

0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Kofi Ansah, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4380, Silver Spring, MD 20993-0002, 301-796-4158.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Psychedelic Drugs: Considerations for Clinical Investigations.” This draft guidance outlines general considerations for drug development programs considering the therapeutic potential of psychedelic drugs for treatment of medical conditions (*e.g.*, psychiatric disorders, substance use disorders).

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on “Psychedelic Drugs: Considerations for Clinical Investigations.” 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. 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 this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 312 relating to the submission of investigational new drug applications have been approved under OMB control number 0910-0014. The collections of information in 21 CFR part 314 relating to the submission of new drug applications have been approved under OMB control number 0910-0001. The collections of information in 21 CFR parts 210 and 211 relating to current good manufacturing practice requirements have been approved under OMB control number 0910-0139. The collections of information relating to the protection of human subjects and institutional review boards in 21 CFR parts 50 and 56 have been approved under OMB control number 0910-0130.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at 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

Dated: June 20, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health and 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) and 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; Chemical Screening and Optimization Facility.

Date: July 20, 2023.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, Eunice Kennedy Shriver National Institute of Child Health and Human Development, 6710B Rockledge Drive, Room 2131D, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Anita Szajek, Ph.D., Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver, National Institute of Child Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Room 2131D, Bethesda, MD 20892, (301) 943-5604, anita.szajek@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.865, Research for Mothers and Children, National Institutes of Health, HHS)

Dated: June 20, 2023.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

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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: Biological Chemistry and Macromolecular Biophysics Integrated Review Group; Maximizing Investigators’ Research Award—E Study Section.

Date: July 6–7, 2023.

Time: 8:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency, Bethesda, One Metro Center, 7400 W Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Vandana Kumari, Ph.D., Scientific Review Officer, Center for Scientific Review, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 496-3290, vandana.kumari@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Small Business Innovation Research/Small Business Technology Transfer.

Date: July 6–7, 2023.

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 (Hybrid Meeting).

Contact Person: Jennifer Di Noia, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1000E, Bethesda, MD 20892, (301) 594-0288, dinoiaj2@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Special Topics: Cellular, Molecular, Bioanalytical and Imaging Technologies.

Date: July 6, 2023.

Time: 9:30 a.m. to 8:00 p.m.