4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA-2026-N-1226]

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in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.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Table 1.-- ANDAs for Which Approval Is Withdrawn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 074316	Cimetidine, tablet, 800 milligrams (mg)	Watson Laboratories, Inc. (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.), 400 Interpace Parkway, Building A, Parsippany, NJ 07054
ANDA 074349	Cimetidine, tablet, 200 mg, 300 mg, and 400 mg	Do.
ANDA 074424	Cimetidine, tablet, 200 mg, 300 mg, 400 mg, and 800 mg	IVAX Pharmaceuticals, Inc. (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.), 400 Interpace Parkway, Building A, Parsippany, NJ 07054
ANDA 074803	Fluoxetine hydrochloride (HCl), capsule, Equivalent to (EQ) 10 mg base and EQ 20 mg base	Barr Laboratories LLC (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.), 400 Interpace Parkway, Building A, Parsippany, NJ 07054
ANDA 075062	Famotidine, tablet, 20 mg and 40 mg	Watson Laboratories, Inc. (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.)
ANDA 075238	Sotalol HCl, tablet, 80 mg, 120 mg, 160 mg, and 240 mg	Do.
ANDA 075297	Paclitaxel, injectable, 6 mg/milliliters (mL)	Teva Pharmaceuticals USA, Inc., 400 Interpace Parkway, Building A, Parsippany, NJ 07054
ANDA 075345	Cimetidine, tablet, 200 mg	IVAX Pharmaceuticals, Inc. (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.)
ANDA 075353	Doxazosin mesylate, tablet, EQ 1 mg base, EQ 2 mg base, EQ 4 mg base, and EQ 8 mg base	Teva Pharmaceuticals USA, Inc.
ANDA 075425	Cimetidine, tablet, 200 mg	Watson Laboratories, Inc. (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.)
ANDA 075426	Doxazosin mesylate, tablet, EQ 1 mg base, EQ 2 mg base, EQ 4 mg base, and EQ 8 mg base	Do.
ANDA 075485	Gabapentin, capsule, 100 mg, 300 mg, and 400 mg	Do.
ANDA 075574	Doxazosin mesylate, tablet, EQ 1 mg base, EQ 2 mg base, EQ 4 mg base, and EQ 8 mg base	Actavis Elizabeth LLC (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.), 400 Interpace Parkway, Building A, Parsippany, NJ 07054
ANDA 075632	Bisoprolol fumarate and hydrochlorothiazide, tablet, 2.5 mg; 6.25 mg, 5 mg; 6.25 mg, and 10 mg; 6.25 mg	IVAX Pharmaceuticals, Inc. (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.)

Application No.	Drug	Applicant
ANDA 076028	Vinorelbine tartrate, injectable, EQ 10 mg base/mL	Teva Pharmaceuticals USA, Inc.

Therefore, approval of the applications listed in table 1, and all amendments and supplements thereto, are 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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