4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-0652]

Fresenius Kabi USA, LLC, 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].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, 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 040265	Methotrexate Sodium Injection, Equivalent to (EQ) 25 milligrams (mg) base/milliliters (mL)	Fresenius Kabi USA, LLC, Three Corporate Dr., Lake Zurich, IL 60047
ANDA 070963	Clonidine Hydrochloride (HCl)	Watson Laboratories, Inc. (an indirect,

Application No.	Drug	Applicant
	Tablets, 0.3 mg	wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.), 400 Interpace Pkwy., Bldg. A, Parsippany, NJ 07054
ANDA 074292	Dobutamine HCl Injection, EQ 12.5 mg base/mL	Hospira, Inc., 275 North Field Dr., Bldg. H1, Lake Forest, IL 60045
ANDA 075069	Etodolac Tablets, 400 mg	Watson Laboratories, Inc.
ANDA 075856	Midazolam HCl Injection, EQ 1 mg base/mL and EQ 5 mg base/mL	Hospira, Inc.
ANDA 084504	Hydralazine HCl Tablets, 25 mg	Watson Laboratories, Inc.
ANDA 090379	Budesonide Delayed Release Capsules, 3 mg	Barr Laboratories, Inc. (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.), 400 Interpace Pkwy., Bldg. A, Morris Corporate Center III, Parsippany, NJ 07054
ANDA 091590	Losartan Potassium Tablets, 25 mg, 50 mg, and 100 mg	Mylan Pharmaceuticals Inc., a Viatris Company, 81 Chestnut Ridge Rd., P.O. Box 4310, Morgantown, WV 26504
ANDA 091652	Hydrochlorothiazide and Losartan Potassium Tablets, 12.5 mg/50 mg, 12.5 mg/100 mg, and 25 mg/100 mg	Do.
ANDA 204361	Eptifibatide Injection, 2 mg/mL and 75 mg/100 mL	USV Private Limited, U.S. Agent, Omega Pharmaceutical Consulting, Inc., 752 West Shuhthagi Lane, New Harmony, UT 84757
ANDA 204362	Eptifibatide Injection, 2 mg/mL	Do.
ANDA 204464	Sodium Fluoride F-18 Injection, 10-200 millicurie/mL	Decatur Memorial Hospital, 2300 North Edward St., Suite 100, Decatur, IL 62526
ANDA 206177	Docetaxel Injection, 20 mg/mL (20 mg/mL), 80 mg/4 mL (20 mg/mL), and 200 mg/10 mL (20 mg/mL)	DFB Oncology, LLC, 3909 Hulen St., Fort Worth, TX 76107
ANDA 206631	Olmesartan Medoxomil Tablets, 5 mg, 20 mg, and 40 mg	Lupin Limited, U.S. Agent, Lupin Pharmaceuticals, Inc., 111 South Calvert St., Harborplace Tower, 21st Floor, Baltimore, MD 21202
ANDA 209399	Olanzapine Tablets, 2.5 mg, 5 mg, and 10 mg	Jiangsu Hansoh Pharmaceutical Group Co., Ltd., U.S. Agent, eVenus Pharmaceutical Laboratories Inc., 506 Carnegie Center, Suite 100, Princeton, NJ 08540

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: July 20, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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