

May 27, 2026, entitled “Drugs for Human Use; Drug Efficacy Study Implementation: Estrogen-Androgen Fixed-Combination Drug Products; Syntest D.S. and Syntest H.S. Tablets; Withdrawal of Hearing Requests; Final Resolution of Drug Efficacy Study Implementation 7661” (91 FR 31462) (the “May 2026 Notice”), as previously extended by the notice published in the **Federal Register** on June 26, 2026 (91 FR 38717) (the “June 2026 Notice”), by an additional 41 days. The effective date of the May 2026 Notice, which was previously extended to September 24, 2026, is hereby further extended to November 4, 2026. This further extension is necessary to allow FDA sufficient time to consider issues raised by interested parties.

DATES: The effective date of the May 27, 2026, notice (91 FR 31462), as previously extended, is further extended to November 4, 2026.

ADDRESSES: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500 between 9 a.m. and 4 p.m., Monday through Friday. Publicly available submissions may be seen in the docket.

The most relevant background documents regarding this matter are available in the docket. However, additional background documents are available upon request (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Amber McKinley, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5171, Silver Spring, MD 20993-0002, 301-796-0061, Amber.McKinley@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On May 27, 2026, FDA published a notice in the **Federal Register** (91 FR 31462) announcing the final resolution of Drug Efficacy Study Implementation (DESI) 7661 for estrogen-androgen fixed-combination drug products. The May 2026 Notice concluded that all outstanding hearing requests for estrogen-androgen fixed-combination drug products under Docket FDA-1998-P-0083 had been withdrawn, and that such products lack substantial evidence of effectiveness for the treatment of

moderate to severe vasomotor symptoms associated with menopause in patients not improved by estrogen alone. The May 2026 Notice stated that shipment in interstate commerce of any drug product identified in the docket, or any identical, related, or similar product, that is not the subject of an approved new drug application or abbreviated new drug application would be unlawful as of June 26, 2026.

On June 26, 2026, FDA published a notice in the **Federal Register** (91 FR 38717) extending the effective date of the May 2026 Notice by 90 days, from June 26, 2026, to September 24, 2026, to allow FDA sufficient time to consider issues raised by interested parties following publication of the May 2026 Notice.

II. Second Extension of Effective Date

FDA has determined that additional time is needed in order to fully consider the issues raised by interested parties. Accordingly, FDA is extending the effective date of the May 2026 Notice by an additional 41 days, from September 24, 2026, to November 4, 2026.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026-17498 Filed 8-26-26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, RFA-DC-27-004: Theories, Models and Methods for Analysis of Complex Data from the Brain September 17, 2026, 09:30 a.m. to September 17, 2026, 06:00 p.m., National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD, 20892 which was published in the **Federal Register** on August 05, 2026, FR Doc. 2026-15910, 91 FR 50556.

This meeting is being amended to change the Panel Name from RFA-DC-27-004: Theories, Models and Methods for Analysis of Complex Data from the Brain to RFA: “Exploratory Research Opportunities Using Invasive Neural Recording and Stimulating Technologies in the Human Brain. The meeting is closed to the public.

Dated: August 24, 2026.

Margaret N. Vardanian,
Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2026-17451 Filed 8-26-26; 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; PAR Panel: Risk Factors for Neurodegeneration.

Date: September 28–29, 2026.

Time: 9:30 a.m. to 7:30 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: Ashley Marie Kopec, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 496-9293, kopecam@csr.nih.gov.

Name of Committee: Biological Chemistry and Macromolecular Biophysics Integrated Review Group; Biochemistry and Biophysics of Membranes Study Section.

Date: September 29–30, 2026.

Time: 9:30 a.m. to 8:30 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: Irina V. Nesmelova, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594-6496, irina.nesmelova@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Topics in Neuroscience and Technology.

Date: September 29, 2026.