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]

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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.

TABLE 1—NDAS FOR WHICH APPROVAL IS WITHDRAWN—Continued

Application No.	Drug	Applicant
NDA 019826	Theophylline and Dextrose 5% Injections in Plastic Container, 40 mg/100 milliliters (mL), 80 mg/100 mL, 160 mg/100 mL, 200 mg/100 mL, 320 mg/100 mL, and 400 mg/100 mL.	B. Braun Medical Inc, 901 Marcon Blvd., Allentown, PA 18109.
NDA 020659	Norvir (ritonavir) Oral Solution, 80 mg/mL	AbbVie Inc. 1 N. Waugekan Rd., North Chicago, IL 60064.
NDA 020706	Emadine (emedastine difumarate) Ophthalmic Solution, 0.05%.	Novartis Pharmaceuticals Co., 1 Health Plaza, East Hanover, NJ 07936–1080
NDA 020884	Aggrenox (aspirin and dipyridamole) Extended-Release Capsules, 25 mg/200 mg.	Boehringer Ingelheim Pharmaceuticals, Inc., 900 Ridgebury Rd, Ridgefield, CT 06877.
NDA 020928	Glucagon Injection, 1 mg/vial	Eli Lilly and Company, Lilly Corporate Center, Indianapolis, IN 46285.
NDA 020972	Sustiva (efavirenz) Capsules, 50 mg, 100 mg, and 200 mg ...	Bristol-Myers Squibb Company, P.O. Box 4000, Princeton, NJ 08543–4000.
NDA 021400	Levitra (vardenafil HCl) Tablets, 2.5 mg, 5 mg, 10 mg, and 20 mg.	Bayer HealthCare Pharmaceuticals Inc.
NDA 021449	Hepsera (adefovir dipivoxil) Tablets, 10 mg	Gilead Sciences, Inc., 333 Lakeside Dr., Foster City, CA 94404.
NDA 021623	Synera (lidocaine and tetracaine) Patch, 70 mg/70 mg	Galen Specialty Pharma US, LLC, 25 Fretz Rd., Souderton, PA 18694.
NDA 022331	Kapvay (clonidine HCl) Extended-Release Tablets, 0.1 mg and 0.2 mg. Jenloga (clonidine HCl) Extended-Release Tablets, 0.1 mg and 0.2 mg.	Concordia Pharmaceuticals, Inc C/O Cardinal Health Reg Sciences, 7400 West 110th St., Suite 150, Overland Park, KS 66210.
NDA 022343	Efavirenz, Lamivudine and Tenofovir Disoproxil Fumarate Tablets, 600 mg/300 mg/300 mg.	Aurobindo Pharma Limited C/O Aurobindo Pharma USA, Inc., 279 Princeton-Highstown Rd., East Windsor, NJ 08520.
NDA 022344	Lamivudine and Tenofovir Disoproxil Fumarate Tablets, 300 mg/300 mg.	Do.
NDA 200179	Staxyn (vardenafil HCl) Orally Disintegrating Tablets, 10 mg	Bayer HealthCare Pharmaceuticals, Inc.
NDA 200671	Durlaza (aspirin) Extended-Release Capsules, 162.5 mg	HESP LLC, 312 Farmington Ave., Farmington, CT 06032.
NDA 202158	Radiogenix System (technetium Tc-99m generator) For the Production of Sodium Pertechnetate Tc 99m Injection, Intravenous, Intravesicular, and Ophthalmic Solution, 30–1153 millicurie/Generator.	NorthStar Medical Radioisotopes, LLC, 1800 Gateway Blvd., Beloit, WI 53511.
NDA 205004	Bortezomib Powder for Injection, 3.5 mg/vial	Fresenius Kabi USA, LLC, 3 Corporate Dr., Lake Zurich, IL 60047.
NDA 205787	Evzio (naloxone HCl) Solution for Injection, 0.4 mg/0.4 mL ...	Kaleo, Inc., 111 Virginia St., Suite 300, Richmond, VA 23219.
NDA 209862	Evzio (naloxone HCl) Auto-Injector for Injection, 2 mg/0.4 mL	Do.

Therefore, approval of the applications listed in table 1, and all amendments and supplements thereto, is hereby withdrawn as of July 3, 2024. Approval of each entire application is withdrawn, including any strengths and dosage forms included in the application but inadvertently missing from table 1. Introduction or delivery for introduction into interstate commerce of products listed in table 1 without an approved new drug application 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 table 1 that are in inventory on July 3, 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 29, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Statement of Organization, Functions, and Delegations of Authority

AGENCY: Food and Drug Administration, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Office of the Commissioner, Headquarters organizations, and Centers have modified their organizational structure

DATES: This organization was approved by the Secretary of Health and Human Services on March 5, 2024, and became effective on May 13, 2024.

FOR FURTHER INFORMATION CONTACT: Yashika Rahaman, Director, Office of Planning, Evaluation, and Risk Management, Office of the Finance, Budget, Acquisitions and Planning, Food and Drug Administration, 10903 New Hampshire Avenue, WO32, Room 4216, Silver Spring, MD 20993, 301–796–4710.

SUPPLEMENTARY INFORMATION: Part D, Chapter D–B, (Food and Drug Administration), the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (35 FR 3685, February 25, 1970; 60 FR 56606, November 9, 1995, 64 FR 36361, July 6, 1999, 72 FR 50112, August 30, 2007; 74 FR 41713, August 18, 2009, 76 FR 45270, July 28, 2011, and 84 FR 22854, May 20, 2019) is amended to reflect the approved Food and Drug Administration's Human Foods reorganization.