

Drug, and Cosmetic Act (FD&C Act) authorizes FDA to award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the award of the priority review voucher. FDA has determined that ISEMBYLD (apitegromab-mstn), approved September 11, 2026, manufactured by Scholar Rock, Inc., meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT:

Quyen Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-2771, Quyen.Tran1@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA is announcing the issuance of a priority review voucher to the sponsor of an approved rare pediatric disease product application. Under section 529 of the FD&C Act (21 U.S.C. 360ff), FDA will award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA has determined ISEMBYLD (apitegromab-mstn), manufactured by Scholar Rock, Inc., meets the criteria for a priority review voucher. ISEMBYLD (apitegromab-mstn) injection is indicated for the treatment of spinal muscular atrophy (SMA) in adults and pediatric patients 2 years of age and older who are currently receiving a survival motor neuron 2 (SMN2)-targeted treatment.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to <https://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm>. For further information about ISEMBYLD (apitegromab-mstn), go to the "Drugs@FDA" website at <https://www.accessdata.fda.gov/scripts/cder/daf/>.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026-21718 Filed 10-23-26; 8:45 am]

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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 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 partially open to the public as indicated below. Individuals who plan to attend as well as those who need special assistance, such as sign language interpretation or other reasonable accommodations, must notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting website (<http://videocast.nih.gov/>).

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 intramural programs and projects as well as the grant applications and/or contract proposals 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 and/or contract proposals, 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: January 25–26, 2027.

Open: January 25, 2027, 12:00 p.m. to 5:00 p.m.

Agenda: Call to order and introductory remarks; NICHD Director's Report; Invited Director, NIA; Scientific Presentation; Voice of the Participant; Concept Clearance; Closing Remarks.

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

Meeting Format: Virtual Meeting.

Closed: January 26, 2027, 9:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

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

Meeting Format: Virtual Meeting.

Contact Person: Joseph Gindhart, Ph.D., Deputy Director, Division of Extramural

Activities, *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Room 2322, 301-435-6975, joe.gindhart@nih.gov.

Registration is not required to attend the open portion of this meeting.

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.

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 No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: October 21, 2026.

Margaret N. Vardanian,

Program Analyst Office of Federal Advisory Committee Policy.

[FR Doc. 2026-21815 Filed 10-23-26; 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

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; Research projects and Exploratory Research projects of Molecular interactions of intracellular proteins.

Date: November 19, 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: Lee Warren Slice, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of

Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 867-5309, slicelw@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA-AI-27 012: Coccidioidomycosis Collaborative Research Centers (P01 Clinical Trial Not Allowed).

Date: November 19–20, 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: Poonam Pegu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (240) 292-0719, poonam.pegu@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships: Cancer Immunology and Immunotherapy A.

Date: November 20, 2026

Time: 8:00 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: Ola Mae Zack Howard, Ph.D., BS, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4192, MSC 7806, Bethesda, MD 20892, 301-451-4467, howardz@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Clinical Decision Making and Clinical Outcomes for Aged Populations.

Date: November 20, 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: Rhoda Keese Moise, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Dr., Bethesda, MD 20892, (304) 594-0702, rhoda.moise@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR-25-156: Limited Competition: High Impact Specialized Innovation Programs in Clinical and Translational Science (RC2).

Date: November 20, 2026.

Time: 10:00 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.

Contact Person: John Harold Laity, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 402-8254, laityjh@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Collaborative International Projects in Musculoskeletal and Oral Research (PF5).

Date: November 20, 2026.

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: Vanessa Dawn Sherk, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 801C, Bethesda, MD 20892, (301) 867-5309, sherkv2@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Special Topics in Bioengineering and Instrumentation.

Date: November 20, 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: Mirela Milesescu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 mirela.milesescu@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Topics in Health Services Research.

Date: November 20, 2026.

Time: 10:00 a.m. to 11:00 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: Angela D. Thrasher, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1000J, Bethesda, MD 20892, (301) 480-6894, thrasherad@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small business: Auditory and Vision Technologies.

Date: November 20, 2026.

Time: 11:00 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: Barbara Susanne Mallon, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 480-8992, mallonb@mail.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: October 22, 2026.

Kuleni D. Onnen,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2026-21816 Filed 10-23-26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Fogarty International Center; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Fogarty International Center Advisory Board.

This will be a hybrid meeting held in-person and virtually and will be open to the public as indicated below.

Individuals who plan to attend in-person or view the virtual meeting 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 open session can be accessed from the Fogarty International Center website (<https://www.fic.nih.gov/About/Advisory>).

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: Fogarty International Center Advisory Board.

Date: February 8–9, 2027.

Closed: February 08, 2027, 3:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate the second level of grant applications.

Address: Fogarty International Center National Institutes of Health Lawton Chiles International House (Stone House) 16 Center Drive, Room B2C02, Bethesda, MD 20892.

Meeting Format: In Person and Virtual Meeting.

Open: February 09, 2027, 9:00 a.m. to 12:00 p.m.

Agenda: Update and discussion of current and planned Fogarty International Center activities.

Address: Fogarty International Center National Institutes of Health Lawton Chiles International House (Stone House), 16 Center Drive, Room B2C02, Bethesda, MD 20892.

Meeting Format: In Person and Virtual Meeting.