II. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov* or *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Persons unable to download an electronic copy of ''Patient-Matched Guides for Orthopedic Implants'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number GUI01400006 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in the following table have been approved by OMB:

21 CFR part	Topic	OMB Control No.
807, subpart E	Premarket notification	0910–0120
820	Current Good Manufacturing Practice (CGMP); Quality Management Systems Regulation (QMSR).	0910–0073
812	Investigational Device Exemption	0910–0078
814, subparts A through E	Premarket approval	0910–0231
800, 801, and 809	Medical Device Labeling Regulations	0910–0485

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–09023 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–2025–P–7054]

Determination That MICARDIS (Telmisartan), Tablets, 20 Milligrams and 80 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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(FDA, Agency, or we) has determined that MICARDIS (telmisartan), tablets, 20 milligrams (mg) and 80 mg, were not withdrawn from sale for reasons of safety or effectiveness.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 these products as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Sungjoon Chi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6216, Silver Spring, MD 20993–0002, 240–402–9674, *Sungjoon.Chi@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). FDA may not approve an ANDA that does not refer to a listed drug.

MICARDIS (telmisartan), tablets, 20 mg and 80 mg, are the subject of NDA 020850, held by Boehringer Ingelheim. NDA 020850 was initially approved on November 10, 1998. MICARDIS is indicated for the treatment of hypertension, to lower blood pressure and for cardiovascular risk reduction in patients unable to take ACE inhibitors.

MICARDIS (telmisartan), tablets, 20 mg and 80 mg, are currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Unichem Pharmaceuticals (USA), Inc. submitted a citizen petition dated December 12, 2025 (Docket No. FDA–2025–P–7054), under 21 CFR 10.30, requesting that the Agency determine whether MICARDIS (telmisartan), tablets, 20 mg and 80 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 MICARDIS (telmisartan), tablets, 20 mg and 80 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that these drug products were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of MICARDIS (telmisartan), tablets, 20 mg and 80 mg, 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 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.