4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-2079]

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in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].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 075160	Metoprolol Tartrate Injectable, 1 milligram (mg)/milliliter (mL)	Hospira, Inc., 275 North Field Dr., Bldg. H1-3S, Lake Forest, IL 60045
ANDA 077029	Calcipotriene Solution, 0.005%	Tolmar, Inc., 701 Centre Ave., Fort

Application No.	Drug	Applicant
		Collins, CO 80526
ANDA 079186	Dorzolamide Hydrochloride (HCl) Solution/Drops, Equivalent to (EQ) 2% base	American Regent, Inc., 5 Ramsey Rd., Shirley, NY 11967
ANDA 200457	Ibuprofen Suspension, 100 mg/5 mL	Arise Pharmaceuticals LLC, 12 Roszel Rd., Unit B202, Princeton, NJ 08543
ANDA 204356	Ammonia N 13 Injectable, 3.75 millicurie (mCi)–260 mCi/mL	Wisconsin Medical Radiopharmacy LLC, 11236 West Lapham St., West Allis, WI 53214
ANDA 205605	Amikacin Sulfate Injectable, EQ 50 mg base/mL	Fresenius Kabi USA, LLC, Three Corporate Dr., Lake Zurich, IL 60047
ANDA 205687	Ammonia N 13 Injectable, 3.75 mCi–260 mCi/mL	Essential Isotopes, LLC, 1513 Research Park Dr., Columbia, MO 65211
ANDA 210265	Fludeoxyglucose F18 Injectable, 20 mCi/mL–200 mCi/mL	University of Texas Southwestern Medical Center, 5323 Harry Hines Blvd., Dallas, TX 75390

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: May 30, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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