supplemental application. Additionally, we are focusing on such drugs that meet the following criteria for a new use: (1) There is compelling scientific evidence to support the effectiveness of the drug for the new use, (2) the dosage form(s) and route(s) of administration for the new use are the same as for an approved indication, and (3) there is a comparable safety profile for the patient populations for the new use and approved indications. FDA is also seeking input on potential candidates for drug repurposing that may not meet all of the above criteria but have preliminary promising data that might address an unmet need. In particular, FDA seeks comments, data (including real-world data), and information on the following topics:

1. *Priority areas:* Initially identified priority chronic disease areas include metabolic diseases, neurodegenerative conditions, women's health conditions (*e.g.,* conditions related to menopause), men's health conditions (*e.g.,* testosterone deficiency), and substance use disorders, as well as rare diseases. Based on your understanding of disease areas with significant unmet medical needs and high potential for effective treatment through drug repurposing, do you agree with these priority areas? Are there any other priority areas you would recommend for inclusion? Please explain your response.

2. *Candidates for drug repurposing:* What candidates for drug repurposing have the greatest potential for effective treatment of particular identified medical conditions?

a. *Scenario 1:* Candidates for which sufficient evidence may already exist to demonstrate their safety and effectiveness for a potential new use.

For FDA to approve a new use, there needs to be data demonstrating that the candidate is safe and effective for use under the conditions prescribed, recommended, or suggested in the drug's labeling (section 505(d) of the FD&C Act). The substantial evidence standard is defined in statute (section 505(d) of the FD&C Act) to mean evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof. The statute permits an approval based on one adequate and well-controlled clinical investigation with confirmatory evidence if FDA determines that the data are sufficient based on relevant science to establish substantial evidence. The substantial evidence of effectiveness standard ensures that sponsors have demonstrated the real effect of a drug.

This scenario would be limited to candidates where no additional data would need to be generated (*e.g.,* from clinical trials), and it may include potential uses for candidates based on publicly available scientific evidence, such as published literature. Please submit ideas for candidates that may have substantial evidence of effectiveness for a new use of a drug for a disease or condition, as well as supporting evidence from the published literature, unpublished adequate and well-controlled investigations that have completed results and analyses, or both.

b. *Scenario 2:* Candidates for which there are preliminary signals from clinical data, but sufficient evidence *does not yet exist* to demonstrate their safety and effectiveness for a new use.

There may be other situations in which there is information that suggests the potential for a clinical benefit of a drug to treat a disease or condition based on preliminary case reports or small pilot studies, but for which larger adequate and well-controlled investigations have not yet taken place. In these situations, the data would not yet be sufficient to support a labeling change; however, they may be suggestive of promising areas that warrant further study. Please submit ideas for candidates that meet these criteria, as well as an overview of the existing data which you believe is promising enough to merit further study.

c. *Scenario 3:* Candidates for which there are preliminary signals from pre-clinical data, but no clinical evidence yet exists to demonstrate their safety and effectiveness for a new use.

There may also be situations in which there is information that suggests the potential for a clinical benefit of a drug to treat a disease or condition based on pre-clinical data—*e.g.,* via high-throughput screening, in vitro models, or artificial intelligence/machine learning—but for which there is currently no clinical evidence. Please submit ideas for candidates that meet these criteria, as well as an overview of the existing data which you believe is promising enough to merit further study.

3. *Approaches to identifying candidates for drug repurposing:* FDA is also interested in exploring new innovative approaches to identifying candidates for drug repurposing. Please describe methods or opportunities that you believe the Agency could use to facilitate the identification of new candidates.

4. *Barriers and opportunities:*

- In cases where there appears to be no commercial interest in adding a new use through a supplemental application, what are the barriers to repurposing drugs to address unmet needs?
- From the perspective of patients and clinicians, what are the barriers to using FDA-approved drugs for unapproved uses when a prescriber determines a drug is medically appropriate for a patient?
- What could FDA and other federal partners do to address these barriers?
- How can FDA and other federal partners collect and use data about unapproved uses for FDA-approved drugs to better understand how they are being used in the community?

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–09366 Filed 5–11–26; 8:45 am]

BILLING CODE 4164–01–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; Institutional Training and Education Review Panel.

Date: May 29, 2026.

Time: 12:30 p.m. to 4:30 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: Klaus B. Piontek, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of

Health, 6701 Rockledge Drive, Bethesda, MD 20892, (240) 276–5413, *klaus.piontek@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Special: Integrated Respiratory Research.

Date: June 11, 2026.

Time: 10:00 a.m. to 6:00 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: Prashant Sharma, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (240) 275–6351, *prashant.sharma@nih.gov.*

Name of Committee: Oncology 2—Translational Clinical Integrated Review Group; Translational Immuno-Oncology Study Section TIO.

Date: June 15, 2026.

Time: 8:00 a.m. to 6:30 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: Maria Elena Cardenas-Corona, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20817, 301–867–5309, *maria.cardenas-corona@nih.gov.*

Name of Committee: Genes, Genomes, and Genetics Integrated Review Group; Genetic Variation and Evolution Study Section.

Date: June 15, 2026.

Time: 9:00 a.m. to 7:00 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: Michael Patrick O'Connell, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 867–5309, *oconnellmp@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Undergraduate Institutional Training and Research Education Grants.

Date: June 15–16, 2026.

Time: 9:00 a.m. to 6:00 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: Marcienne Wright, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Dr., Bethesda, MD 20892, (301) 594–3878, *marci.wright@nih.gov.*

Name of Committee: Healthcare Delivery and Methodologies Integrated Review Group; Science of Implementation in Health and Healthcare Study Section.

Date: June 15, 2026.

Time: 9:00 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: Lauren Penney, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 496–1968, *penneyls@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Special Topics: Cellular Processes in Aging and Development.

Date: June 15, 2026.

Time: 9:15 a.m. to 7:00 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: Raj K Krishnaraju, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 435–1047, *kkrishna@csr.nih.gov.*

Name of Committee: Biobehavioral and Behavioral Processes Integrated Review Group; Biobehavioral Regulation, Learning and Ethology Study Section.

Date: June 15, 2026.

Time: 9:30 a.m. to 6:00 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: Sara Louise Hargrave, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institute of Health, 6701 Rockledge Drive, Room 3170, Bethesda, MD 20892, (301) 443–7193, *hargravesl@mail.nih.gov.*

Name of Committee: Applied Therapeutics for Cancer Integrated Review Group; Mechanisms of Cancer Therapeutics A Study Section.

Date: June 16, 2026.

Time: 8:30 a.m. to 6:30 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: Careen K. Tang-Toth, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6214, MSC 7804 Bethesda, MD 20892, (301)435–3504, *tothct@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: May 7, 2026.

Denise M. Santeufemio,

Supervisory Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2026–09323 Filed 5–11–26; 8:45 am]

BILLING CODE 4167–05–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 meetings 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: June 22, 2026.

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.

Meeting Format: Virtual Meeting.

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

Agenda: Report from Institute Director.

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

Meeting Format: Virtual 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, MSC 9834, Rockville, MD 20892–9834, (240) 669–5036, *poeky@mail.nih.gov.*