CMC changes as described in the guidances remains relevant. The SUPAC guidances assist in reducing the number of CMC changes that require approval of a supplemental application, which can minimize delays in distribution of the product, give companies greater control over their production resources, and result in significant net savings to industry. In addition, the SUPAC guidances allow FDA to focus resources on those changes that pose the greatest risk to product quality thereby improving efficiency and promoting timely continual improvement in accordance with current good manufacturing practice. We acknowledge, however, that the effectiveness of the SUPAC guidances may be impacted by subsequent guidances (*e.g.,* ICH Q9(R1) and ICH Q12)), where particular recommendations in those guidances either supersede or potentially conflict with certain recommendations in the SUPAC guidances. For example, the principles described in ICH Q12 (*e.g.,* how enhanced development can inform the nature and extent of established conditions, further elaboration on change management as an aspect of the pharmaceutical quality system) are intended to enhance industry's ability to manage many CMC changes with greater efficiency and with less regulatory oversight prior to implementation of the change. Accordingly, FDA is considering updating the SUPAC guidances to improve their utility and effectiveness in light of evolving science, to ensure they continue to reflect the Agency's current thinking on risk-based approaches to CMC changes, and to enable manufacturers to more effectively evaluate changes within their quality systems prior to submitting a CMC change for evaluation.

Interested persons are invited to provide detailed comments and information related to the contents of this notice. To facilitate input, we have developed the following questions about the SUPAC guidances:

1. How are the recommendations provided in the SUPAC guidances still helpful and meaningful to regulated industry?

a. Are there sections of the SUPAC guidances that are particularly beneficial and are important to retain, either partially or in their entirety, because they reflect current risk-based approaches and are currently being referenced by applicants to support CMC changes?

b. Are the risk-based principles described in the SUPAC guidances being used to help inform applicants in other ways in addition to supporting CMC changes?

2. What challenges do you have when interpreting or applying the recommendations in the SUPAC guidances?

a. Are there sections of the SUPAC guidances that should be removed because they are no longer relevant or meaningful?

b. When referencing the SUPAC guidances for recommendations on a CMC change, are you able to effectively evaluate changes within your quality system and readily identify both the type and the corresponding level of change (*i.e.,* major, moderate, or minor) based on the information provided in the SUPAC guidances? If not, please specify what challenges you have when making this determination.

c. Are there areas of overlap or inconsistencies among the various SUPAC guidances or in other FDA guidances on CMC changes that may cause confusion when trying to apply the recommendations? Please specify the areas of overlap or inconsistencies.

3. How can FDA provide clarity on the recommendations provided in the SUPAC guidances? For example:

a. Should FDA consider reorganizing the content in the SUPAC guidances, for example, by either combining the multiple SUPAC guidances into a single guidance, or separating topics in the individual guidances, so that recommendations are easier to interpret and apply?

b. Are there recommendations from other FDA guidances, for example, the studies described in the draft guidance for industry titled ''Physicochemical and Structural (Q3) Characterization of Topical Drug Products Submitted in ANDAs'' (87 FR 64230),[1] that if included in the SUPAC guidances, might help to reduce regulatory burden?

c. How might the recommendations in the SUPAC guidances be better aligned with current risk assessment and postapproval lifecycle management principles and tools (*e.g.,* postapproval change management protocols, established conditions)?

4. Are there new topics that should be added to the SUPAC guidances?

These questions are not meant to be exhaustive, and we are also interested in any other pertinent information interested persons would like to share on this topic. This feedback will help inform the Agency's general policy development direction. FDA encourages commenters to provide the specific rationale and basis for their comments, including any available supporting data and information.

[1] When final, this guidance will represent the FDA's current thinking on this topic. For the most recent version of a guidance, check the FDA guidance web page at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.*

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–04196 Filed 3–2–26; 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: Biobehavioral and Behavioral Processes Integrated Review Group; Adult Lifespan Psychopathology Study Section.

Date: April 2–3, 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: Benjamin G Shapero, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3182, MSC 7848, Bethesda, MD 20892, (301) 402–4786, *shaperobg@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Nucleic Acid Therapeutic Delivery (NATD).

Date: April 2, 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: Jingwu Xie, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594–8625, *jingwu.xie@nih.gov.*

Name of Committee: Social and Community Influences on Health Integrated Review Group; Social Sciences and Population Studies A Study Section.
Date: April 2, 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: Suzanne Ryan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3139, MSC 7770, Bethesda, MD 20892, (301) 435–1712, *ryansj@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Early Development of Vaccines Against Infectious Diseases.
Date: April 2, 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: Vanitha Sundaresa Raman, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301–435–0000, *vanitha.raman@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Institutional Research Rigor (STIRR) Program.
Date: April 3, 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: Abhignya Subedi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301–594–6143, *abhi.subedi@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Medical Imaging Investigations.
Date: April 3, 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: Carlos J Perez-Torres, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 480–0451, *carlos.perez-torres@nih.gov.*

Name of Committee: Biological Chemistry and Macromolecular Biophysics Integrated Review Group; Macromolecular Structure and Function C Study Section.
Date: April 6–7, 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: Guillermo Andres Bermejo, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 827–5742, *bermejog@mail.nih.gov.*

Name of Committee: Biological Chemistry and Macromolecular Biophysics Integrated Review Group; Maximizing Investigators' Research Award B Study Section.
Date: April 6–7, 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: Sudha Veeraraghavan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4166, MSC 7846, Bethesda, MD 20892, (301) 827–5263, *sudha.veeraraghavan@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Career Development Award Review.
Date: April 6–7, 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: Bita Nakhai, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Dr., Bethesda, MD 20892, (301) 594–3258, *nakhaib@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Learning, Memory, Language, Communication, and Related Neuroscience.
Date: April 6–7, 2026.
Time: 10:00 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: Alicia Mariel Jais, Ph.MD., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Dr., Bethesda, MD 20892, (301) 867–5309, *mariel.jais@nih.gov.*

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review Group; Neuroscience of Interoception and Chemosensation Study Section.
Date: April 7, 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: Myongsoo Matthew Oh, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1011F, Bethesda, MD 20892, (301) 435–1042, *ohmm@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR–23–145: Maximizing Investigators Research Award for Early Stage Investigators.
Date: April 7–8, 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: Adam Lawrence Heuberger, Ph.D., Scientific Review Officer, National Institutes of Health, 6701 Rockledge Dr., Bethesda, MD 20892, (301) 828- 2907, *adam.heuberger@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: February 26, 2026.

Bruce A. George,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2026–04140 Filed 3–2–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

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Name of Committee: Center for Scientific Review Special Emphasis Panel; Mentored Career Development Awards SEP.
Date: April 2, 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.