DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10971]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by October 26, 2026.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. By *regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier: __/OMB Control Number: __, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collections

1. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Acute Hospital Care at Home (AHCAH) Quantity, Intensity, and Mix of Services (QIMS) Data Collection Tool; *Use:* This is a new information collection request. The Consolidated Appropriations Act (CAA) of 2026 Section 6210(c) requires CMS to evaluate care provided to patients served through the Acute Hospital Care at Home (AHCAH) initiative, including the quantity, intensity, and mix of services (QIMS) furnished. This includes, but not limited to, the number of clinician visits, food services, and pharmacy services provided to patients while on the hospital-at-home service.

To participate in the AHCAH initiative hospitals are granted individual waivers at the CMS Certification Number (CCN) level. The AHCAH initiative waives specific Hospital Conditions of Participation (CoPs), 42 CFR 483, which require nursing services to be provided on premises 24 hours a day, 7 days a week and the immediate availability of a registered nurse for care of any patient.

In-patient healthcare services are provided to patients served under the AHCAH initiative. CMS has developed a tool to quantify the mix and intensity of the services for the purposes of analysis as required by CAA 2026. CMS is seeking OMB approval for information collection via this tool.

CMS will use this information to describe the quantity, mix, and intensity of services (QIMS) provided to patients in the AHCAH initiative. This includes patients admitted from an emergency department (ED) and patients transferred from an inpatient hospital unit. CMS will use this data to report to Congress. *Form Number:* CMS–10971 (OMB control number: 0938–NEW); *Frequency:* Annually; *Affected Public:* Individuals and Households; Private Sector—Not-for-profit institutions and Business or other for-profits; Federal Government and State, Local or Tribal Governments; *Number of Respondents:* 365; *Total Annual Responses:* 13,000; *Total Annual Hours:* 13,000. (For policy questions regarding this collection contact Cheryl Lehane at (617) 461–4888.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2026–17484 Filed 8–26–26; 8:45 am]

BILLING CODE 4169–69–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–1998–P–0083 (formerly 76N–0377); DESI 7661]

Drugs for Human Use; Drug Efficacy Study Implementation: Estrogen-Androgen Fixed-Combination Drug Products; Second Extension of Effective Date of Final Resolution of Drug Efficacy Study Implementation 7661

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice; second extension of effective date.

SUMMARY: The Food and Drug Administration (FDA or Agency) is extending the effective date of the notice published in the **Federal Register** on

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]

BILLING CODE 4164–01–P

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]

BILLING CODE 4167–05–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; 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.