

3. *The date the application was approved:* November 16, 2023. FDA has verified the applicant's claim that NDA 218197 was approved on November 16, 2023.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 1,071 days or 5 years of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to <https://www.regulations.gov> at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: June 13, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–11320 Filed 6–18–25; 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; Small Business: Therapeutic Development for CNS Injuries, Neurovascular, and Neurological Disorders.

Date: July 15, 2025.

Time: 9:30 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: Gagan Deep Bajaj, Ph.D., Scientific Review Officer, National Institute on Drug Abuse, NIH, Scientific Review Branch, 11601 Landsdown Street, 3WF Room 09A01, Bethesda, MD 20892, (301) 402–6965, gagan.bajaj@nih.gov.

Name of Committee: Musculoskeletal, Oral and Skin Sciences Integrated Review Group; Musculoskeletal Tissue Engineering Study Section.

Date: July 17–18, 2025.

Time: 8:30 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: Thomas Zeyda, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 480–6921, thomas.zeyda@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Biomaterials, Delivery, and Nanotechnology.

Date: July 17–18, 2025.

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: David R. Filpula, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6181, MSC 7892, Bethesda, MD 20892, 301–435–2902, filpuladr@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Medical Imaging.

Date: July 17–18, 2025.

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: Saejeong J. Kim, Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W640, Rockville, MD 20850, saejeong.kim@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Biomedical Sensing, Measurement and Instrumentation.

Date: July 17–18, 2025.

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: Steven Anthony Ripp, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594–3010, steven.ripp@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Digestive Sciences.

Date: July 17–18, 2025.

Time: 9:00 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: Ganesan Ramesh, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2182 MSC 7818, Bethesda, MD 20892, 301–827–5467, ganesan.ramesh@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Disease Management, Risk Prevention, and Health Behavior Change.

Date: July 17–18, 2025.

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: Helen Huang, Ph.D., Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6710B Rockledge Drive, Room 2137D, Bethesda, MD 20892, (301) 435–8207, helen.huang@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Therapeutic Development for Alzheimer's Disease and Related Dementias (ADRD) and Neurodegenerative Disorders.

Date: July 17–18, 2025.

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: Kathryn Partlow, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1016D, Bethesda, MD 20892, (301) 594–2138, partlowkc@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: June 16, 2025

Sterlyn H. Gibson,

Program Specialist Office of Federal Advisory Committee Policy.

[FR Doc. 2025–11285 Filed 6–18–25; 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

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Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Biobehavioral Processes.

Date: July 15, 2025.

Time: 8:00 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, Scientific Review Branch, National Institutes of Neurological Disorders and Stroke, 6001 Executive Blvd., Rockville, MD 20852, abhi.subedi@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Biophysical, Physiological, Pharmacological and Bioengineering Neuroscience and Vision.

Date: July 17–18, 2025.

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: Steven G Britt, MD, Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, NINDS/NIH, NSC, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892, (301) 480–1953, steve.britt@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Review of the Centers of Biomedical Research Excellence (COBRE) Phase 1.

Date: July 17–18, 2025.

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: Manas Chattopadhyay, Ph.D., National Institutes of Health, 45 Center Drive, Bethesda, MD 20872, manasc@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Clinical Care and Health Interventions.

Date: July 18, 2025.

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: Karen Nieves Lugo, Ph.D., MPH, Scientific Review Officer, National Institute on Minority Health and Health Disparities, National Institutes of Health, 7201 Wisconsin Ave, Ste 533, Bethesda, MD 20892, 301–402–1366, karen.nieveslugo@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Seeking products to address social needs impacting substance use disorders.

Date: July 18, 2025.

Time: 9:00 a.m. to 1:00 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: Kearly A Cope, Ph.D., MPH, BA, Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6705 Rockledge Drive, Room 209–A, Bethesda, MD 20892–7924, 301–827–7912, copeka@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA Panel: Real-World Data for AD/ADRD and the AD Sequencing Project Consortium.

Date: July 18, 2025.

Time: 10:00 a.m. to 4:00 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: Gianina Ramona Dumitrescu, Ph.D., MPH, Scientific Review Officer, SRB, National Institute on Aging, National Institutes of Health, 5601 Fishers Lane, Suite 8B, Rockville, MD 20892, (301) 827–0696, ramona.dumitrescu@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: June 17, 2025.

Sterlyn H Gibson,

Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–11396 Filed 6–18–25; 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; RFA–ES–25–003: Time-Sensitive Research Opportunities in Environmental Health Sciences.

Date: July 17, 2025.

Time: 9:00 a.m. to 10:00 a.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: Abigail A Haydon, MPH, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Dr., Bethesda, MD 20892, (301) 435–4806, haydonaba@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Mentored Clinical and Basic Science.

Date: July 17–18, 2025.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.