This draft guidance is necessary because of the burgeoning interest in the development of novel optical imaging drugs and imaging devices to assist standard surgical procedures in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This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Developing Drugs for Optical Imaging.''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]

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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 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