(PDPs), and Programs of All-Inclusive Care for the Elderly (PACE) organizations report financial information demonstrating the organization has a fiscally sound operation. The FSRR is designed to capture financial data of these contracting entities. The Division of Finance and Benefits (DFB) within the Medicare Advantage Contract Administration Group (MCAG) of CMS is assigned the responsibility of reviewing ongoing financial performance of the contracting entities.

All contracting organizations must submit audited annual financial statements one time per year. In addition to the audited annual submission, Health Plans with a negative net worth and/or a net loss and the amount of that loss is greater than one-half of the organization's total net worth submit quarterly financial statements for fiscal soundness monitoring. Part D organizations are required to submit three (3) quarterly financial statements. Lastly, PACE organizations are required to file four (4) quarterly financial statements for the first three (3) years in the program. After the first three (3) years, PACE organizations with a negative net worth and/or a net loss and the amount of that loss is greater than one-half of the organization's total net worth must submit quarterly financial statements for fiscal soundness monitoring. *Form Number:* CMS–906 (OMB control number: 0938–0496); *Frequency:* Quarterly and Yearly*; Affected Public:* Private Sector (Business or other for-profits, Not-for-Profit Institutions); *Number of Respondents:* 251; *Total Annual Responses:* 1,004*; Total Annual Hours:* 335. *(For policy questions regarding this collection contact Christa M. Zalewski at (410) 786–1971.)*

William N. Parham, III,

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

[FR Doc. 2024–28458 Filed 12–4–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–5354]

Determination That Bentyl Preservative Free (Dicyclomine Hydrochloride) Injection, 10 Milligrams/Milliliters, and Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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The Food and Drug Administration (FDA or Agency) has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness.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 these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Stacy Kane, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6236, Silver Spring, MD 20993–0002, 301–796–8363, *Stacy.Kane@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 generally known as the ''Orange Book.'' Under FDA regulations, a drug is 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).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved, and (3) when a person petitions for such a determination under 21 CFR 10.25(a) and 10.30. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for safety or effectiveness reasons, the Agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

FDA has become aware that the drug products listed in the table are no longer being marketed.

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

Application No.	Drug name	Active ingredient(s)	Dosage form/route	Strength(s)	Applicant
NDA 008370	BENTYL PRESERVATIVE FREE.	Dicyclomine Hydrochloride	Injectable; Injection	10 Milligrams (mg)/Milliliters (mL).	AbbVie.
NDA 012104	KENALOG	Triamcinolone Acetonide	Spray; Topical	0.147 mg/Gram (g)	Sun Pharmaceutical Industries Limited.
NDA 017806	THALLOUS CHLORIDE TL 201.	Thallous Chloride TL–201	Injectable; Intravenous	1 Millicurie (mCi)/mL; 2 mCi/mL.	Lantheus.
NDA 017823	HALOG	Halcinonide	Solution; Topical	0.10%	Sun Pharmaceutical Industries Limited.
NDA 018849	LIDEX	Fluocinonide	Solution; Topical	0.05%	Alvogen.
NDA 020551	NIMBEX	Cisatracurium Besylate	Injectable; Injection	Equivalent to (EQ) 2 mg Base/mL.	AbbVie.
NDA 020551	NIMBEX PRESERVATIVE FREE.	Cisatracurium Besylate	Injectable; Injection	EQ 2 mg Base/mL; EQ 10 mg Base/mL.	AbbVie.

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]

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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