a notice announcing the availability of a draft guidance entitled ''Q5A(R2) Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin.'' The notice gave interested persons an opportunity to submit comments by January 13, 2023. After consideration of the comments received and revisions to the guideline, a final draft of the guideline was submitted to the ICH Assembly and endorsed by the regulatory agencies in November 2023.

This guidance revises and finalizes the updates included in the draft guidance issued on November 14, 2022. Like the draft guidance, the final guidance reflects updates in scientific advances and regulatory expectations since the publication of the ICH guidance for industry, ''Q5A Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin,'' issued in September 1998. These revisions include descriptions of new classes of products now in scope, inclusion of new virus detection technologies, clarification of new validation strategies, and considerations specific to new manufacturing approaches, such as continuous manufacturing. The final guidance expands on the draft by including additional detail on the strategy for replacement of conventional testing methods with alternatives and additional details to better describe the scope of products addressed in the guidance. Additional definitions were added to the glossary to better align with terminology elsewhere in the guidance as well as guidances that may be read in parallel (*e.g.,* ICH guidance for industry ''Q13 Continuous Manufacturing of Drug Substances and Drug Products,'' available at *https://www.fda.gov/media/165775/download*).

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Q5A(R2) Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin.'' 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 parts 210 and 211 pertaining to current good manufacturing practice have been approved under OMB control number 0910–0139. The collections of information in 21 CFR part 312 for the submissions of investigational new drug applications have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 601 for the submissions of biologics license applications have been approved under OMB control number 0910–0338. The collections of information 21 CFR part 58 pertaining to good laboratory practices for nonclinical laboratory studies have been approved under OMB control number 0910–0119.

III. Electronic Access

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

Dated: January 8, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–00407 Filed 1–10–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood 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 Heart, Lung, and Blood Advisory Council.

The meeting will be held virtually and is open to the public as indicated below. Individuals who plan to attend the virtual meeting and 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 meeting can be accessed from the NIH Videocast at the following links: *http://videocast.nih.gov/* or *https://www.nhlbi.nih.gov/about/advisory-and-peer-review-committees/advisory-council.*

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 Heart, Lung, and Blood Advisory Council.

Date: February 6, 2024.

Closed: 10:00 a.m. to 11:00 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge I, 6705 Rockledge Drive, Rockville, MD 20892 (Virtual Meeting).

Open: 11:00 a.m. to 2:00 p.m.

Agenda: To discuss program policies and issues.

Place: National Institutes of Health, Rockledge I, 6705 Rockledge Dr., Bethesda, MD 20892 (Virtual Meeting).

Virtual Access: https://www.nhlbi.nih.gov/about/advisory-and-peer-review-committees/advisory-council.

Please note, the link to the videocast meeting will be posted within a week of the meeting date.

Contact Person: Valerie L. Prenger, Ph.D., MPH, Deputy Director, Division of Extramural Research Activities, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Room 207–C, Bethesda, MD 20892–7924, 301–435–0270, *Valerie.Prenger@nih.gov.*

Any member of the public interested in presenting oral comments to the committee may notify the Contact Person listed on this notice at least 10 days in advance of the meeting. Interested individuals and representatives of organizations may submit a letter of intent, a brief description of the organization represented, and a short description of the oral presentation. Only one representative of an organization may be allowed to present oral comments and if accepted by the committee, presentations may be limited to five minutes. Both printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the committee by forwarding their 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: *www.nhlbi.nih.gov/meetings/nhlbac/index.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: January 8, 2024.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–00440 Filed 1–10–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health and Human Development; Notice of Closed Meetings

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: Eunice Kennedy Shriver, National Institute of Child Health and Human Development, Initial Review Group, Population Sciences Study Section.

Date: March 1, 2024.

Time: 10:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Eunice Kennedy Shriver, National Institute of Child Health and Human Development, 6710B Rockledge Drive, Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Christiane M. Robbins, Scientific Review Officer, Scientific Review Branch (SRB), DER, Eunice Kennedy Shriver, National Institute of Child Health and Human Development, NIH, DHHS, 6710B Rockledge Drive, Rm. 2121B, Bethesda, MD 20817, 301–451–4989, *crobbins@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: January 5, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–00369 Filed 1–10–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health and Human Development; Notice of Closed Meetings

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: Eunice Kennedy Shriver National Institute of Child Health and Human Development Special Emphasis Panel; Member Conflict: Biobehavioral and Behavioral Sciences Study Section.

Date: March 12, 2024.

Time: 10:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Eunice Kennedy Shriver National Institute of Child Health and Human Development, 6710B Rockledge Drive, Bethesda, MD 20817, (Virtual Meeting).

Contact Person: Magnus A. Azuine, Ph.D., Scientific Review Branch Eunice Kennedy Shriver National Institute, of Child Health & Human Development, NIH 6710B Rockledge Drive, Room 2125C Bethesda, MD 20817, (301) 480–4645, *magnus.azuine@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: January 8, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–00442 Filed 1–10–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; 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: Neurological Sciences Training Initial Review Group; Neurological Sciences Training 3 Study Section.

Date: February 5–6, 2024.

Time: 7:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: New Orleans Marriott, 555 Canal Street, New Orleans, LA 70130.

Contact Person: Lataisia Cherie Jones, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, NINDS/NIH, 6001 Executive Blvd., Rockville, MD 20852, 301–496–9223, *lataisia.jones@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS.)

Dated: January 5, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–00370 Filed 1–10–24; 8:45 am]

BILLING CODE 4140–01–P