

available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: 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.

FOR FURTHER INFORMATION CONTACT: Amber Barrett, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “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 (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Allegations of Regulatory Misconduct Voluntarily Submitted to the Center for Devices and Radiological Health

OMB Control Number 0910–0769—Extension

This information collection supports the voluntary submission of allegations of regulatory misconduct to FDA’s Center for Devices and Radiological

Health (CDRH). An allegation of regulatory misconduct is a claim that a medical device manufacturer or individuals marketing medical devices or electronic products regulated by CDRH may be doing so in a manner that violates the law. Reporting these allegations can help make FDA aware of regulatory concerns it may not learn of otherwise. This information can help FDA identify the potential risks to patients and determine whether further investigation is warranted, as well as any steps needed to address or correct a potential violation. Anyone may file a complaint reporting an allegation of regulatory misconduct. FDA encourages people submitting allegations to include supporting information and contact information in case additional information is needed for FDA to understand the allegation and act on the report; however, you can choose to submit a report anonymously. FDA will not share your identity or contact information with anyone outside FDA unless required to do so by law, regulation, or court order.

Allegations of regulatory misconduct may include failure to register and list a medical device, marketing uncleared or unapproved products, failure to follow quality system requirements, or misleading promotion.

You can submit an allegation through the Allegations of Regulatory Misconduct Form (<https://www.fda.gov/medical-devices/reporting-allegations-regulatory-misconduct/allegations-regulatory-misconduct-form>), by email, or by regular mail.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Electronic submission of voluntary allegations to CDRH	2,800	1	2,800	0.25 (15 minutes) ...	700

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimated burden for the information collection reflects an overall increase of 75 hours and a corresponding increase of 300 responses. We attribute this adjustment to an increase in the number of submissions we received over the last few years.

Grace R. Graham,
Deputy Commissioner for Policy, Legislation, and International Affairs.
[FR Doc. 2026–17377 Filed 8–25–26; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–P–3104]

Determination That CABAZITAXEL (Cabazitaxel) Solution (Injection), 60 Milligrams/6 Milliliters (10 Milligrams/Milliliter), Was 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 CABAZITAXEL (cabazitaxel) solution (injection), 60 milligrams (mg)/6 milliliters (mL) (10 mg/mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for Cabazitaxel (cabazitaxel) solution (injection), 60 mg/6 mL (10 mg/mL), if all other legal and regulatory requirements are met.

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]

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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