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Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs,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 30, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2025–00237 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–D–3780]

Developing Drugs for Optical Imaging; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Developing Drugs for Optical Imaging.'' The purpose of this guidance is to provide recommendations to sponsors regarding clinical trial design features that support development and approval of optical imaging drugs that are used in conjunction with imaging devices and intended as intraoperative aids for the detection of pathology such as tumors or to enhance the conspicuity of normal anatomical structures.

DATES: Submit either electronic or written comments on the draft guidance by April 8, 2025 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment 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 comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment 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 written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2024–D–3780 for ''Developing Drugs for Optical Imaging.'' Received comments will be placed in the docket and, except for those 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 a comment with confidential information that you do not wish to be made publicly available, submit your comments 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 comments. 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 comments 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 to read background documents or the electronic and written/paper comments received, 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, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Libero Marzella, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–2050; or Erica Takai, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5456, Silver Spring, MD 20993–0002, 301–796–6353.

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Developing Drugs for Optical Imaging.'' The purpose of this guidance is to provide recommendations to sponsors regarding clinical trial design features that support development and approval of optical imaging drugs that are used in conjunction with imaging devices and intended as intraoperative aids for detection of pathology such as tumors or to enhance the conspicuity of normal anatomical structures.

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