Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Moon Choi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–2894, email: *GeMDAC@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 and/or video conferencing platform.

The Committee will discuss new drug application 214927, for arimoclomol, submitted by Zevra Denmark A/S, for the treatment of adults and pediatric patients 2 years of age and older with Niemann-Pick disease type C.

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 and/or video conference meeting will be available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link. For online participants the meeting will include slide presentations with audio and video 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 to the Docket (see **ADDRESSES**) on or before July 25, 2024, will be provided to the Committee. Oral presentations from the public will be scheduled between approximately between 2:25 p.m. and 3:25 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 July 17, 2024. 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 July 18, 2024.

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 Moon Choi (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. 1001 *et seq.*). This meeting notice also serves as notice that, pursuant to 21 CFR 10.19, the requirements in 21 CFR 14.22(b), (f), and (g) relating to the location of advisory committee meetings are hereby waived to allow for this meeting to take place both in-person and using an online meeting platform. This waiver is in the interest of allowing greater transparency and opportunities for public participation, in addition to convenience for advisory committee members, speakers, and guest speakers. The conditions for issuance of a waiver under 21 CFR 10.19 are met.

Dated: July 5, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–15127 Filed 7–9–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–0001]

Workshop To Consider Artificial Intelligence in Drug and Biological Product Development; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public workshop titled ''Artificial Intelligence (AI) in Drug & Biological Product Development.'' Convened and supported by a cooperative agreement between FDA and the Clinical Trials Transformation Initiative (CTTI), the purpose of the public workshop is to bring drug developers and AI experts together to discuss guiding principles for the responsible use of AI in the development of safe and effective drugs and biological products. The workshop format will include presentations and panel discussions.

DATES: The public workshop will be held virtually and in-person on August 6, 2024, from 10 a.m. to 5:30 p.m. Eastern Time. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: Participants can join the public workshop either virtually using the Zoom platform or in person at the FDA Great Room, located at 10903 New Hampshire Ave., Silver Spring, MD, 20993. The link for the public workshop will be sent to registrants upon registration.

FOR FURTHER INFORMATION CONTACT: Marsha Samson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6330, Silver Spring, MD 20993–0002, 301–837–7407, *Marsha.Samson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

This public workshop will convene experts in AI including drug sponsors, academia, and technology organizations to discuss guiding principles that are being applied by innovators to promote the responsible use of AI in the development of safe and effective drugs.

II. Topics for Discussion at the Public Workshop

At the public workshop, FDA plans to convene experts in AI to discuss topics, including but not limited to:

1. Optimizing model design through multidisciplinary expertise. Specifically, discussants will explore the importance of integrating experts from diverse fields, such as medicine, statistics, pharmacology, data science, and engineering to ensure the development of optimal AI models.

2. Exploring strategies for overcoming common data-related challenges, namely, the availability of fit-for-use data that can be used in drug development. Topics will include data availability and access via federated learning, data quality issues (*i.e.,* representativeness of data, bias, etc.), and the use of synthetic data.

3. Balancing model performance, explainability, and transparency of AI models. Additionally, discussants will share strategies for assessing the need to integrate humans into the decision-making process (human-in-the-loop and/or human-on-the-loop).

4. Identifying key gaps and challenges hindering the use of AI in drug and biological product development and exploring potential strategies, collaborations, and initiatives to address these challenges. Considering actionable next steps to advance the responsible use of AI in developing safe, effective, and quality drugs.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following website: *https://duke.zoom.us/meeting/register/tJcrcu-qrTMiHdayh1J3JhkCi6XkvmAIFey6.* Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and people interested in attending this public workshop must register to receive a link to the meeting. Registrants will receive confirmation email after they register.

If you need special accommodations due to a disability, please contact *Kelly.Franzetti@duke.edu* no later than July 30, 2024. Please note, closed captioning will be available automatically.

Dated: July 5, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–15125 Filed 7–9–24; 8:45 am]

BILLING CODE 4164–01–P

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; Small Business Metabolism.

Date: August 2, 2024.

Time: 12:00 p.m. to 2:30 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: Dianne Hardy, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6175, MSC 7892, Bethesda, MD 20892, 301–435–1154, *dianne.hardy@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Topics on HIV Comorbidities, Coinfections and Associated Cancers.

Date: August 5, 2024.

Time: 10:00 a.m. to 6:00 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: Raul Rojas, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6185, Bethesda, MD 20892, (301) 451–6319, *rojasr@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Respiratory Sciences.

Date: August 6–7, 2024.

Time: 9:00 a.m. to 8:00 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: Michael L. Bloom, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6187, MSC 7804, Bethesda, MD 20892, 301–451–0132, *bloomm2@mail.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 5, 2024.

David W. Freeman,

Supervisory Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–15112 Filed 7–9–24; 8:45 am]

BILLING CODE 4140–01–P

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; Small Business Metabolism.

Date: July 26, 2024.

Time: 1:00 p.m. to 3:30 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: Dianne Hardy, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6175, MSC 7892, Bethesda, MD 20892, 301–435–1154, *dianne.hardy@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Topics in Hypersensitivity, Autoimmunity and Immune-mediated Diseases.

Date: August 2, 2024.

Time: 11:00 a.m. to 5:00 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: Alok Mulky, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4203, Bethesda, MD 20892, (301) 435–3566, *mulkya@mail.nih.gov.*