This draft guidance is necessary because of the burgeoning interest in the development of novel optical imaging drugs and imaging devices to assist standard surgical procedures in a variety of clinical contexts. Surgeons use these imaging drugs with imaging devices during surgery to assist the standard of care direct visual inspection and palpation of tissue in the surgical field. The imaging drugs, for example, enhance the ability of the surgeon to distinguish tumors from normal tissue. Therefore, the drugs can increase the likelihood of a safe and complete removal of cancers and can minimize the risk of unintended injury to normal anatomical structures. The use of minimally invasive surgical approaches is a contributing factor driving the development of optical imaging products because of the loss of touch perception and more limited field of view with these procedures. For instance, the development of molecularly targeted fluorescent optical drugs aims to facilitate a surgeon's ability to identify the margins of primary tumors and contiguous tumor lesions to achieve a surgical cure.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Developing Drugs for Optical Imaging.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR 201.56 and 201.57 relating to the content and format requirements for labeling of drugs and biologics have been approved under OMB control number 0910–0572. The collections of information in 21 CFR part 312 relating to the investigational new drug application pathway, which includes clinical trials and clinical trial design, have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 relating to the submission of new drug applications and abbreviated new drug applications have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 601 for the submission of biologics license applications have been approved under OMB control number 0910–0338. The collections of information in 21 CFR part 812 relating to investigational device exemptions have been approved under OMB control number 0910–0078.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents*, or *https://www.regulations.gov*.

Dated: December 26, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2025–00213 Filed 1–7–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–0604]

Withdrawal of Food and Drug Administration Notice Regarding Yong Sheng Jiao; Denial of Hearing; Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is issuing this notice to withdraw the December 5, 2024, **Federal Register** notice entitled ''Yong Sheng Jiao; Denial of Hearing; Final Debarment Order'' because the document provided the incorrect bases for debarment and omitted edited language. A corrected notice document is published elsewhere in this **Federal Register**.

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: In the **Federal Register** of December 5, 2024 (89 FR 96655), FDA published a notice entitled ''Yong Sheng Jiao; Denial of Hearing; Final Debarment Order.'' The notice incorrectly reflected language for debarment and omitted edited language. The published document did not evince all changes and edits relevant to this notice. For this reason, the notice, Docket No. FDA–2024–N–0604, as published in the **Federal Register** on December 5, 2024, is hereby withdrawn.

Dated: December 31, 2024.

George M. Warren,

Director, Office of Scientific Integrity.

[FR Doc. 2025–00125 Filed 1–7–25; 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 importing or offering for import any drug into the United States. 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 January 8, 2025.

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) 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 judgment convicting and sentencing Jiao to 2 years of probation and fines.

Jiao's conviction stemmed from conduct, occurring on or about and between 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 Unites States by illegally importing and introducing misbranded dipyrone into interstate commerce in violation of sections 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 section 306(b)(1) of the FD&C Act.

The Proposal explained that the maximum period of debarment for an individual subject to permissive 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 on January 8, 2024. 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 appears to challenge 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 appears to challenge 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 a misbranded drug into the United States. The basis for Jiao's guilty plea was his causing a misbranded drug to enter the United States, not the subsequent shipment to his 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 claims that his supplier was responsible for shipping the misbranded product and that he relabeled the product before further shipment fail to raise a genuine and substantial issue of fact regarding the nature and seriousness of his offense under section 306(c)(3)(A) of the FD&C Act, and the OSI Director will treat this consideration 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 ''allowed'' 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 adequate information regarding additional steps he took that mitigate the effects of the offenses he committed on the public under section 306(c)(3)(C) of the FD&C Act, and thus, he has a failed to raise a genuine and substantial issue of fact with respect to that consideration.

Furthermore, insofar as Jiao intends to argue that FDA's policies regarding dipyrone at the time of his criminal conduct diminish the nature and seriousness of his offense, he has also failed to raise a genuine and substantial issue of fact with respect to the consideration under section 306(c)(3)(A) of the FD&C Act. As set forth above, he has mischaracterized FDA's enforcement policies regarding dipyrone at the time of his criminal conduct. More importantly, as part of his guilty plea, he admitted to intentionally and knowingly causing the introduction of a misbranded drug into the United States with an intent to defraud or mislead the Federal Government. Even assuming that FDA might have exercised its enforcement discretion with respect to that drug under a narrow set of circumstances, his own criminal conduct prevented the Agency from assessing those circumstances with respect to the drug he offered for import into the United States.

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) 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 finding, Jiao is debarred for a period of 5 years from importing or offering for import any drug into the United States, effective January 8, 2025. 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 Jiao, is a prohibited act.

Dated: December 31, 2024.

George M. Warren,

Director, Office of Scientific Integrity.

[FR Doc. 2025–00126 Filed 1–7–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Maternal, Infant, and Early Childhood Home Visiting Program Model Eligibility Review Survey

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice with request for comment.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR. Specifically, HRSA is inviting public comment on its proposed survey to identify evidence-based service delivery models that funding recipients may use to provide services under HRSA's MIECHV Program.

DATES: Comments on this ICR should be received no later than March 10, 2025.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14NWH04, 5600 Fishers Lane, Rockville, Maryland, 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Joella Roland, the HRSA Information Collection Clearance Officer, at (301) 443–3983.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program Model Eligibility Review Survey, OMB No. 0915–xxxx—New

Abstract: HRSA, through its Maternal and Child Health Bureau, oversees the MIECHV Program in partnership with the Administration for Children and Families (ACF) within HHS. The MIECHV Program supports voluntary, evidence-based home visiting services during pregnancy and to families with young children up to kindergarten entry living in at-risk communities. The MIECHV Program was last reauthorized in December 2022.[1] One key program requirement is that programs deliver services using models that meet HHS criteria for evidence of effectiveness.[2] HRSA and ACF define such service delivery models as ''evidence-based.'' ACF administers the Home Visiting Evidence of Effectiveness (HomVEE) review process to identify early childhood home visiting models that demonstrate evidence of effectiveness.[3] However, not all evidence-based service delivery models approved through the HomVEE process meet MIECHV statutory requirements as enacted in the last reauthorization of the program in 2022 such that they may be used to carry out the MIECHV Program in fidelity to applicable program requirements.

HRSA previously issued a Request for Information notice and request for comment regarding its proposal to standardize criteria for assessing model eligibility to be implemented using MIECHV Program funds in 2021.[4] This ICR reflects new MIECHV statutory provisions that were added in December 2022 and thus replaces that 2021 notice. HRSA is issuing this ICR to propose a survey to identify service delivery models that meet both HHS criteria for evidence of effectiveness, as determined by HomVEE review, and applicable MIECHV statutory requirements, and therefore may be used by eligible entities to provide home visiting services through the MIECHV Program. This will be accomplished by validating whether evidence-based models, as determined by HomVEE, align with the MIECHV Program's statutory requirements, as further discussed in this notice. This process will ensure that models used by funding recipients (and their local implementing agencies) to deliver MIECHV Program services effectively support programs in meeting core components of the MIECHV Program, including those added during the program's 2022 reauthorization.

Following approval of this ICR request, HRSA will assess all models that meet HHS criteria for evidence of effectiveness, as determined by the HomVEE review, to determine their MIECHV eligibility by requesting information from home visiting model developers through a standardized survey. As of November 20, 2024, HomVEE lists 24 models that meet HHS criteria for evidence of effectiveness.[5] Upon receiving the survey from HRSA, model developers will have 30 days to provide requested information on model characteristics, resources, and processes. A panel of HRSA reviewers will assess the survey responses against the MIECHV statutory requirements. Any of the 24 evidence-based models that also meet these criteria will be considered eligible for MIECHV Program implementation and remain eligible for implementation after the end of the current performance period.

[1] Section 6101 of the Consolidated Appropriations Act, 2023, Public Law 117–328, recently amended Section 511 of the Social Security Act, as added by the Patient Protection and Affordable Care Act, Public Law 111–148, section 2951, and extended appropriated funding through FY 2027.

[2] 42 U.S.C. 711(d)(3)(C)(i).

[3] The current HHS criteria for evidence-based models can be found at: *https://homvee.acf.hhs.gov/about-us/hhs-criteria.*

[4] HRSA, HHS. ''Statutory Requirements and Process Standardization: Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program Model Eligibility Review.'' **Federal Register** 86, no. 184 (September 27, 2021): 53329. *https://www.federalregister.gov/d/2021-20853.*

[5] HomVEE lists home visiting models that meet HHS criteria for evidence of effectiveness at: *https://homvee.acf.hhs.gov/HRSA-Models-Eligible-MIECHV-Grantees.*