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 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.
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 June 6, 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 June 6, 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: May 2, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–09914 Filed 5–6–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–3827]

Adam Paul Runsdorf: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) permanently debarring Adam Paul Runsdorf from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Mr. Runsdorf was convicted of a felony under Federal law for conduct that relates to the regulation of a drug product under the FD&C Act. Mr. Runsdorf was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. As of February 25, 2024 (30 days after receipt of the notice), Mr. Runsdorf has not responded. Mr. Runsdorf's failure to respond and request a hearing constitutes a waiver of Mr. Runsdorf's right to a hearing concerning this matter.

DATES: This order is applicable May 7, 2024.

ADDRESSES: Any application by Mr. Runsdorf for special termination of debarment under section 306(d)(4) of the FD&C Act (21 U.S.C. 335a(d)(4)) may be submitted at any time as follows:

Electronic Submissions

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. An application submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your application will be made public, you are solely responsible for ensuring that your application does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such

as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your application, that information will be posted on *https://www.regulations.gov.*

• If you want to submit an application with confidential information that you do not wish to be made available to the public, submit the application as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

• *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For a written/paper application submitted to the Dockets Management Staff, FDA will post your application, as well as any attachments, except for information submitted, marked, and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All applications must include the Docket No. FDA–2023–N–3827. Received applications will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit an application with confidential information that you do not wish to be made publicly available, submit your application only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of your application. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852 between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500. Publicly available submissions may be seen in the docket.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Compliance and Enforcement, Office of Policy, Compliance, and Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 240–402–8743, *debarments@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(B) of the FD&C Act requires debarment of an individual from providing services in any capacity to a person that has an approved or pending drug product application if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the regulation of any drug product under the FD&C Act. On July 27, 2023, Adam Paul Runsdorf was convicted as defined in section 306(l)(1) of the FD&C Act, in the U.S. District Court for the Eastern District of Texas-Beaumont Division, when the court entered judgment against him, after his plea of guilty, to Conspiracy to Traffick in Drugs with Counterfeit Mark in violation of 18 U.S.C. 371, 18 U.S.C. 2320(a)(4) and Trafficking in Drugs with Counterfeit Mark in violation of 18 U.S.C. 2320(a)(4), 18 U.S.C. 2320(b)(3)(A). The underlying facts supporting the conviction are as follows:

As contained in the Third Superseding Indictment, and as contained in Factual Basis and Stipulation memorandum, between approximately April 2014 and February 2021, Mr. Runsdorf conspired to distribute counterfeit cough syrup. Specifically, Mr. Runsdorf owned a group of pharmaceutical companies including Woodfield Pharmaceutical LLC, a contract manufacturing company, and Woodfield Distribution LLC, a third-party logistics company (collectively, ''Woodfield''). On April 25, 2014, Mr. Runsdorf acquired Pernix Manufacturing LLC (Pernix). Pernix had, in January 2014, entered into an agreement with Byron A. Marshall and his Drug Trafficking Organization (DTO) to copy and manufacture cough syrup according to the directions of Marshall and his associates.

Marshall was not licensed or authorized to distribute cough syrup and any background check of the personal information provided by Marshall to Pernix or later Woodfield would have revealed that he was not a licensed physician. Initially, Marshall sought to copy Actavis Prometh VC with Codeine (Actavis). Actavis is a purple, peach-mint flavor prescription cough syrup that was in demand as a street drug. Marshall and his associates wanted to mass produce and traffic a counterfeit version of Actavis that contained Promethazine, but not Codeine. On April 24, 2014, Actavis Holdco US discontinued production of the Actavis product due to its widespread abuse by recreational drug users. A Pernix product-development scientist worked with Marshall and his associates to re-create the Actavis product without Codeine and Promethazine in order to re-create the syrup base, which is a necessary component of cough syrup. Marshall and his associates would add Promethazine to the counterfeit substance prior to bottling and distribution in order to create the drug. Marshall and his DTO also obtained counterfeited commercial-grade pharmaceutical labels designed to look exactly like the genuine labels for the prescription cough syrup from another supplier. Later in the conspiracy, Marshall and his DTO asked Woodfield employees to reformulate other cough syrup to use in their drug trafficking scheme to include Hi-Tech Promethazine Hydrocholoride and Codeine Phosphate Oral Solution and Wockhardt Promethazine Syrup Plain.

As Pernix was scaling-up production of the syrup base for Marshall and his DTO in April 2014, Mr. Runsdorf acquired Pernix. Mr. Runsdorf retained Pernix employees but made changes to management staff who oversaw and were responsible for producing the syrup base for the Marshall DTO, to which they knew the Marshall DTO was adding active ingredients. During the conspiracy, Marshall communicated directly with Mr. Runsdorf regarding production of the counterfeit cough syrup. At Mr. Runsdorf's request, Marshall paid Woodfield in cash only, and Woodfield employees mailed the cash directly to him.

Mr. Runsdorf knew his company was producing thousands of gallons of the counterfeit cough syrup to be distributed to drug traffickers in Texas and other States. Woodfield's production of syrup base for Marshall and his DTO bypassed the protocols for safety and quality testing. Initially, there were no batch records to document the

production of the syrup as required. Woodfield provided the syrup to Marshall and his DTO without any corresponding documentation that identified the ingredients of the syrup; practices that continued until February 2019 when Woodfield started creating paper records for some of the cough syrup batches Woodfield made for the DTO. From 2014 through February 2021, the conspiracy between the Marshall DTO produced and distributed, or attempted to produce and distribute, approximately 65,920 gallons of counterfeit cough syrup. The total amount of cash paid by Marshall and his DTO to Mr. Runsdorf was approximately at least $3 million.

As a result of this conviction, FDA sent Mr. Runsdorf, by certified mail, on January 23, 2024, a notice proposing to permanently debar him from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on a finding, under section 306(a)(2)(B), that Mr. Runsdorf was convicted of two felonies under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. The proposal informed Mr. Runsdorf of the proposed debarment and offered him an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Runsdorf received the proposal and notice of opportunity for a hearing on January 26, 2024. Mr. Runsdorf failed to request a hearing within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and waived any 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(a)(2)(B) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. Runsdorf has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act.

As a result of the foregoing finding, Mr. Runsdorf is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application, effective (see **DATES**) (see sections 306(a)(2)(B) and 306(c)(2)(A)(ii) of the FD&C Act). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses in any capacity the services of Mr. Runsdorf during his debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Mr. Runsdorf provides services in any capacity to a person with an approved or pending drug product application during his period of debarment, he will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new drug application from Mr. Runsdorf during his period of debarment, other than in connection with an audit under section 306 of the FD&C Act (section 306(c)(1)(B) of the FD&C Act). Note that, for purposes of sections 306 and 307 of the FD&C Act, a ''drug product'' is defined as a ''drug subject to regulation under section 505, 512, or 802 of this FD&C Act [(21 U.S.C. 355, 360b, or 382)] or under section 351 of the Public Health Service Act [(42 U.S.C. 262)]'' (section 201(dd) of the FD&C Act (21 U.S.C. 321(dd))).

Dated: May 2, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–09917 Filed 5–6–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–1032]

Risk Evaluation and Mitigation Strategy Logic Model: A Framework to Link Program Design With Assessment; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''REMS Logic Model: A Framework to Link Program Design With Assessment.'' The guidance describes FDA's risk evaluation and mitigation strategy (REMS) logic model. The REMS logic model is a framework that FDA recommends, which provides applicants with a systematic, structured approach to the design, implementation, and evaluation of a REMS. The aim of applying the REMS logic model is to develop clear goals, objectives, and strategies that align with the intended outcomes and to help applicants of new drug applications (NDAs), biologics license applications (BLAs), and abbreviated new drug applications (ANDAs) incorporate REMS assessment planning into the design of a REMS. The principles in this guidance apply to designing a REMS, developing a REMS assessment, and modifying a REMS.

DATES: Submit either electronic or written comments on the draft guidance by August 5, 2024 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2024–D–1032 for ''REMS Logic Model: