



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2024-N-0604]

Yong Sheng Jiao: Denial of Application for Termination of Debarment.

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is denying Yong Sheng Jiao's application for termination of debarment under the Federal Food, Drug, and Cosmetic Act (FD&C Act). Mr. Jiao was given notice of the proposed denial of his application for termination of his debarment and was given an opportunity to request a hearing to show why his application for termination of debarment should be granted. As of June 16, 2025 (30 days after receipt of the notice), Mr. Jiao had not requested a hearing and through his attorney informed FDA he would not be requesting a hearing in this matter. Mr. Jiao's failure to respond and request a hearing constitutes a waiver of his right to a hearing concerning this matter.

DATES: This order is applicable [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: Submit comments electronically at <https://www.regulations.gov>. Written comments may be submitted to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Field Enforcement, Office of Field Regulatory Operations, Office of Inspections and Investigations, Food and Drug Administration, 240-402-8743 or debarments@fda.hhs.gov.

SUPPLEMENTARY INFORMATION

I. Background

Section 306(b)(1)(D) of the FD&C Act (21 U.S.C. 335a(b)(1)(D)) permits debarment of an individual from importing or offering for import any drug into the United States if FDA finds, as required by section 306(b)(3)(C) of the FD&C Act, that the individual has been convicted of a felony for conduct relating to the importation into the United States of any drug or controlled substance.

On January 24, 2023, Mr. 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 Mr. Jiao to 2 years of probation and fines. Mr. 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. Mr. 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. Mr. 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 Mr. Jiao of its proposal to issue an order under section 306(b)(1)(D) of the FD&C Act debaring him for a period of 5 years from importing or offering to import any drug into the United States. FDA's proposal was based on a finding that Mr. Jiao was convicted, as defined in section 306(l)(1) of the FD&C Act, for conduct relating to the importation of any drug or controlled substance into the United States. Mr. Jiao requested a hearing on the proposed debarment, and on January 8, 2025, FDA issued an order under section 306(b)(1) of the FD&C Act denying the

request for a hearing and debarring Mr. Jiao for 5 years from importing or offering for import any drug into the United States.

On February 16, 2025, Mr. Jiao, through his attorney, submitted an application for termination of debarment to FDA pursuant to section 306(d)(1) of the FD&C Act. Pursuant to 306(d)(3)(B)(ii), FDA will grant an application to terminate a debarment if it finds that, as relevant here, termination of that individual's debarment would "serve[] the interests of justice" and "adequately protect the integrity of the drug approval process." Mr. Jiao's application did not assert or provide a basis to conclude that termination is appropriate here.

By letter dated May 13, 2025, the Office of Inspections and Investigations (OII) (formerly ORA) offered Mr. Jiao an opportunity for a hearing, under 21 C.F.R. part 12, on OII's proposal to deny his application for termination of his debarment. The proposal reflected OII's assessment that, considering all favorable and unfavorable information in light of the remedial public health purposes underlying debarment, terminating Mr. Jiao's debarment would not serve the interests of justice or adequately protect the integrity of the drug approval process.

OII sent Mr. Jiao the letter proposing to deny his application for termination of his debarment, by certified mail, on May 14, 2025. In addition to informing him about OII's proposal, the letter offered Mr. Jiao an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted an election not to use the opportunity for a hearing and a waiver of any contentions concerning this action. Mr. Jiao received the proposal and notice of opportunity for a hearing on May 15, 2025. On June 17, 2025, Mr. Jiao's attorney informed FDA that Mr. Jiao was not requesting a hearing in this matter. As such, Mr. Jiao failure to request a hearing within the timeframe prescribed by regulation constitutes a waiver of his opportunity for a hearing and any contentions concerning his application for termination of debarment (21 CFR part 12).

II. Conclusion

Therefore, the Division of Field Enforcement, Office of Inspections and Investigations, under section 306(d) of the FD&C Act, under authority delegated to the Director, Division of Enforcement, denies Mr. Jiao's application for termination of debarment. Mr. Jiao has failed to request a hearing and has waived his right to have a hearing on OII's proposal to deny his application for termination of his debarment. 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 Mr. Jiao is a prohibited act.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025-19163 Filed: 9/30/2025 8:45 am; Publication Date: 10/1/2025]