not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list MICARDIS (telmisartan), tablets, 20 mg and 80 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. 2026–09011 Filed 5–6–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–4291]

Teva Pharmaceuticals USA, Inc., et al.; Withdrawal of Approval of 15 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 15 abbreviated new drug applications (ANDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of June 8, 2026.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993–0002, 301–796–3471, *Martha.Nguyen@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The applicants listed in Table 1 have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

TABLE 1—ANDAS FOR WHICH APPROVAL IS WITHDRAWN

Application No.	Drug	Applicant
ANDA 076905 ...	Finasteride tablet, 1 milligram (mg)	Teva Pharmaceuticals USA, Inc., 400 Interpace Parkway, Building A, Parsippany, NJ 07054.
ANDA 077028 ...	Cilostazol tablet, 100 mg	Actavis Elizabeth LLC. (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.), 400 Interpace Parkway, Building A, Parsippany, NJ 07054.
ANDA 077671 ...	Amlodipine besylate tablet, Equivalent to (EQ) 2.5 mg base, EQ 5 mg base, and EQ 10 mg base.	Watson Laboratories, Inc. (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.), 400 Interpace Parkway, Building A, Parsippany, NJ 07054.
ANDA 077679 ...	Carboplatin injectable, 50 mg/5 milliliter (mL) (10 mg/mL), 150 mg/15 mL (10 mg/mL), and 450 mg/45 mL (10 mg/mL).	Pharmachemie B.V. (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.), 400 Interpace Parkway, Building A, Parsippany, NJ 07054.
ANDA 078166 ...	Ciprofloxacin extended-release tablet, 212.6 mg; EQ 287.5 mg base and 425.2 mg; EQ 574.9 mg base.	Par Health USA LLC., U.S. Agent for PH Health Limited, 9 Great Valley Parkway, Malvern, PA 19355.
ANDA 078631 ...	Carboplatin injectable, 50 mg/5 mL (10 mg/mL), 150 mg/15 mL (10 mg/mL), 450 mg/45 mL (10 mg/mL), and 600 mg/60 mL (10 mg/mL).	Pliva Lachema AS (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.), 400 Interpace Parkway, MCC Blue Building A, Parsippany, NJ 07054.
ANDA 078724 ...	Ezetimibe tablet, 10 mg	Teva Pharmaceuticals USA, Inc.
ANDA 078984 ...	Anastrozole tablet, 1 mg	Watson Laboratories, Inc.
ANDA 089895 ...	Chlorzoxazone tablet, 500 mg	Barr Laboratories LLC. (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.), 400 Interpace Parkway, Building A, Parsippany, NJ 07054.
ANDA 090797 ...	Pantoprazole sodium delayed-release tablet, EQ 20 mg base and EQ 40 mg base.	Actavis Totowa LLC. (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.), 400 Interpace Parkway, Building A, Parsippany, NJ 07054.
ANDA 091539 ...	Irbesartan and hydrochlorothiazide tablet, 12.5 mg; 150 mg and 12.5 mg; 300 mg.	Watson Laboratories, Inc.
ANDA 202235 ...	Ibandronate sodium injectable, EQ 3 mg base/3 mL	Freyr INC., U.S. Agent for CHEMI S.p.A., 150 College Rd. West, Suite 102, Princeton, NJ 08540.
ANDA 210285 ...	Dimethyl fumarate delayed-release capsule, 120 mg and 240 mg.	Upsher-Smith Laboratories, LLC., U.S. Agent for Sawai USA, Inc., 6701 Evenstad Dr. N, Suite 300, Maple Grove, MN 55369.
ANDA 213158 ...	Esomeprazole magnesium delayed-release pellets capsule, EQ 20 mg base and EQ 40 mg base.	The WhiteOak Group, LLC., U.S. Agent for Cisen Pharmaceutical Co., Ltd., 1629 K St. NW, Suite 300, Washington, DC 20006.
ANDA 216407 ...	Ketorolac tromethamine tablet, 10 mg	Parexel International, U.S. Agent for Atnahs Pharma US Limited, 541 Church at North Hills St., Suite 1000, Raleigh, NC 27609.

Therefore, approval of the applications listed in Table 1, and all amendments and supplements thereto, is hereby withdrawn as of June 8, 2026. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from Table 1. Introduction or delivery for introduction into interstate commerce of products listed in Table 1 without an approved new drug application or ANDA violates sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)). Drug products that are listed in Table 1 that are in inventory on June 8, 2026 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–0008]

Advisory Committee; Blood Products Advisory Committee; Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of Federal advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Blood Products Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Blood Products Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the May 13, 2028, expiration date.

DATES: Authority for the Blood Products Advisory Committee will expire on May 13, 2026, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Advisory Committee Oversight and Management Staff, Office of the Chief Scientist, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 3215, Silver Spring, MD 20993–0002, (301) 796–8220, *ACOMSSubmissions@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to 21 CFR 14.40(b) and 41 CFR 102–3.65 and following approval by the Department of Health and Human Services and review by the General Services Administration, FDA is announcing the renewal of the Blood Products Advisory Committee (the Committee). The Committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Committee advises and informs the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drug and biological products for human use, as well as, when required, any other product under the regulatory authority of FDA. The Committee reviews and evaluates available data concerning the safety, effectiveness, and appropriate use of blood, products derived from blood and serum or biotechnology which are intended for use in the diagnosis, prevention, or treatment of human diseases, and as required, any other products for which FDA has regulatory responsibility. The Committee also advises the Commissioner of Food and Drugs of its findings regarding screening and testing (to determine eligibility) of donors and labeling of the products, on clinical and laboratory studies involving such products, on the affirmation or revocation of biological products licenses. The Committee may consider the quality and relevance of FDA's research program, which provides scientific support for the regulation of these products, and makes appropriate recommendations to the Commissioner.

The Committee will function at times as a medical device panel under the Federal Food, Drug, and Cosmetic Act Medical Device Amendments of 1976. As such, the Committee recommends classification of devices subject to its review into regulatory categories; recommends the assignment of a priority for the application of regulatory requirements for devices classified in the standards or premarket approval category; advises on formulation of product development protocols and reviews premarket approval applications for those devices to recommend changes in classification as appropriate; recommends exemption of certain devices from the application of portions of the Act; advises on the necessity to ban a device; and responds to requests from the Agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices.

The Committee shall consist of a core of at least thirteen voting members including the Chair. Subject to legal and regulatory requirements, members and the Chair are selected by and serve at the discretion of the Commissioner or designee. Each member, including the Chair, will be selected from among authorities knowledgeable in the fields of clinical and administrative medicine, hematology, immunology, blood banking, surgery, internal medicine, biochemistry, engineering, biological and physical sciences, biotechnology, computer technology, statistics, epidemiology, sociology/ethics, and related specialties.

Members will be invited to serve for terms of up to four years, or for less time at the discretion of the Commissioner or designee. Non-Federal members of this committee will serve either as Special Government Employees or representatives. Federal members will serve as Regular Government Employees or Ex-Officios.

In addition to the voting members, the Commissioner or designee may identify consumer and/or industry representatives to join the Committee (or serve as alternate representatives) as non-voting representative member(s), via a process consistent with legal and regulatory requirements. Individuals currently employed at FDA-regulated companies, such as pharmaceutical and medical device manufacturers, shall not be selected to serve as members of the Committee unless this Committee is expected to address issues for which inclusion of an industry representative is required by statute. If this Committee includes an industry representative, the Commissioner or designee will determine whether to invite them to participate in meetings on a case-by-case basis, according to applicable legal and regulatory requirements.

The Commissioner or designee shall have the authority to select members of other scientific and technical FDA advisory committees to serve temporarily as voting members and to designate consultants to serve temporarily as voting members when: (1) expertise is required that is not available among current voting standing members of the Committee (when additional voting members are added to the Committee to provide needed expertise, a quorum will be based on the combined total of regular and added members), or (2) to comprise a quorum when, because of unforeseen circumstances, a quorum is or will be lacking.

A quorum for the Committee is a majority of the current voting members present at the time, provided that FDA may specify a quorum that is less than a majority of the current voting