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in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of January 18, 2024.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

[FR Doc. 2023–27853 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–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

document announced the withdrawal of approval of 103 new drug applications and 35 abbreviated new drug applications (ANDAs) from multiple applicants, withdrawn as of March 13, 2009. The document erroneously included ANDA 75–108. The correct ANDA is ANDA 76–108 for Amiodarone hydrochloride (HCl) injection, 50 milligrams (mg)/milliliter (mL), held by Hospira, Inc., 275 North Field Dr., Lake Forest, IL 60045–5046. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993–0002, 301–796–3137, *Kimberly.Lehrfeld@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 11, 2009 (74 FR 6896), appearing on page 6900 in FR Doc. E9–2901, the following correction is made:

On page 6900, in the table, in the first column, the Application No. for the entry for Amiodarone HCL Injection, 50 mg/mL held by Hospira Inc., 275 North Field Dr., Lake Forest, IL 60045–5046 is corrected to ANDA 76–108.

Dated: December 14, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–27859 Filed 12–18–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0955–0019]

Agency Information Collection Request; 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before February 20, 2024.

ADDRESSES: Submit your comments to *Sherrette.Funn@hhs.gov* or by calling (202) 264–0041 and *PRA@HHS.GOV*.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0955–0019 and project title for reference, to Sherrette A. Funn, email: *Sherrette.Funn@hhs.gov*, *PRA@HHS.GOV* or call (202) 264–0041 the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: National Survey of Health Information Exchange Organizations (HIO).

Type of Collection: Revision of a previously approved collection.

OMB No.: 0955–0019.

Abstract: Under the Department of Health and Human Services, Office of National Coordinator for Health Information and Technology, Electronic health information exchange (HIE) was one of three goals specified by Congress in the 2009 Health Information Technology for Economic and Clinical Health (HITECH) Act to ensure that the $30 billion federal investment in certified electronic health records (EHRs) resulted in higher-quality, lower-cost care. Subsequent legislation and regulations have continued to prioritize the sharing of data electronically across EHRs and other health information systems. Health information exchange organizations (HIOs) play a pivotal role facilitating health information exchange across disparate providers, labs, pharmacies, public health departments, and others. This information collection request will gather data from HIOs across the nation through the administration of a survey of HIOs to generate the most current national statistics and associated actionable insights to inform policy efforts. The timely collection of national data from our survey will assess current capabilities of HIOs to support effective electronic information sharing within the U.S. healthcare system.

Since prior to HITECH there has been ongoing assessment of trends in the capabilities of HIOs to support clinical exchange through nationwide surveys of HIOs. These prior surveys and studies have collected data on organizational structure, financial viability, geographic coverage, scope of services, scope of participants, perceptions of information blocking, support for public health exchange, and participation in national networks and the Technical Exchange Framework and Common Agreement (TEFCA). Continuing the ongoing data collection will be useful to construct a current and comprehensive picture of HIOs' role in facilitating exchange and ensuring rapid access to important health care data and information when it matters most, including vital data to address public health emergencies.

The survey will collect data on HIO capabilities to support electronic health information exchange, their maturity, and challenges they face. There are five key areas that require assessment: (1) adoption of technical standards; (2) perceptions related to information blocking; (3) HIE coordination at the federal level; (4) public health data exchange; and (5) organizational demographics, including technical capabilities offered by HIOs and the challenges they face in supporting electronic health information exchange.

This is a 3-year request for OMB approval.

ANNUALIZED BURDEN HOUR TABLE

Forms (if necessary)	Respondents (if necessary)	Number of respondents	Number of responses per respondents	Average burden per response	Total burden hours
	U.S. based public and private HIOs	100	1	45/60	75
Total			1		75