• 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]

BILLING CODE 4164–01–P

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.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that RIOMET (metformin hydrochloride) Oral Solution, 500 milligrams (mg)/5 milliliters (mL) has not been withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Tereza Hess, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6286, Silver Spring, MD 20993–0002, 301–796–1546, *tereza.hess@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

RIOMET (metformin hydrochloride) Oral Solution, 500 mg/5 mL, is the subject of NDA 021591, held by Ranbaxy Signature LLC, and initially approved on September 11, 2003. RIOMET is a biguanide indicated as an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients 10 years of age and older with type 2 diabetes mellitus.

In a letter dated November 14, 2022, Ranbaxy Signature LLC notified FDA that RIOMET (metformin hydrochloride) Oral Solution, 500 mg/5 mL had been withdrawn from sale as of November 2019. RIOMET (metformin hydrochloride) Oral Solution, 500 mg/5 mL is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Oryza Pharmaceuticals, Inc. submitted a citizen petition dated March 9, 2023 (Docket No. FDA–2023–P–0884), under 21 CFR 10.30, requesting that the Agency determine whether RIOMET (metformin hydrochloride) Oral Solution, 500 mg/5 mL, was withdrawn from sale for reasons of safety or effectiveness. Bionpharma, Inc. submitted a citizen petition dated December 22, 2023 (Docket No. FDA–2023–P–5687) under 21 CFR 10.30, also requesting that the Agency determine whether RIOMET (metformin hydrochloride) Oral Solution, 500 mg/5 mL, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that RIOMET (metformin hydrochloride) Oral Solution, 500 mg/5 mL, has not been withdrawn from sale for reasons of safety or effectiveness. The petitioners have identified no data or other information suggesting that RIOMET (metformin hydrochloride) Oral Solution, 500 mg/5 mL, was withdrawn from sale for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of RIOMET (metformin hydrochloride) Oral Solution, 500 mg/5 mL, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list RIOMET (metformin hydrochloride) Oral Solution, 500 mg/5 mL, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug product may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: March 7, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2025–04020 Filed 3–12–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0026]

Issuance of Priority Review Voucher; Rare Pediatric Disease Product; Gomekli (mirdametinib)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. The Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes FDA to award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the award of the priority review voucher. FDA has determined that GOMEKLI (mirdametinib), approved on February 11, 2025, manufactured by SpringWorks Therapeutics, Inc., meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Cathryn Lee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1394.

SUPPLEMENTARY INFORMATION: FDA is announcing the issuance of a priority review voucher to the sponsor of an approved rare pediatric disease product application. Under section 529 of the FD&C Act (21 U.S.C. 360ff), FDA will