request for a rebate reduction along with supporting documentation. *Form Number:* CMS–10858 (OMB control number: 0938–new); *Frequency:* Once; *Affected Public:* Private Sector and Business or other for-profits; *Number of Respondents:* 10; *Total Annual Responses:* 10; *Total Annual Hours:* 310. (For policy questions regarding this collection contact Elisabeth Daniel at 667–290–8793.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2024–12122 Filed 5–31–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–5023]

Shanif Abdul Punjani: 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) debarring Shanif Abdul 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 Defraud the United States. 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 March 6, 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 June 3, 2024.

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–2023–N–5023. 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, at 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 August 16, 2023, Mr. Punjani was convicted as defined in section 306(l)(1) of the FD&C Act in the U.S. District Court for the 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 Defraud the United States in violation of 18 U.S.C. 371. The underlying facts supporting the conviction are as follows: As contained in the Information and the Government's Sentencing Statement from Mr. Punjani's case, in or about March 2019, and continuing until February 2021, he imported thousands of Aurogra 100mg Sildenafil tablets, which were male enhancement pills manufactured in India, but not authorized for sale in the United States. Sildenafil is the same active pharmaceutical ingredient (API) as that 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 the FDA meaning that they did not have the same assurance of safety or efficacy as FDA approved drugs. Mr. Punjani would use commercial shippers to ship the tablets from India to his home where Mr. Punjani would organize them in order to resell them to wholesale businesses and convenience stores in Georgia. The labeling on the drugs Mr. Punjani resold did not contain adequate directions for use and he dispensed these prescription drugs without the prescription of a practitioner licensed by law to administer the drugs. At one point, Customs and Border Patrol (CBP) sent Mr. Punjani a notice warning him that pills he had offered for import had been seized because they were in violation of the FD&C Act. Mr. Punjani ignored this notice and others CBP and FDA later sent him. Ultimately Mr. Punjani imported thousands of illegal pills over several years.

As a result of this conviction, FDA sent Mr. Punjani, by certified mail, on January 30, 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 Defraud the United States in violation of 18 U.S.C. 371, was for conduct relating to the importation into the United States of any drug or controlled substance because Mr. Punjani illegally imported and introduced unapproved and misbranded prescription drug products into interstate commerce. 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 February 5, 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 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 Mr. Shanif Abdul 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 (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. Punjani is a prohibited act.

Dated: May 29, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–12064 Filed 5–31–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–2462]

Pfizer, Inc., et al.; Withdrawal of Approval of 23 New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 23 new drug applications (NDAs) 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 July 3, 2024.

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: The applicants listed in table 1 have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process 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.

TABLE 1—NDAS FOR WHICH APPROVAL IS WITHDRAWN

Application No.	Drug	Applicant
NDA 012427	Didrex (benzfetamine hydrogen chloride (HCl)) Tablets, 25 milligrams (mg) and 50 mg.	Pfizer, Inc., 66 Hudson Boulevard East, New York, NY 10001.
NDA 016131	Clomid (clomiphene citrate) Tablets, 50 mg	Sanofi US Services Inc., C/O Sanofi-Aventis U.S. LLC, 55 Corporate Dr., Bridgewater, NJ 08807.
NDA 016584	Navane (thiothixene HCl) Capsules, 1 mg, 2 mg, 5 mg, 10 mg, and 20 mg.	Do.
NDA 019032	Tenex (guanfacine HCl) Tablets, 1 mg, 2 mg, and 3 mg	Promius Pharma, LLC, C/O Dr. Reddy's Laboratories Inc., 107 College Rd. East, Princeton, NJ 08540.
NDA 019776	Concentraid (desmopressin acetate) Nasal Solution, 0.01% ..	Ferring Pharmaceuticals Inc., 100 Interpace Parkway, Parsippany, NJ 07054.