

except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)). Submit written requests for single copies of the draft guidance to the Division of Inspectorate Policy, Office of Inspections and Investigations, Food and Drug Administration, Element Building, 12420 Parklawn Dr., Rockville, MD 20852. Send two self-addressed adhesive labels to assist the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Patrick Clouser, Office of Inspections and Investigations, Food and Drug Administration, Element Building, 12420 Parklawn Dr., Rockville, MD 20852, 240-402-5276, [Patrick.Clouser@fda.hhs.gov](mailto:Patrick.Clouser@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

#### **I. Background**

FDA is announcing the availability of a draft guidance document entitled "Questions and Answers Regarding Mandatory Cosmetics Recalls: Guidance for Industry." The purpose of this draft guidance document, when finalized, is to provide guidance to industry on the implementation of the mandatory cosmetics recall provisions of section 611 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act or the Act), which was added by section 3502 of the Modernization of Cosmetics Regulation Act of 2022 (MoCRA). The guidance is in the form of Questions and Answers and provides answers to common questions that might arise about these mandatory recall provisions and FDA's current thinking regarding their implementation.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA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 mandatory cosmetics recalls. 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.

As we develop final guidance on this topic, FDA will consider comments on costs or cost savings the guidance may generate, relevant for Executive Order 14192.

#### **II. Paperwork Reduction Act of 1995**

FDA tentatively concludes that this draft guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

#### **III. Electronic Access**

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

**Lowell M. Zeta,**

*Acting Deputy Commissioner for Policy, Legislation, and International Affairs.*

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### **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 a meeting of the National Advisory Child Health and Human Development 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 Advisory Child Health and Human Development Council.

*Date:* March 20, 2026.

*Time:* 1:00 p.m. to 4:00 p.m.

*Agenda:* To review and evaluate to review and evaluate grant applications.

*Address:* Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes, 6710B Rockledge Drive, Bethesda, MD 20817.

*Meeting Format:* Virtual Meeting.

*Contact Person:* Rebekah S. Rasooly, Ph.D., Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Bethesda, MD 20817, Phone: 301-827-2599, Email: [Rebekah.rasooly@nih.gov](mailto:Rebekah.rasooly@nih.gov).

Information is also available on the Institute's/Center's home page: <https://www.nichd.nih.gov/about/advisory/council>, where an agenda and any additional information for the meeting will be posted when available.

(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: December 15, 2025.

**David W. Freeman,**

*Supervisory 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:* Center for Scientific Review Special Emphasis Panel; RFA: NIH Blueprint and BRAIN Initiative Diversity Specialized Predoctoral to Postdoctoral Advancement in Neuroscience (D-SPAN) Award (F99/K00 Clinical Trial Not Allowed).

*Date:* January 21, 2026.

*Time:* 9:00 a.m. to 3:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Address:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

*Meeting Format:* Virtual Meeting.