



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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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 -- ANDAs for Which Approval Is Withdrawn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

Application No.	Drug	Applicant
		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,

Application No.	Drug	Applicant
		NC 27609

Therefore, approval of the applications listed in Table 1, and all amendments and supplements thereto, is hereby withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. 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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] 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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