Administration, 10904 New Hampshire Ave., Bldg. 22, Rm. 4118, Silver Spring, MD 20993–0003, 301–769–1036.

Regarding the ICH: Jill Adleberg, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6364, Silver Spring, MD 20993–0002, 301–796–5259, *Jill.Adleberg@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''M7(R2) Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk.'' The guidance was prepared under the auspices of ICH. ICH seeks to achieve greater regulatory harmonization worldwide to ensure that safe, effective, high-quality medicines are developed, registered, and maintained in the most resource-efficient manner.

By harmonizing the regulatory requirements in regions around the world, ICH guidelines enhance global drug development, improve manufacturing standards, and increase the availability of medications. For example, ICH guidelines have substantially reduced duplicative clinical studies, prevented unnecessary animal studies, standardized the reporting of important safety information, and standardized marketing application submissions.

The six Founding Members of the ICH are FDA; the Pharmaceutical Research and Manufacturers of America; the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; and the Japanese Pharmaceutical Manufacturers Association. The Standing Members of the ICH Association include Health Canada and Swissmedic. ICH membership continues to expand to include other regulatory authorities and industry associations from around the world (refer to *https://www.ich.org/*).

ICH works by engaging global regulatory and industry experts in a detailed, science-based, and consensus-driven process that results in the development of ICH guidelines. The regulators around the world are committed to consistently adopting these consensus-based guidelines, realizing the benefits for patients and for industry.

As a Founding Regulatory Member of ICH, FDA plays a major role in the development of each of the ICH guidelines, which FDA then adopts and issues as guidance for industry. FDA's guidance documents do not establish legally enforceable responsibilities. Instead, they describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited.

In the **Federal Register** of April 7, 2022 (87 FR 20435), FDA published a notice announcing the availability of a draft guidance for industry entitled ''M7(R2) Addendum: Application of the Principles of the ICH M7 Guideline to Calculation of Compound-Specific Acceptable Intakes,'' which included ICH assembly approved changes, including the separation of the main guidance and addendum into two separate documents. In the **Federal Register** of September 29, 2020 (85 FR 61009), FDA published a notice announcing the availability of a draft guidance for industry entitled ''M7 Assessment and Control of DNA reactive (Mutagenic) Impurities in Pharmaceuticals To Limit Potential Carcinogenic Risk—Questions and Answers.'' The notices gave interested persons an opportunity to submit comments by May 9, 2022, and December 28, 2020, respectively.

After consideration of the comments received and revisions to the guidances, final drafts of the guidance and supplemental documents were submitted to the ICH Assembly and endorsed by the regulatory Agencies on May 24, 2022, and April 3, 2023.

These guidances finalize the above draft guidances issued on April 7, 2022, and September 29, 2020, with no significant changes. The M7(R2) Guidance is intended to be read in conjunction with two accompaniment documents, the M7(R2) Addendum and the M7(R2) Questions and Answers. The core M7(R2) Guidance includes information on mutagenic impurities and changes to HIV treatment duration. The M7(R2) Addendum contains monographs for mutagenic chemicals that are common in pharmaceutical manufacturing or are useful to illustrate the principles for deriving compound-specific intakes described in the core guidance. The M7(R2) Questions and Answers facilitate consistent implementation by clarifying issues and concerns identified since the first version of the final guidance for industry, ''M7 Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk,'' published in 2014.

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 ''M7(R2) Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk.'' 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 these guidances contains no collection of information, they do refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for these guidances. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338. The collections of information pertaining to 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively. The collections of information in 21 CFR parts 210 and 211 pertaining to current good manufacturing practice requirements have been approved under OMB control number 0910–0139.

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: July 19, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–15645 Filed 7–24–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; 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), 552b(c)(6), title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, 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; Prenatal and Childhood Health Disparities (ENRICHED) Study.

Date: August 15, 2023.

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

Agenda: To review and evaluate contract proposals.

Place: National Institute of Child Health and Human Development, 6710B Rockledge Drive, Room 2125C, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Magnus A. Azuine, Ph.D., Scientific Review Officer, 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. 93.865, Research for Mothers and Children, National Institutes of Health, HHS)

Dated: July 19, 2023.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–15688 Filed 7–24–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; 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: National Cancer Institute Special Emphasis Panel; Institutional Research Training Grant.

Date: August 16, 2023.

Time: 1:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W234, Rockville, Maryland 20850 (Telephone Conference Call).

Contact Person: Adriana Stoica, Ph.D., Scientific Review Officer, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W234, Rockville, Maryland 20850, 240–276–6368, *Stoicaa2@mail.nih.gov.*

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI Program Project (P01) Review SEP–A.

Date: September 14–15, 2023.

Time: 9:00 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W618, Rockville, Maryland 20850 (Telephone Conference Call).

Contact Person: E. Tian, Ph.D. Scientific Review Officer, Research Program Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W618, Rockville, Maryland 20850, 240–276–6611, *tiane@mail.nih.gov.*

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI Transition Career Development Award and Institutional Research Training Grants.

Date: September 20, 2023.

Time: 10:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W234, Rockville, Maryland 20850 (Telephone Conference Call).

Contact Person: Adriana Stoica, Ph.D., Scientific Review Officer, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W234, Rockville, Maryland 20850, 240–276–6368 *Stoicaa2@mail.nih.gov.*

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI SPORE (P50) Review I.

Date: September 21–22, 2023.

Time: 9:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W248, Rockville, Maryland 20850 (Telephone Conference Call).

Contact Person: Anita T. Tandle, Ph.D., Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W248, Rockville, Maryland 20850, 240–276–5085, *tandlea@mail.nih.gov.*

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI Program Project (P01) Review SEP–B.

Date: September 28–29, 2023.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W120, Rockville, Maryland 20850 (Telephone Conference Call).

Contact Person: Majed M. Hamawy, Ph.D., Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive Room 7W120, Rockville, Maryland 20850, 240–276–6457, *mh101v@nih.gov.*

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI Informatics Technologies for Cancer Research I.

Date: September 28–29, 2023.

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

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W236, Rockville, Maryland 20850, (Telephone Conference Call).

Contact Person: Shuli Xia, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W236, Rockville, Maryland 20850, 240–276–5256 *shuli.xia@nih.gov.*

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI SPORE II.

Date: September 28–29, 2023.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W244, Rockville, Maryland 20850 (Telephone Conference Call).

Contact Person: John Paul Cairns, Ph.D. Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W244, Rockville, Maryland 20850, 240–276–5415, *paul.cairns@nih.gov.*

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI Program Project (P01) Review SEP–C.

Date: October 11–12, 2023.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W634, Rockville, Maryland 20850 (Telephone Conference Call).

Contact Person: Michael E. Lindquist, Ph.D., Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W634, Rockville, Maryland 20850, *mike.lindquist@nih.gov.*

Name of Committee: National Cancer Institute Initial Review Group; Career Development Study Section (J).

Date: October 12–13, 2023.

Time: 10:00 a.m. to 6:00 p.m.