4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2024-N-1917]

Fresenius Kabi USA, LLC, et. al.; Withdrawal of Approval of 12 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 12 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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].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 040379	Fluorouracil Injectable, 50 milligrams (mg)/milliliter (mL)	Fresenius Kabi USA, LLC, Three Corporate Dr., Lake Zurich, IL

Application No.	Drug	Applicant
		60047
ANDA 062901	Ampicillin Sodium; Sulbactam Sodium Injectable, Equivalent to (EQ) 2 grams (gm) base/vial; EQ 1 gm base/vial, and EQ 1 gm base/vial; EQ 500 mg base/vial	Pfizer Inc., 66 Hudson Blvd East, New York, NY 10001
ANDA 071981	Droperidol Injectable, 2.5 mg/mL	Hospira Inc., 275 North Field Dr., Bldg. H1-3S, Lake Forest, IL 60045
ANDA 202546	Ribavirin Tablets, 200 mg, 400 mg, 500 mg, and 600 mg	RegCon Solutions, LLC, U.S. Agent for Beximco Pharmaceuticals USA Inc., 10525 Vista Sorrento Parkway, Suite 100, San Diego, CA 92121
ANDA 203544	Sodium Fluoride F-18 Injectable, 10–200 millicurie (mCi)/mL	SOFIE Co. dba SOFIE, 21000 Atlantic Blvd., Suite 730, Dulles, VA 20166
ANDA 203773	Dexmedetomidine Hydrochloride (HCl) Injectable, EQ 200 microgram (mcg) base/2 mL (EQ 100 mcg base/mL)	American Regent, Inc., 5 Ramsey Rd., Shirley, NY 11967
ANDA 203884	Amiodarone HCl Injectable, 50 mg/mL	Hospira Inc.
ANDA 204315	Sodium Fluoride F-18 Injectable, 10–200 mCi/mL	B&H Consulting Services, Inc., U.S. Agent for Shertech Laboratories, LLC, 50 Division St., Suite 206, Somerville, NJ 08876
ANDA 204366	Ammonia N 13 Injectable, 3.75–260 mCi/mL	Do.
ANDA 204854	Meropenem for Injection, 500 mg/vial and 1 gm/vial	Freyr Inc., U.S. Agent for Daewoong Pharmaceutical Co., Ltd., 150 College Rd. West, Suite 102, Princeton, NJ 08540

Application No.	Drug	Applicant
ANDA 206710	Paricalcitol Capsules, 1 mcg, 2 mcg, and 4 mcg	Alvogen PB Research and Development LLC, U.S. Agent for Lotus Pharmaceutical Co., Ltd. Nantou Plant, 44 Whippany Rd., Suite 300, Morristown, NJ 07960
ANDA 208695	Bosentan Tablets, 62.5 mg, and 125 mg	Hikma Pharmaceuticals USA Inc., 1809 Wilson Rd., Columbus, OH 43228

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 listed in the table 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 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: May 2, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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