the opportunity for a hearing and of any contentions concerning this action. Mr. Kosolcharoen received the proposal and notice of opportunity for a hearing on November 26, 2024. Mr. Kosolcharoen 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 Division of Field Enforcement Director, Office of Inspections and Investigations, under section 306(a)(2)(B) of the FD&C Act, under authority delegated to the Director, Division of Enforcement finds that Mr. John Warrington Kosolcharoen 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. Kosolcharoen is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application including, but not limited to, a BLA, effective (see **DATES**) (see sections 306(a)(2)(B) and 306(c)(2)(A)(ii) of the FD&C Act, (21 U.S.C. 335a(a)(2)(B) and 335a(c)(2)(A)(ii))). Any person with an approved or pending drug product application including, but not limited to, a BLA, who knowingly employs or retains as a consultant or contractor, or otherwise uses in any capacity the services of Mr. Kosolcharoen 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. Kosolcharoen provides services in any capacity to a person with an approved or pending drug product application including, but not limited to, a BLA during his period of debarment he will be subject to civil money penalties (section 307(a)(7) of the FD&C Act (21 U.S.C. 335b(a)(7))). In addition, FDA will not accept or review any abbreviated new drug application from Mr. Kosolcharoen 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 (21 U.S.C. 335a(c)(1)(B))). Note that, for purposes of sections 306 and 307 of the FD&C Act (21 U.S.C. 335a and 335b), 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, 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: March 7, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2025–04031 Filed 3–12–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3314]

Alnashir Alibhai Punjani: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring Alnashir Alibhai Punjani for a period of 5 years from importing or offering for import any drug into the United States. FDA bases this order on a finding that Mr. Punjani was convicted of one felony count under Federal law for conspiracy to deliver and introduce unapproved drugs. The factual basis supporting Mr. Punjani's conviction, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Mr. Punjani was given notice of the proposed debarment and was given an opportunity to request a hearing to show why he should not be debarred. As of November 10, 2024 (30 days after receipt of the notice), Mr. Punjani had not responded. Mr. Punjani's failure to respond and request a hearing constitutes a waiver of his right to a hearing concerning this matter.

DATES: This order is applicable March 13, 2025.

ADDRESSES: Any application by Mr. Punjani for termination of debarment under section 306(d)(1) of the FD&C Act (21 U.S.C. 335a(d)(1)) 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–2024–N–3314. 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, or *debarments@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(1)(D) of the FD&C Act permits debarment of an individual from importing or offering for import any drug into the United States if FDA finds, as required by section 306(b)(3)(C) of the FD&C Act, that the individual has been convicted of a felony for conduct relating to the importation into the United States of any drug or controlled substance.

On June 18, 2024, Mr. Punjani was convicted, as defined in section 306(l)(1) of the FD&C Act, in the U.S. District Court for Northern District of Georgia-Atlanta Division, when the court accepted his plea of guilty and entered judgment against him for the offense of conspiracy to deliver and introduce unapproved drugs in violation of 18 U.S.C. 371 and 21 U.S.C. 331(c) and 333(a)(2) (sections 301(c) and 303(a)(2) of the FD&C Act). The underlying facts supporting the conviction are as follows:

As contained in the information, filed on January 18, 2024, in or about March 2019, and continuing until in or about September 2022, Mr. Punjani imported thousands of AUROGRA 100 mg tablets, VIGORE 100 mg tablets, and CENFORCE 100 mg tablets, which were male enhancement pills manufactured in India, but not authorized for sale in the United States by FDA. These pills contained the active pharmaceutical ingredient (API) sildenafil. Sildenafil is the same API used in the prescription drug VIAGRA. The FDA approved drugs containing the active ingredient sildenafil are only available by prescription and may cause serious side effects for those suffering from cardiovascular disease, hypertension, bleeding disorders, and other related health conditions. The drugs Mr. Punjani imported and resold had not been approved by FDA meaning that they did not have the same assurance of safety or efficacy as FDA approved drugs. Per the information, Mr. Punjani used commercial shippers to ship the tablets from India to multiple locations in Georgia where he, with the intent to defraud and mislead, organized them for resell in the state of Georgia. The labeling on the drugs Mr. Punjani resold did not contain adequate directions for use.

FDA sent Mr. Punjani, by certified mail, on September 26, 2024, a notice proposing to debar him for a 5-year period from importing or offering for import any drug into the United States. The proposal was based on a finding under section 306(b)(3)(C) of the FD&C Act that Mr. Punjani's felony conviction under Federal law for conspiracy to deliver and introduce unapproved drugs in violation of 18 U.S.C. 371 and sections 301(c) and 303(a)(2) of the FD&C Act, was for conduct relating to the importation into the United States of any drug or controlled substance into the United States because Mr. Punjani illegally imported and introduced unapproved and misbranded prescription drug products into interstate commerce in the United States. In proposing a debarment period, FDA weighed the considerations set forth in section 306(c)(3) of the FD&C Act that it considered applicable to Mr. Punjani's offense and concluded that the offense warranted the imposition of a 5-year period of debarment.

The proposal informed Mr. Punjani 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. Punjani received the proposal and notice of opportunity for a hearing on October 11, 2024. Mr. Punjani 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 Division of Field Enforcement Director, Office of Inspections and Investigations, under section 306(b)(3)(C) of the FD&C Act, under authority delegated to the Director, Division of Enforcement, finds that Mr. Alnashir Alibhai Punjani 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. Punjani 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, the importing or offering for import into the United States of any drug by, with the assistance of, or at the direction of Mr. Punjani is a prohibited act.

Dated: March 7, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2025–04029 Filed 3–12–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2023–P–0884 and FDA–2023–P–5687]

Determination That RIOMET (Metformin Hydrochloride) Oral Solution, 500 Milligrams/5 Milliliters Has Not Been Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.