FOR FURTHER INFORMATION CONTACT: Nisha Shah, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6222, Silver Spring, MD 20993–0002, 301–796–4455, *Nisha.Shah@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approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).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may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)).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.

CABAZITAXEL (cabazitaxel) solution (injection), 60 mg/6 mL (10 mg/mL), is the subject of NDA 207970, held by Actavis LLC, an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc. (referred to as Actavis LLC), and initially approved on March 14, 2024. CABAZITAXEL (cabazitaxel) solution (injection), 60 mg/6 mL (10 mg/mL) is indicated in combination with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer previously treated with a docetaxel-containing treatment regime.

In a letter dated September 6, 2024, Actavis LLC notified FDA that CABAZITAXEL (cabazitaxel) solution (injection), 60 mg/6 mL (10 mg/mL), was being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book.

Steve Jensen of ProPharma submitted a citizen petition dated March 24, 2026, (Docket No. FDA–2026–P–3104), under 21 CFR 10.30, requesting that the Agency determine whether CABAZITAXEL (cabazitaxel) solution (injection), 60 mg/6 mL (10 mg/mL), was 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 CABAZITAXEL (cabazitaxel) solution (injection), 60 mg/6 mL (10 mg/mL), was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that this drug product, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of CABAZITAXEL (cabazitaxel) solution (injection), 60 mg/6 mL (10 mg/mL), from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list CABAZITAXEL (cabazitaxel) solution (injection), 60 mg/6 mL (10 mg/mL), 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. ANDAs that refer to this drug product may 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 this drug product 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. 2026–17401 Filed 8–25–26; 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

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

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

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that an in-person meeting is scheduled to be held for the Microbiome Subcommittee of the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB).

DATES: The meeting is scheduled to be held on September 2, 2026, from 12:00 p.m. to 5:00 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.

ADDRESSES: The meeting will be held in-person at the Hubert H. Humphrey Building, Room 800, 200 Independence Avenue SW, Washington, DC 20201.

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: The Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB), established by Executive Order 13676, is continued by Section 505 of Public Law 116–22, the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (PAHPAIA). Activities and duties of the PACCARB are governed by the provisions of the Federal Advisory Committee Act (FACA), Public Law 92–463, as amended (5 U.S.C. App.), which sets forth standards for the formation and use of federal advisory committees.

The PACCARB shall advise and provide information and recommendations to the Secretary of Health and Human Services (Secretary) regarding programs and policies

intended to reduce or combat antibiotic-resistant bacteria that may present a public health threat and improve capabilities to prevent, diagnose, mitigate, or treat such resistance. The PACCARB shall function solely for advisory purposes.

Such advice, information, and recommendations may be related to improving: the effectiveness of antibiotics; research and advanced research on, and the development of, improved and innovative methods for combating or reducing antibiotic resistance, including new treatments, rapid point-of-care diagnostics, alternatives to antibiotics, including alternatives to animal antibiotics, and antimicrobial stewardship activities; surveillance of antibiotic-resistant bacterial infections, including publicly available and up-to-date information on resistance to antibiotics; education for health care providers and the public with respect to up-to-date information on antibiotic resistance and ways to reduce or combat such resistance to antibiotics related to humans and animals; methods to prevent or reduce the transmission of antibiotic-resistant bacterial infections; including stewardship programs; and coordination with respect to international efforts in order to inform and advance the United States capabilities to combat antibiotic resistance.

The focus of the September 2, 2026, meeting will be on current trends and gaps in microbiome science. The meeting will focus on innovative and emerging topics in antimicrobial resistance (AMR) and the microbiome. Written public comments can be emailed to *CARB@hhs.gov* by midnight August 31, 2026, and should be limited to no more than one page. All public comments received prior to September 2, 2026, will be provided to the subcommittee members.

Sarah Mcclelland,

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

[FR Doc. 2026–17404 Filed 8–25–26; 8:45 am]

BILLING CODE 4150–44–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket No. HHS–OASH–2026–0232]
Temporary Placement of 7-

Hydroxymitragynine Above a Specified Threshold in Schedule I; Extension of Comment Period

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

ACTION: Notice; request for information; extension of comment period for the Request for Information and for its information collection provisions.

SUMMARY: The Office of the Assistant Secretary for Health (OASH or we) is extending the comment period to solicit input and comments on a Request for Information (RFI) on a proposed threshold for 7-hydroxymitragynine (7–OH) scheduling under the Controlled Substances Act that appeared in the **Federal Register** of July 6, 2026. Public comments submitted to this docket will be provided by the Secretary for Health and Human Services for consideration by the Attorney General. We are taking this action in response to a request for an extension to allow interested persons additional time to provide comments and input.

DATES: Submit either electronic or written comments, data, or information by September 10, 2026.

ADDRESSES: *Request for Information (RFI) Docket:* You may examine the full RFI docket at *regulations.gov* under HHS–OASH–2026–0232. To submit a response, click the ''Comment'' button inside Docket: HHS–OASH–2026–0232 and follow all instructions.

FOR FURTHER INFORMATION CONTACT: Ruben Hernandez Segarra, *Ruben.HernandezSegarra@hhs.gov*

SUPPLEMENTARY INFORMATION:

In the **Federal Register** of July 6, 2026, we published an RFI entitled ''Temporary Placement of 7-Hydroxymitragynine Above a Specified Threshold in Schedule I; Request for Information'' with a comment period that closed on July 31, 2026. This RFI sought input on the proposed 7–OH threshold that was listed by the Drug Enforcement Administration (DEA) that was issued in the **Federal Register** entitled ''Schedules of Controlled Substance: Temporary Placement of 7-Hydroxymitragynine Above a Specified Threshold in Schedule I.''

OASH has received a request for an extension of the comment period on this RFI to allow any interested persons additional time to provide comments. OASH has considered the request and is granting the extension of the comment period to allow any interested persons additional opportunity to provide comments. OASH believes that this extension allows adequate time for any interested persons to fully consider and submit comments.

Note that OASH is not soliciting comments on any permanent scheduling decision, the general safety or utility of kratom-derived products, or other policy questions outside the scope of the threshold determination for temporary scheduling. Public comments submitted to this docket will be provided by the Secretary for Health and Human Services for consideration by the Attorney General.

Brian Christine

Assistant Secretary for Health, Department of Health and Human Services.

[FR Doc. 2026–17409 Filed 8–25–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Notice of Adoption of Categorical Exclusions Under Section 109 of the National Environmental Policy Act

AGENCY: Office of the Secretary, Department of Homeland Security.

ACTION: Notice of Adoption of Categorical Exclusions pursuant to Section 109 of the National Environmental Policy Act, 42 U.S.C. 4336c.

SUMMARY: The Department of Homeland Security (DHS or Department) is notifying the public and documenting the adoption of thirty-five categorical exclusions (CEs) under the National Environmental Policy Act (NEPA). This notice identifies the types of actions to which DHS will apply the CEs, the considerations that DHS will use in determining the applicability of the CEs, and the consultation between the agencies on the use of the CEs, including application of extraordinary circumstances.

DATES: The adoption is effective August 26, 2026.

FOR FURTHER INFORMATION CONTACT: Jennifer DeHart Hass, Director, Environmental Planning Branch, by email at *jennifer.hass@hq.dhs.gov* or by telephone at (202) 834–4346.

SUPPLEMENTARY INFORMATION:

I. Background

National Environmental Policy Act and Categorical Exclusions

The National Environmental Policy Act, 42 U.S.C. 4321–4347, as amended