additional populations. If necessary, ORR will work with OMB to reflect updates to the survey or respondents through revision or nonsubstantive change requests.

As an emergency approval, this questionnaire will be approved immediately. Comments will be considered for the following extension request, if pursued.

Respondents: Afghans who might have received ORR benefits and services.

Annual Burden Estimates: Semi-structured telephone interviews will be conducted with Afghans who received ORR benefits and services and are likely to have additional assistance needs and vulnerabilities. Interviews will be based on available contact information. Phone interviews are voluntary and are expected to take about 30 minutes.

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Annual burden hours
ROWI Questionnaire	1,800	1	.50	900

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: ORR is authorized to conduct this survey under the Refugee Act of 1980 (8 U.S.C. 1522(a)(3)).

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2026–17856 Filed 8–31–26; 8:45 am]

BILLING CODE 4184–89–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–P–6538]

Determination That NAMENDA (Memantine Hydrochloride) Tablets, 5 Milligrams and 10 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) has determined that NAMENDA (memantine hydrochloride) tablets, 5 milligrams (mg) and 10 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as the ANDAs meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Awo Archampong-Gray, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6243, Silver Spring, MD 20993–0002, 301–796–0110, *Awo.Archampong-Gray@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

NAMENDA (memantine hydrochloride) tablets, 5 mg and 10 mg, are the subject of NDA 021487, held by AbbVie Inc., and initially approved on October 16, 2003. NAMENDA is indicated for the treatment of moderate to severe dementia of the Alzheimer's type.

NAMENDA (memantine hydrochloride) tablets, 5 mg and 10 mg, are currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Newcastle Bioscience LLC submitted a citizen petition dated June 5, 2026 (Docket No. FDA–2026–P–6538), under 21 CFR 10.30, requesting that the Agency determine whether NAMENDA (memantine hydrochloride) tablets, 5 mg and 10 mg, were voluntarily withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that NAMENDA (memantine hydrochloride) tablets, 5 mg and 10 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that NAMENDA (memantine hydrochloride) tablets, 5 mg and 10 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of NAMENDA (memantine hydrochloride) tablets, 5 mg and 10 mg, from sale. We have also independently evaluated

relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list NAMENDA (memantine hydrochloride) tablets, 5 mg and 10 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to these drug products. Additional ANDAs for these drug products may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–17812 Filed 8–31–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Microbiome Subcommittee of the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria; Correction

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health.

ACTION: Notice; Correction. 1st Public Meeting of the Microbiome Subcommittee of the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria.

SUMMARY: The Department of Health and Human Services published a document in the **Federal Register** of August 26, 2026 concerning the first public meeting of the Microbiome Subcommittee of the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB). The document contained incorrect time for the meeting.

FOR FURTHER INFORMATION CONTACT: Sarah Mcclelland, M.P.H., Designated Federal Officer, Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services, Email: *CARB@hhs.gov.*

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of August 26, 2026, in FR Doc. 2026–17404, on page 1, correct the **DATES** caption to read:

DATES: The meeting is scheduled to be held on September 2, 2026, from 9:30 a.m. to 12:30 p.m. ET (times are tentative and subject to change). The confirmed times and agenda items for the meeting will be posted on the website for the PACCARB at *http://www.hhs.gov/paccarb* when this information becomes available.

Dated: August 27, 2026.

Sarah Mcclelland,

Designated Federal Officer, Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria, Office of the Assistant Secretary for Health.

[FR Doc. 2026–17793 Filed 8–31–26; 8:45 am]

BILLING CODE 4150–44–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 Imaging Guided Interventions and Surgery Study Section, October 15, 2026, 09:00 a.m. to October 16, 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 13, 2026, 91 FR 52311.

This meeting is being amended to change the contact person from Steven A. Ripp to Ella Jones, Ph.D., Scientific Review Officer, Center for Scientific Review, NIH, 6701 Rockledge Drive, Bethesda MD 20892, Ph. (301) 496–0777. The meeting is c The meeting is closed to the public.

Dated: August 27, 2026.

Bruce A. George,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2026–17850 Filed 8–31–26; 8:45 am]

BILLING CODE 4167–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; 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 Council on Drug Abuse.

The meeting will be held as a virtual meeting and is open to the public, as indicated below. Individuals who plan to view the virtual meeting and need special assistance such as sign language interpretation or other reasonable accommodations to view the meeting, should notify Dr. Gillian Acca via email at *gillian.acca@nih.gov* four days in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting website at *http://videocast.nih.gov/.*

A portion of 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: National Advisory Council on Drug Abuse.

Date: September 8, 2026.

Closed: 10:30 a.m. to 11:45 a.m.

Agenda: To review and evaluate grant applications.

Open: 1:00 p.m. to 4:30 p.m.

Agenda: Presentations and other business of the Council.

Meeting Format: Virtual Meeting.

Place: National Institutes of Health, National Institute on Drug Abuse, Three White Flint North, 11601 Landsdown Street, Bethesda, MD 20852.

Contact Person: Susan R.B. Weiss, Ph.D., Director, Division of Extramural Research, Office of the Director, National Institute on Drug Abuse, NIH, Three White Flint North, RM 09D08, 11601 Landsdown Street, Bethesda, MD 20852, 301–443–6480, *sweiss@nida.nih.gov*

Contact Person: Gillian Acca, Ph.D., Health Scientist Administrator, Division of Extramural Research, Office of Extramural Policy, National Institute on Drug Abuse, NIH, Three White Flint North, RM 09C70, 11601 Landsdown Street, Bethesda, MD 20852, 301–827–5863, *gillian.acca@nih.gov*

Any interested person may file written comments with the committee by forwarding the statement to Dr. Gillian Acca via email at *gillian.acca@nih.gov.* The statement