TABLE 1—DRUG PRODUCTS NOT WITHDRAWN FROM SALE FOR REASONS OF SAFETY OR EFFECTIVENESS—Continued

Application No.	Drug name	Active ingredient(s)	Dosage form/route	Strength(s)	Applicant
NDA 020837	XOPENEX	Levalbuterol Hydrochloride.	Solution; Inhalation	EQ 0.0103% Base; EQ 0.021% Base; EQ 0.042% Base; EQ 0.25% Base.	Hikma.
NDA 020857	COMBIVIR	Lamivudine; Zidovudine	Tablet; Oral	150 mg; 300 mg	Viiv Health Care.
NDA 020977	ZIAGEN	Abacavir Sulfate	Tablet; Oral	EQ 300 mg Base	Viiv Health Care.
NDA 021205	TRIZIVIR	Abacavir Sulfate, Lamivudine, Zidovudine.	Tablet; Oral	EQ 300 mg Base, 150 mg, 300 mg.	Viiv Health Care.
NDA 021223	ZOMETA	Zoledronic Acid	Injectable; Intravenous	EQ 4 mg Base/100 mL; EQ 4 mg Base/5 mL.	Novartis.
NDA 021548	LEXIVA	Fosamprenavir Calcium	Tablet; Oral	EQ 700 mg Base	Viiv Health Care.
NDA 021695	ANTARA (MICRONIZED)	Fenofibrate	Capsule; Oral	90 mg	Lupin.
NDA 021738	EXTINA	Ketoconazole	Aerosol, Foam; Topical	2%	Mylan.
NDA 021861	PATANASE	Olopatadine Hydrochloride	Spray, Metered; Nasal	0.665 mg/Spray	Novartis.
NDA 022128	SELZENTRY	Maraviroc	Tablet; Oral	25 mg; 75 mg	Viiv Health Care.
NDA 022350	ONGLYZA	Saxagliptin Hydrochloride	Tablet; Oral	EQ 2.5 mg Base; EQ 5 mg Base.	AstraZeneca AB.
NDA 050440	KEFLET	Cephalexin	Tablet; Oral	EQ 250 mg Base; EQ 500 mg Base.	Eli Lilly and Company.
NDA 050558	ZINACEF	Cefuroxime Sodium	Injectable; Intramuscular, Intravenous.	EQ 750 mg Base/Vial; EQ 1.5 g Base/Vial; EQ 7.5 g Base/Vial.	PAI Pharma.
NDA 050567	POLYTRIM	Polymyxin B Sulfate, Trimethoprim Sulfate.	Solution/Drops; Ophthalmic.	10,000 Units/mL, EQ 1 mg Base/mL.	Allergan.
NDA 050588	CEFOTAN	Cefotetan Disodium	Injectable; Injection	EQ 10 g Base/Vial	PAI Pharma.
NDA 050795	DORYX	Doxycycline Hyclate	Tablet, Delayed Release; Oral.	EQ 75 mg Base; EQ 150 mg Base.	Mayne Pharma.
NDA 200678	KOMBIGLYZE XR	Metformin Hydrochloride, Saxagliptin Hydrochloride.	Tablet, Extended Release; Oral.	500 mg, EQ 5 mg Base; 1 g, EQ 5 mg Base; 1 g, EQ 2.5 mg Base.	AstraZeneca AB.
NDA 201194	OXYCODONE HYDROCHLORIDE.	Oxycodone Hydrochloride	Solution; Oral	5 mg/5 mL	VistaPharm, LLC.
NDA 204427	KERYDIN	Tavaborole	Solution; Topical	5%	Anacor Pharmaceuticals, Inc.
NDA 204592	ZORVOLEX	Diclofenac	Capsule; Oral	35 mg	Zyla.
NDA 204790	TIVICAY	Dolutegravir Sodium	Tablet; Oral	EQ 10 mg Base; EQ 25 mg Base.	Viiv Health Care.
NDA 215868	MIDAZOLAM IN 0.8% SODIUM CHLORIDE.	Midazolam	Solution; Intravenous	50 mg/50 mL (1 mg/mL)	Exela Pharma.

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the drug products in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the drug products listed are unaffected by the discontinued marketing of the products subject to these applications. Additional ANDAs that refer to these products may also be approved by the Agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: November 27, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2024–28433 Filed 12–4–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–0604]

Yong Sheng Jiao; Denial of Hearing; Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is denying a request for a hearing submitted by Yong Sheng Jiao, also known as Yongsheng Jiao and Wilson Jiao (Jiao), and is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring Jiao for 5 years 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 Jiao was convicted of a felony under Federal law for conduct relating to the importation into the United States of any drug or controlled substance under the FD&C Act. In determining the appropriateness and period of Jiao's debarment, FDA considered the relevant factors listed in the FD&C Act. Jiao submitted a request for hearing but failed to file with the Agency information and analyses sufficient to create a basis for a hearing.

DATES: The order is applicable December 5, 2024.

ADDRESSES: Any application for termination of debarment by Jiao under section 306(d) of the FD&C Act (21 U.S.C. 335a(d)) (application) may be submitted 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

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 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–0604. An application will be placed in the docket and, unless 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. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your application and you must identify this information as ''confidential.'' 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: Karen Fikes, Office of Scientific Integrity, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4232, Silver Spring, MD 20993, 301–796–9603.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(1)(D) of the FD&C Act permits FDA to debar an individual if the Agency finds that the individual 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. On January 24, 2023, Jiao, the owner and operator of Santec Chemicals Corporation and Syntec Pharma Corporation, pled guilty to a Felony count of Causing the Delivery of Misbranded Drugs into Interstate Commerce in violation of sections 301(a), 303(a)(2), and 502(a) of the FD&C Act (21 U.S.C. 331(a), 333(a)(2), and 352(a)). Then, on January 8, 2024, the U.S. District Court for the Eastern District of New York entered a judgement convicting and sentencing Jiao to 2 years of probation and fines.

Jiao's conviction stemmed from conduct, occurring between on or about November 30, 2017, and April 30, 2020, relating to the importation of a drug, dipyrone, which is not approved for use in the United States. Jiao imported dipyrone from suppliers located in China into the United States, addressed to one of his businesses, Santec Chemicals Corporation. The shipments of dipyrone were misbranded in that they were either not labeled or they were falsely labeled as sebacic acid. Jiao pled guilty to knowingly and intentionally introducing into interstate commerce, with the intent to defraud and mislead the Federal Government, the misbranded drug dipyrone.

By letter dated March 18, 2024, FDA's Office of Regulatory Affairs (ORA) notified Jiao of its proposal to debar him for a period of 5 years (Proposal). As explained in the Proposal, Jiao's conviction stemmed from conduct relating to the importation of any drug or controlled substance into the United States by illegally importing and introducing misbranded dipyrone, an unapproved drug, into interstate commerce in violation of 301(a), 303(a)(2), and 502(a) of the FD&C Act. An individual convicted of a felony for conduct related to the importation into the United States of any drug or controlled substance may be subject to debarment as set forth in section 306(b)(3)(C) of the FD&C Act. Therefore, ORA found, on the basis of Jiao's conviction, that Jiao is subject to debarment under 306(b)(1)(D) of the FD&C Act.

The Proposal explained that the maximum period of debarment for a Felony under section 306(c)(2)(A)(iii) of the FD&C Act is 5 years. The Proposal also outlined findings concerning the three relevant factors that ORA considered in determining the appropriateness and period of debarment, as provided in section 306(c)(3) of the FD&C Act: (1) the nature and seriousness of any offense involved; (2) the nature and extent of voluntary steps to mitigate the impact on the public of any offense involved; and (3) prior convictions under the FD&C Act or under other Acts involving matters within the jurisdiction of FDA. ORA found that the nature and seriousness of the offense and the nature and extent of voluntary steps to mitigate the effect on the public are unfavorable factors for Jiao. ORA found the lack of prior convictions involving matters within FDA jurisdiction as a favorable factor for Jiao. ORA concluded that the facts supporting the unfavorable factors outweigh those supporting the favorable factor, thereby warranting a 5-year period of debarment. The Proposal also informed Jiao of an opportunity to request a hearing under section 306(i) of the FD&C Act and part 12 (21 CFR part 12).

In response to the Proposal, Jiao submitted a timely request for a hearing, which included a notice of appearance and a statement of intent to prepare and submit materials in support of the hearing request. In a letter submitted to the Dockets Management Staff dated May 12, 2024, Jiao submitted information in support of his request for a hearing (Response). Jiao's Response included multiple documents meant to

address the two unfavorable factors identified in ORA's Proposal.

Under the authority delegated to him by the Commissioner of Food and Drugs, the Director, Office of Scientific Integrity (OSI Director) has considered Jiao's request for a hearing. Hearings are granted only if there is a genuine and substantial issue of fact. A request for a hearing may not rest upon mere allegations or denials but must present specific facts showing that there is a genuine and substantial issue of fact that justifies a hearing. Hearings will not be granted on issues of policy or law, on mere allegations, denials or general descriptions of positions and contentions, or on data and information insufficient to justify the factual determination urged (see 21 CFR 12.24(b)). The OSI Director has considered Jiao's arguments and concluded that they are unpersuasive and fail to raise a genuine and substantial issue of fact requiring a hearing.

II. Argument in Support of a Hearing

Jiao's Response included documents and claims that challenge ORA's proposed findings in determining the appropriateness and period of permissive debarment. Specifically, Jiao argues that he should not be ''punished'' for wrongdoing by his company's supplier in China and that he incorrectly signed the plea agreement due to a misunderstanding, contending that FDA approved bulk importation of dipyrone during the time of his illegal importation. As a preliminary matter, debarment, under section 306 of the FD&C Act, is a remedial measure to protect public health, not a punishment. (See *DiCola* v. *FDA,* 77 F.3d 504, 507 (D.C. Cir. 1996) (permanent debarment of convicted individual is not punishment, but instead is a remedy to protect the integrity of the drug industry and public confidence in that industry)). Insofar as Jiao is arguing that he is actually innocent of the offense to which he pled guilty, under section 306(l) of the FD&C Act a person is convicted of a criminal offense, *inter alia,* when a Federal court enters a judgment of conviction or when a Federal court accepts a plea of guilty. The administrative record, including Jiao's supporting documents, establishes that he pled guilty in Federal court on January 24, 2023. After accepting Jiao's guilty plea, the Federal court entered a judgment of conviction. Jiao does not dispute the court's judgment of conviction or acceptance of his guilty plea based on his admission to knowingly and intentionally importing misbranded dipyrone with an intent to defraud or mislead the Federal Government. Jiao cannot now dispute the facts to which he admitted in support of his guilty plea during the criminal proceedings against him. Federal court is the proper venue for any challenge to Jiao's guilty plea based on a claim of actual innocence, not this remedial proceeding.

Jiao next challenges the proposed period of debarment, arguing that the two considerations in section 306(c)(3) of the FD&C Act deemed unfavorable in the Proposal should be treated as favorable in light of the arguments and documents submitted by him in support of his hearing request. Relying on the Presentence Investigation Report, Plea Agreement, and Mitigation Letter from his criminal proceedings, Jiao first challenges ORA's findings regarding the nature and seriousness of his offense under section 306(c)(3)(A) of the FD&C Act. Jiao contends that, as reflected in the documents from his criminal proceedings, his supplier in China is the cause of shipping the dipyrone as sebacic acid to avoid the ''unreasonable testing requirement in China'' and that he relabeled the product before shipment to customers. As noted above, however, Jiao pled guilty to causing the introduction of an unapproved and misbranded drug into the United States. The basis for his guilty plea was his misbranding the product upon entry into the United States, not the subsequent shipment to customers. Without FDA premarket review, such illegally imported drugs pose a significant risk to patients because they lack findings of safety and effectiveness, manufacturing quality standards, and appropriate labeling for use. Inasmuch as Jiao admitted, as part of his guilty plea, to ''knowingly, intentionally, and voluntarily'' causing the introduction of such drugs into the United States with an intent to defraud or mislead the Federal Government, Jiao's attempts to mitigate the nature and seriousness of his offense by placing some responsibility on his suppliers and claiming that he relabeled the product before further shipment fail to raise a genuine and substantial issue of fact regarding the consideration under 306(c)(3)(A) of the FD&C Act, which the OSI Director will treat as unfavorable.

Jiao also argues that FDA should treat as favorable the consideration under section 306(c)(3)(C) of the FD&C Act, which requires the Agency to consider ''the nature and extent of voluntary steps to mitigate the impact on the public of any offense involved'' in determining the appropriateness and period of his debarment. Citing a **Federal Register** document from 2019 (84 FR 64080, November 20, 2019), Jiao argues that FDA ''approved'' dipyrone for bulk importation and that, therefore, his company's sales after 2019 should not have created a negative ''impact on the public.'' Jiao's reading of this **Federal Register** document is incorrect. FDA did not indicate in this **Federal Register** document that the Agency was either approving, or exercising enforcement discretion with respect to bulk dipyrone for use in compounding under limited circumstances. Regardless, as discussed above, Jiao admitted to knowingly and intentionally importing a misbranded drug with an intent to defraud or mislead the Federal Government. Any change in FDA's enforcement policies with respect to that drug would not qualify as a voluntary step taken by Jiao to mitigate the impact of his offense on the public, nor does he provide information regarding any additional steps he took to mitigate the effects of his offense on the public under section 306(c)(3)(C) of the FD&C Act. Accordingly, Jiao has failed to raise a genuine and substantial issue of fact with respect to ORA's proposed finding that he did not to take any voluntary steps to mitigate the potential impact on the public under section 306(c)(3)(C) of the FD&C Act, and thus the OSI Director will treat this consideration as unfavorable. Additionally, as FDA's enforcement policies with respect to dipyrone remain unchanged, Jiao's argument would not affect the nature and seriousness of his offense, under 306(c)(3)(A) of the FD&C Act or alter the OSI Director's treatment of this consideration as unfavorable.

Based on the undisputed record, including the facts to which Jiao pled guilty in his criminal proceedings, a 5-year debarment period is appropriate. Although it is undisputed that Jiao has no previous criminal convictions related to matters within the jurisdiction of FDA, this single favorable factor does not counterbalance the nature and seriousness of his offense and lack of voluntary steps promptly taken to mitigate the impact of his offense on the public. Therefore, the OSI Director agrees with ORA's conclusion that ''the facts supporting the unfavorable factors outweigh those supporting the favorable factor, and therefore warrant imposition of a five-year period of debarment.''

III. Findings and Order

Therefore, the OSI Director, under section 306(b)(1)(D) of the FD&C Act and authority delegated to him by the Commissioner of Food and Drugs, finds that Jiao 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 and is subject to debarment, as set forth in section 306(b)(3)(C) of the FD&C Act. FDA has considered the applicable factors listed in section 306(c)(3) of the FD&C Act and determined that a debarment period of 5 years is appropriate.

As a result of the foregoing findings, Jiao is debarred for 5 years from providing services in any capacity to a person with an approved or pending drug product application under sections 505, 512, or 802 of the 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), effective December 5, 2024 (see 21 U.S.C. 335a(c)(1)(B) and (c)(2)(A)(iii) and 21 U.S.C. 321(dd)). Any person with an approved or pending drug product application, who knowingly uses the services of Jiao, in any capacity during his period of 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 Jiao, during his period of debarment, provides services in any capacity to a person with an approved or pending drug product application, 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 applications submitted by or with the assistance of Jiao during his period of debarment (section 306(c)(1)(B) of the FD&C Act).

Dated: November 27, 2024.

George M. Warren,

Director, Office of Scientific Integrity.

[FR Doc. 2024–28452 Filed 12–4–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer at (240) 276–0361. Comments are invited on: (a) whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including leveraging automated data collection techniques or other forms of information technology.

Proposed Project: Revision to the Community Mental Health Services Block Grant and Substance Use Prevention, Treatment, and Recovery Services Block Grant FY 2026–2027 Application Plan and Report Guide (OMB No. 0930–0168)

SAMHSA is requesting approval from the Office of Management and Budget (OMB) to revise the 2026–2027 Community Mental Health Services Block Grant (MHBG) and Substance Use Prevention, Treatment, and Recovery Services (SUPTRS) Block Grant Application Plan and Report Guide.

Currently, the SUPTRS BG and the MHBG differ on a number of their practices (*e.g.,* data collection at individual or aggregate levels) and statutory authorities (*e.g.,* method of calculating MOE, stakeholder input requirements for planning, set asides for specific populations or programs, etc.). Historically, the Centers within SAMHSA that administer these block grants have had different approaches to application requirements and reporting. To compound this variation, states have different structures for accepting, planning, and accounting for the block grants and the prevention set aside within the SUPTRS BG. As a result, how these dollars are spent and what is known about the services and clients that receive these funds varies by block grant and by State.

SAMHSA has conveyed that block grant funds must be directed toward four purposes: (1) to fund priority treatment and support services for individuals without insurance or who cycle in and out of health insurance coverage; (2) to fund those priority treatment and support services not covered by Medicaid, Medicare, or private insurance offered through the exchanges and that demonstrate success in improving outcomes and/or supporting recovery; (3) to fund universal, selective and indicated prevention activities and services that align with SAMHSA's six prevention strategies; and (4) to collect performance and outcome data to determine the ongoing effectiveness of behavioral health prevention, treatment and recovery support services and to plan the implementation of new services on a nationwide basis.

States will need help to meet future challenges associated with, the implementation and management of an integrated physical health, mental health, and substance use disorder service system. SAMHSA has established standards and expectations that will lead to an improved system of care for individuals with or at risk of mental and substance use disorders. Therefore, this application package continues to fully exercise SAMHSA's existing authority regarding states, U.S. territories, freely associated states, and the Red Lake Band of Chippewa Indians' (subsequently referred to as ''states'') use of block grant funds as they fully integrate behavioral health services into the broader health care continuum.

Consistent with previous applications, the FY 2026–2027 application has required sections and other sections where additional information is requested. The FY 2026–2027 application requires states to submit a face sheet, a table of contents, a behavioral health assessment and plan, reports of expenditures and persons served, an executive summary, and funding agreements and certifications. In addition, SAMHSA is requesting information on key areas that are critical to the states' success in addressing health care equity. Therefore, as part of this block grant planning process, states should identify promising or effective strategies as well as technical assistance needed to implement the strategies identified in their plans for FYs 2026 and 2027. SAMHSA has made changes to the Block Grant Plan and Report requirements for FFY 2026 and 2027. These changes are necessary to ensure that funds are spent in an appropriate and timely manner. Adjustments were made to pre-existing tables in the plan and report.

On the BG narrative portion of the Block Grant Plan document changes include editorial changes and minor language clarifications throughout the document. Examples include changing ''call centers'' to ''contact centers'' and ''paraprofessionals'' to ''peer support specialists and recovery coaches, prevention specialists'' as appropriate throughout the document. In addition, updated guidance on best practices and conditions under which states may use BG funds for improvements to their health information technology (IT) and systems have been made. On the MHBG