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: Tiana Barnes, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6196, Silver Spring, MD 20993–0002, 301–796–2882, *Tiana.Barnes@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Biosimilar User Fee Act reauthorization, known as BsUFA III,[1] authorizes FDA to assess and collect user fees for certain activities in connection with biosimilar product development and review of applications submitted under section 351(k) of the Public Health Service Act (PHS Act) (42 U.S.C. 262(k)). An application submitted under section 351(k) of the PHS Act must demonstrate, among other things, that a proposed biosimilar product is highly similar to, and has no clinically meaningful differences from, an FDA-licensed reference product. To date, FDA has issued a series of guidance documents to facilitate development of biosimilar products. Under section 351(k)(8)(D) of the PHS Act, if FDA issues product class-specific guidance with respect to the licensure of biosimilar products, the guidance must include a description of the criteria that FDA will use to determine whether a biological product is highly similar to a reference product in such product class and the criteria, if available, that FDA will use to determine whether a biological product meets the standards for interchangeability described in section 351(k)(4) of the PHS Act.

Under BsUFA III, FDA has committed to, among other things, the development of guidance documents focusing on formal meetings between FDA and sponsors or applicants of BsUFA products and topics related to interchangeable biosimilar biological products (interchangeable biosimilars or interchangeable biosimilar products) (see Biosimilar Biological Product Reauthorization Performance Goals and Procedures Fiscal Years 2023 Through 2027, available at *https://www.fda.gov/media/152279/download*). These guidance documents are not product-specific or product class-specific but rather apply across many products and product classes. In contrast, under the GDUFA science and research program, FDA conducts research in support of various regulatory science initiatives, the results of which support development of both general and product-specific guidance for industry.

As part of the BsUFA III program, FDA has updated its biosimilar action plan [2] and is revisiting how best to advance the development of new biosimilar products. FDA guidance can enhance scientific and regulatory clarity for the biosimilar product development community and, when finalized, represents FDA's current thinking on the matter.

II. Issues for Consideration and Request for Information and Comments

FDA is seeking input from industry on whether product-specific guidance outlining the development program for a particular product would be valuable to the biosimilar product development community. A model for this approach is the GDUFA science and research program that, among other things, supports the issuance of product-specific guidance documents, of which there are currently over 2,000.[3] Alternatively, FDA is seeking input on whether product class-specific guidance, which may apply more broadly to a class of products, would be valuable to the biosimilar product development community. Specifically, FDA is seeking input on the following questions:

1. Which would be more useful for accelerating biosimilar development: guidance documents that focus on a particular product (product-specific guidance), or guidance documents that are cross-cutting for a class of biosimilar products (product class-specific guidance) such as monoclonal antibodies?

2. Should FDA focus on development of guidance documents for biological products (or classes of biological products) for which there are no approved biosimilars? Or would it be useful for FDA to continue to develop guidance on biosimilar development programs even after one or more biosimilar products have been approved for that biological product or class of biological products?

Dated: July 18, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–16405 Filed 7–24–24; 8:45 am]

BILLING CODE 4164–01–P

[1] See *https://www.fda.gov/industry/biosimilar-user-fee-amendments/bsufa-iii-fiscal-years-2023-2027.*

[2] See *https://www.fda.gov/drugs/biosimilars/biosimilars-action-plan#clarity.*

[3] See the Product-Specific Guidances for Generic Drug Development web page at *https://www.accessdata.fda.gov/scripts/cder/psg/index.cfm.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Council for Human Genome Research.

This is a hybrid meeting held in-person and virtually and is open to the public as indicated below. Individuals who plan to attend in-person or view the virtual meeting and need special assistance or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The meeting will be videocast and can be accessed from *https://www.genome.gov/event-calendar/103rd-Meeting-of-National-Advisory-Council-for-Human-Genome-Research.*

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 for Human Genome Research.

Date: September 9–10, 2024.

Closed: September 09, 2024, 9:00 a.m. to 10:00 a.m.

Agenda: To review and evaluate grant applications.

Place: National Human Genome Research Institute, National Institutes of Health, 6700 Rockledge Drive, Suite 1100, Bethesda, MD 20892 (Hybrid Meeting).

Open: September 09, 2024, 10:00 a.m. to 6:00 p.m.

Agenda: Report of Institute Director and Institute Staff.

Place: National Human Genome Research Institute, National Institutes of Health, 6700B Rockledge Drive, Suite 1100, Bethesda, MD 20892 (Hybrid Meeting).

Closed: September 10, 2024, 9:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Human Genome Research Institute, National Institutes of Health, 6700 Rockledge Drive, Suite 1100, Bethesda, MD 20892 (Hybrid).

Contact Person: Jennifer L. Troyer, Ph.D., Director, Division of Extramural Operations, National Human Genome Research Institute, National Institutes of Health, NIH 6700 Rockledge Drive, Suite 3100, Bethesda, MD 20892, (301) 480–3565, *troyerj@mail.nih.gov.*

Information is also available on the Institute's/Center's home page: *http://www.genome.gov/council,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: July 19, 2024.

David W. Freeman,

Supervisory Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–16327 Filed 7–24–24; 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; Topics in Clinical Informatics and Data Analytics II.

Date: August 13, 2024.

Time: 10:00 a.m. to 4:00 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: Jessica Bellinger, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3158, Bethesda, MD 20892, (301) 827–4446, *bellingerjd@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Cancer Therapeutics.

Date: August 15, 2024.

Time: 1:00 p.m. to 4:30 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: Careen K Tang-Toth, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6214, MSC 7804, Bethesda, MD 20892, (301) 435–3504, *tothct@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 19, 2024.

David W. Freeman,

Supervisory Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–16325 Filed 7–24–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Advancing Translational Sciences; 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 Center for Advancing Translational Sciences Special Emphasis Panel; Industrialization and Translation of Extracellular Vesicles for use in Regenerative Medicine (ITERM).

Date: October 24, 2024.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Center for Advancing Translational Sciences, National Institutes of Health, 9609 Medical Center Drive, Rockville, MD 20850.

Contact Person: Alumit Ishai, Ph.D., Scientific Review Officer, Office of Grants Management and Scientific Review, National Center for Advancing Translational Sciences, National Institutes of Health, 9609 Medical Center Drive, MSC 9793, Rockville, MD 20892 (301) 496–9539, *alumit.ishai@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.350, B—Cooperative Agreements; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: July 19, 2024.

David W. Freeman,

Supervisory Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–16323 Filed 7–24–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2024–0619]

Great Lakes Pilotage Advisory Committee Meeting; September 2024 Meeting

AGENCY: U.S. Coast Guard, Department of Homeland Security.

ACTION: Notice of open Federal advisory committee meeting.

SUMMARY: The Great Lakes Pilotage Advisory Committee (Committee) will meet in Massena, New York, to discuss matters relating to Great Lakes Pilotage, including review of proposed Great Lakes Pilotage regulations and policies. The meeting will be open to the public.

DATES:

Meeting: The Committee will meet on Tuesday, September 10, 2024, from 8 a.m. to 5:30 p.m. Eastern Daylight Time (EDT). Please note that this meeting may adjourn early if the Committee has completed its business.

Comments and supporting documentations: To ensure your comments are received by Committee members prior to the meeting, submit your written comments no later than August 30, 2024.

ADDRESSES: The meeting will be held at the Saint Lawrence Seaway Visitor Center at Eisenhower Lock, 76 Barnhart Island Road, Massena, NY 13662.

Pre-registration Information: Pre-registration is not required for access to the meeting.

The Great Lakes Pilotage Advisory Committee is committed to ensuring all participants have equal access regardless of disability status. If you require reasonable accommodation due to a disability to fully participate, please email Mr. Francis Levesque at *Francis.R.Levesque@uscg.mil.* or call (571) 308–4941 as soon as possible.

Instructions: You are free to submit comments at any time, including orally at the meeting, but if you want Committee members to review your comment before the meeting, please submit your comments no later than August 30, 2024. We are particularly interested in comments on the topics in the ''Agenda'' section below. We