available, you can provide this information on the cover sheet and not in the body of your comments and you must identify the information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Jessica Seo, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–7699, email: *PCNS@fda.hhs.gov,* 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 FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* 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. The committee will discuss supplemental biologics license application 761269/s-001, for LEQEMBI (lecanemab) solution for intravenous infusion, submitted by Eisai, Inc., for the treatment of early Alzheimer's disease. This product was approved under 21 CFR 314.500 (subpart H, accelerated approval regulations) for the treatment of Alzheimer's disease. Confirmatory studies are studies to verify and describe the clinical benefit of a product after it receives accelerated approval. The committee will discuss the confirmatory study, BAN2401–G000–301, conducted to fulfill postmarketing requirement 4384–1 detailed in the January 6, 2023, approval letter, available at *https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2023/761269Orig1s000ltr.pdf.*

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 May 25, 2023, 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 17, 2023. 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 18, 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 Jessica Seo (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 5, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–07526 Filed 4–10–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Global Affairs; Stakeholder Listening Session in preparation for the 76th World Health Assembly

ACTION: Notice of public listening session; request for comments.

Time and date: The listening session will be held Wednesday, May 3, 2023, from 10:00 a.m. to 12:00 p.m., Eastern Daylight Time.

Place: The session will be held virtually, with online and dial-in information shared with registered participants.

Status: This session is open to the public but requires RSVP to *oga.rsvp@hhs.gov* by Friday, April 20, 2023. *See RSVP section below for details.*

SUPPLEMENTARY INFORMATION:

Purpose: The U.S. Department of Health and Human Services (HHS) is charged with leading the U.S. delegation to the 76th World Health Assembly and will convene a Stakeholder Listening Session.

The World Health Assembly is the decision-making body of WHO. It is attended by delegations from all WHO Member States and focuses on a health agenda prepared by the World Health Organization Executive Board. The main functions of the World Health Assembly are to determine the policies of the Organization, appoint the Director-General, supervise financial policies, and review and approve the proposed programme budget.

The Stakeholder Listening Session is designed to seek input from stakeholders and subject matter experts to help inform and prepare for U.S. government engagement with the World Health Assembly.

Matters to be Discussed: The listening session will discuss resolutions and other decisions to be covered at the 76th World Health Assembly. Topics will

include those found in the agenda and will be organized by agenda item. A provisional agenda of the 76th World Health Assembly can be found at: *https://apps.who.int/gb/ebwha/pdf_files/EB152/B152(20)-en.pdf.* Additional information about the World Health Assembly can be found at: *https://www.who.int/about/governance/world-health-assembly.* Participation is welcome from all stakeholder communities.

RSVP: Persons seeking to participate in the listening session *must register by April 20, 2023.*

Registrants must include their full name, email address, and organization, if any, and indicate whether they are registering as a *listen-only attendee* or as a *speaker participant* to *oga.rsvp@hhs.gov.*

Requests to participate as a speaker must include all of the following information:

1. The name and email address of the person desiring to participate
2. The organization(s) that person represents, if any
3. Identification of agenda item(s) of interest

Other Information: This listening session will be recorded for the benefit of the members of the US Government who will participate in WHA76.

Written comments should be emailed to *oga.rsvp@hhs.gov* with the subject line ''*Written Comment Re: Stakeholder Listening Session for WHA76*'' by Wednesday, May 10, 2023.

We look forward to your comments on the 76th World Health Assembly.

Dated: March 20,2023.

Susan Kim,

Chief of Staff, Office of Global Affairs.

[FR Doc. 2023–07562 Filed 4–10–23; 8:45 am]

BILLING CODE 4150–38–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Minority Health and Health Disparities; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Council on Minority Health and Health Disparities.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend as well as those who need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting website (*http://videocast.nih.gov/*).

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 Advisory Council on Minority Health and Health Disparities.

Date: May 22, 2023.

Closed: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 31 Center Drive, Building 31/6C, Rm A/B, Bethesda, MD 20892.

Name of Committee: National Advisory Council on Minority Health and Health Disparities.

Date: May 23, 2023.

Open: 8:00 a.m. to 3:00 p.m.

Agenda: Opening Remarks, Administrative Matters, Director's Report, Presentations, and Other Business of the Council.

Place: National Institutes of Health, 31 Center Drive, Building 31/6C, Rm A/B, Bethesda, MD 20892.

Contact Person: Paul Cotton, Ph.D., RDN, Director, Office of Extramural Research Activities, National Institute on Minority Health and Health Disparities, National Institutes of Health, 6707 Democracy Boulevard, Suite 800, Bethesda, MD 20892, 301–402–1366, *paul.cotton@nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has procedures at *https://www.nih.gov/about-nih/visitor-information/campus-access-security* for entrance into on-campus and off-campus facilities. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors attending a meeting on campus or at an off-campus federal facility will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: NIMHD: *https://www.nimhd.nih.gov/about/advisory-council/,* where an agenda and any additional information for the meeting will be posted when available.

Dated: April 5, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–07547 Filed 4–10–23; 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 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 Aging Special Emphasis Panel; DNA and Aging.

Date: May 9, 2018.

Time: 12:01 p.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Greg Bissonette, Ph.D., Scientific Review Officer, National Institute on Aging, National Institutes of Health, Gateway Building, Suite 2W200, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301–402–1622, *bissonettegb@mail.nih.gov.*

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