

contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(b)(3)(C) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Jeremy Walenty has been convicted of a felony under Federal law for conduct relating to the importation into the United States of any drug or controlled substance. FDA finds that the offense should be accorded a debarment period of 5 years as provided by section 306(c)(2)(A)(iii) of the FD&C Act.

As a result of the foregoing finding, Mr. Walenty is debarred for a period of 5 years from importing or offering for import any drug into the United States, effective (see **DATES**). Pursuant to section 301(cc) of the FD&C Act (21 U.S.C. 331(cc)), the importing or offering for import into the United States of any drug by, with the assistance of, or at the direction of Mr. Walenty is a prohibited act.

Dated: December 14, 2023.
Lauren K. Roth,
Associate Commissioner for Policy.
 [FR Doc. 2023-27855 Filed 12-18-23; 8:45 am]
BILLING CODE 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approval of the applications be withdrawn.

DATES: Approval is withdrawn as of January 18, 2024.

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.
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 January 18, 2024. 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 January 18, 2024 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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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0026]

Apothecon, et al.; Withdrawal of Approval of 103 New Drug Applications and 35 Abbreviated New Drug Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** on February 11, 2009. The