You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3103, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Donna Rivera, Oncology Center of Excellence, Food and Drug Administration, *OCE-Guidances@fda.hhs.gov;* or Phillip Kurs, Center for Biologics Evaluation and Research, Food and Drug Administration, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Development of Cancer Drugs for Use in Novel Combination—Determining the Contribution of the Individual Drugs' Effects.'' This draft guidance describes FDA's recommendations for characterizing the safety and effectiveness of individual drugs for use in a novel combination regimen (*i.e.,* demonstrating the contribution of each drug to the overall effect that is observed for the population) in treating cancer, including use of data external to a trial for demonstration of contribution of effect for the following types of novel combinations in oncology: (1) two (or more) investigational drugs that have not been previously approved by FDA for any indication; (2) an investigational drug with a drug(s) approved for a different indication; or (3) two (or more) drugs approved for a different indication(s). This guidance expands on the recommendations in the 2013 guidance for industry entitled ''*Codevelopment of Two or More New Investigational Drugs for Use in Combination.*''

Combination therapy in oncology is an important treatment modality. Scientific advances have increased our understanding of the pathophysiological processes that underlie many cancers. This increased understanding has provided further impetus to develop new therapeutic approaches using combinations of drugs directed at multiple therapeutic targets to improve treatment response, minimize adverse events, or both. A novel combination of drugs may be considered for development when the necessity of each drug in the proposed combination is supported by a strong biologic rationale including the nonclinical characterization of each drug in the combination and early clinical evidence. A critical aspect of codevelopment of novel combinations of oncology drugs is the characterization of the safety and effectiveness of the individual drugs in the combination because the benefit of using the individual drugs in combination is weighed against the added toxicity when they are used together. In some cases, the conventional approach to demonstrating contribution of effect by employing a standard factorial design may be infeasible. Therefore, FDA is providing recommendations regarding the use of external data for demonstrating the contribution of the individual drugs to the effect of a combination regimen and the key aspects to consider including selection of data source(s) and endpoints, and suitability of a data source.

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 ''Development of Cancer Drugs for Use in Novel Combination—Determining the Contribution of the Individual Drugs' Effects.'' 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

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 part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; and the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338.

III. Electronic Access

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

Dated: July 14, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–13366 Filed 7–16–25; 8:45 am]

BILLING CODE 4164–01–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 a meeting of the National Center for Advancing Translational Sciences 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 Center for Advancing Translational Sciences Advisory Council.

Date: August 19, 2025.

Time: 3:00 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Center for Advancing Translational Sciences, National Institutes of Health, NCI Shady Grove 1E323, 9609 Medical Center Drive, Rockville, MD 20892.

Meeting Format: Video Assisted Meeting.

Contact Person: Anna L. Ramsey-Ewing, Ph.D., Executive Secretary, National Center for Advancing, Translational Sciences, 9609 Medical Center Drive, Room 1E454, Rockville, MD 20850, (301) 435–0809, *anna.ramseyewing@nih.gov.*

Any interested person may file written comments with the committee by forwarding the 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.

(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 14, 2025.

Bruce A. George,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–13369 Filed 7–16–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of meetings of the National Advisory Allergy and Infectious Diseases Council.

The meeting will be open to the public. The open sessions will be videocast and can be accessed from the NIH Videocasting and Podcasting website (*http://videocast.nih.gov*). Individuals who plan to attend 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 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 Advisory Allergy and Infectious Diseases Council.

Date: September 25, 2025.

Closed: 8:30 a.m. to 10:30 a.m.

Agenda: To review and evaluate grant applications.

Address: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Grand Hall, Rockville, MD 20892 (Video Assisted Meeting).

Open: 10:30 a.m. to 11:45 a.m.

Agenda: Reports from NIAID Acting Director and NIH Director.

Address: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Grand Hall, Rockville, MD 20892 (Video Assisted Meeting).

Contact Person: Kelly Y. Poe, Ph.D., Director, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F41, Bethesda, MD 20892–9834, (240) 669–5036, *poeky@mail.nih.gov*.

Name of Committee: National Advisory Allergy and Infectious Diseases Council, Division of AIDS Subcommittee.

Date: September 25, 2025.

Open: 1:00 p.m. to 4:30 p.m.

Agenda: Reports from Division Director and Division Staff.

Address: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Grand Hall, Rockville, MD 20892 (Video Assisted Meeting).

Contact Person: Kelly Y. Poe, Ph.D., Director, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 55601 Fishers Lane, Room 3F41, Bethesda, MD 20892–9834, (240) 669–5036, *poeky@mail.nih.gov*.

Name of Committee: National Advisory Allergy and Infectious Diseases Council, Division of Microbiology and Infectious Diseases.

Open: 1:00 p.m. to 4:20 p.m.

Agenda: Reports from Division Director and Division Staff.

Address: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Garden Room 2, Rockville, MD 20892 (Video Assisted Meeting).

Contact Person: Kelly Y. Poe, Ph.D., Director, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F41, Bethesda, MD 20892–9834, (240) 669–5036, *poeky@mail.nih.gov*.

Name of Committee: National Advisory Allergy and Infectious Diseases Council, Division of Microbiology and Infectious Diseases Subcommittee.

Open: 1:00 p.m. to 4:30 p.m.

Agenda: Reports from Division Directors and Division Staff.

Address: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Garden Room 1, Rockville, MD 20892 (Video Assisted Meeting).

Contact Person: Kelly Y. Poe, Ph.D., Director, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3F41, Bethesda, MD 20892–9834, (240) 669–5036. *poeky@mail.nih.gov*.

Information is also available on the Institute's/Center's home page: *https://www.niaid.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. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: July 15, 2025.

Bruce A. George,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–13435 Filed 7–16–25; 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 Fellowships: Neuroscience Topics

Date: August 12–13, 2025.

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

Agenda: To review and evaluate grant applications.

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

Meeting Format: Virtual Meeting.

Contact Person: Jasenka Borzan, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd, Room 6142, MSC 9606, Bethesda, MD 20892–9606, *jasenka.borzan@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Topics in Alloimmunity and Transplantation Immunology.

Date: August 14, 2025.

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

Contact Person: Anthony David Foster, Ph.D., Scientific Review Officer, The Center