4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-5431]

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in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].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 the 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 063081	Tobramycin Sulfate, Injectable, Equivalent to (EQ) 1.2 milligrams (mg) base/milliliters (mL), EQ 1.6 mg base/mL, EQ 80 mg base/100 mL	Hospira, Inc., 275 North Field Dr., Building H1-3S, Lake Forest, IL 60045
ANDA 063112	Tobramycin Sulfate, Injection, EQ 10 mg base/mL	Do.

Application No.	Drug	Applicant
ANDA 078907	Fentanyl Citrate, Troche/Lozenges, EQ 0.2 mg base, EQ 0.4 mg base, EQ 0.6 mg base, EQ 0.8 mg base, EQ 1.2 mg base, EQ 1.6 mg base	SpecGx LLC, 385 Marshall Ave., Webster Groves, MO 63119
ANDA 080629	Promethazine Hydrochloride (HCl), Injectable, 50 mg/mL	Watson Laboratories, Inc. (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.), 400 Interpace Parkway, Building A, Parsippany, NJ 07054
ANDA 091170	Zoledronic Acid, Injectable, EQ 4 mg base/5 mL	Breckenridge Pharmaceutical, Inc., 15 Massirio Dr., Suite 201, Berlin, CT 06037
ANDA 201846	Azelastine HCl, Metered Spray, 0.2055 mg/spray	Apotex Corp, U.S. Agent for Apotex Inc., 2400 North Commerce Parkway, Suite 400, Weston, FL 33326
ANDA 207698	Nevirapine Extended-Release Tablets, 400 mg	Aurobindo Pharma USA, Inc., U.S. Agent for Aurobindo Pharma Limited, 279 Princeton-Hightstown Rd., East Windsor, NJ 08520
ANDA 208616	Nevirapine Extended-Release Tablets, 100 mg	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 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: December 14, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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