4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-0074]

Watson Laboratories, Inc., et al.; Withdrawal of Approval of Eight 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 eight 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].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, 240-402-6980, Martha.Nguyen@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process described 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.

Application No.	Drug	Applicant
ANDA 075152	Diclofenac Potassium Tablets, 50 milligrams (mg)	Watson Laboratories, Inc. (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.), 400 Interpace Pkwy., Bldg. A,

Application No.	Drug	Applicant
		Parsippany, NJ 07054
ANDA 091376	Topotecan Hydrochloride (HCl) for Injection, Equivalent to (EQ) 4 mg base/vial	Fresenius Kabi USA, LLC, Three Corporate Dr., Lake Zurich, IL 60047
ANDA 091471	Efavirenz Tablets, 600 mg	Mylan Pharmaceuticals Inc., a Viatris Company, 3711 Collins Ferry Rd., Morgantown, WV 26505
ANDA 200463	Itraconazole Capsules, 100 mg	Mylan Pharmaceuticals Inc., a Viatris Company, 781 Chestnut Ridge Rd., Morgantown, WV 26504
ANDA 202395	Ziprasidone HCl Capsules, EQ 20 mg base, EQ 40 mg base, EQ 60 mg base, and EQ 80 mg base	Do.
ANDA 203170	Docetaxel Injection, 40 mg/milliliter	Jiangsu Hengrui Pharmaceuticals Co., Ltd., U.S. Agent, eVenus Pharmaceutical Laboratories Inc., 506 Carnegie Center, Suite 100, Princeton, NJ 08540
ANDA 203574	Mesalamine Delayed Release Tablets, 1.2 grams	Mylan Pharmaceuticals Inc., a Viatris Company, 781 Chestnut Ridge Rd., Morgantown, WV 26504
ANDA 208177	Atazanavir Sulfate Capsules, EQ 150 mg base, EQ 200 mg base, and EQ 300 mg base	Do.

Therefore, approval of the applications listed in the table, 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 the table. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table 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.

Dated: January 25, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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