Nesar Uddin Akanda, Ph.D., M.D., Scientific Review Officer, Scientific Review Branch, National Institute on Aging, 7201 Wisconsin Avenue, Gateway Bldg., Suite 2E405, Bethesda, MD 20892, (301) 594–8984, *nesar.akanda@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: December 15, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–28023 Filed 12–20–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a 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 materials, 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 Library of Medicine Special Emphasis Panel; Conflicted and Other Applications (R01, R13 and K99 and Curation).

Date: March 28, 2024.

Time: 11:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Library of Medicine, 8600 Rockville Pike, Bethesda, MD 20892 (Video Assisted Meeting).

Contact Person: Ali Sharma, Ph.D., Scientific Review Officer, National Library of Medicine, NIH, 6705 Rockledge Drive, Suite 500, Bethesda, MD 20892–7968, *ali.sharma@nih.gov.*

(Catalogue of Federal Domestic Assistance Program No. 93.879, Medical Library Assistance, National Institutes of Health, HHS)

Dated: December 15, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–28071 Filed 12–20–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; 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