4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-3474]

Zhang Xiao Dong: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring Zhang Xiao Dong for a period of 5 years from importing articles of food (including dietary supplements) or offering such articles for importation into the United States. FDA bases this order on a finding that Mr. Dong was convicted, as defined in the FD&C Act, of a felony count under Federal law for conduct relating to the importation into the United States of an article of food. Mr. Dong was given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. As of November 19, 2019 (30 days after receipt of the notice), Mr. Dong has not responded. Mr. Dong'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 applications for termination of debarment to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Enforcement, Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, or at debarments@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(1)(C) of the FD&C Act (21 U.S.C. 335a(b)(1)(C)) permits FDA to debar an individual from importing an article of food or offering such an article for import into the United States if FDA finds, as required by section 306(b)(3)(A) 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 food.

On December 20, 2018, Mr. Dong was convicted as defined in section 306(l)(1)(A) of the FD&C Act, in the United States District Court for the Northern District of Texas Dallas Division, when the court entered judgment against him for the offense of Mail Fraud in violation of 18 U.S.C. 1343.

FDA's finding that the debarment is appropriate is based on the felony conviction referenced herein. The factual basis for this conviction is as follows: As contained in the Factual Resume in his case, filed on March 12, 2018, Mr. Dong, along with other employees of his employer Genabolix USA, Inc. and Shanghai Yongyi Biotechnology Co., Ltd. (Genabolix), did in or around February 2017, agree to sell synthetic stimulant ingredients, including 1,4 Dimethylamylamine (1,4-DMAA), to a purported dietary supplement manufacturer. That manufacturer told Mr. Dong that the ingredients supplied by Mr. Dong would not be accurately

listed on the labels of the finished dietary supplements produced with those ingredients. As Mr. Dong knew, the synthetic stimulant ingredients would be omitted from the ingredient label of the dietary supplements so that American retailers would sell the product. Mr. Dong then sent unlabeled shipments of these ingredients to a third party in the United States. Subsequently, on June 8, 2017, Mr. Dong (along with others) caused 50kg of 1,3 Dimethylamylamine (1,3-DMAA) to be shipped via commercial carrier in interstate commerce in the United States.

As a result of this conviction, FDA sent Mr. Dong, by certified mail on October 18, 2019, a notice proposing to debar him for a period of 5 years from importing articles of food or offering such articles for import into the United States. The proposal was based on a finding under section 306(b)(1)(C) of the FD&C Act that Mr. Dong's felony conviction for Mail Fraud in violation of 18 U.S.C. 1343, constitutes conduct relating to the importation into the United States of an article of food because Mr. Dong unlawfully imported synthetic stimulant ingredients which Mr. Dong then caused to be shipped in interstate commerce and ultimately used in dietary supplements that did not list the synthetic stimulants as an ingredient.

The proposal was also based on a determination, after consideration of the relevant factors set forth in section 306(c)(3) of the FD&C Act, that Mr. Dong should be subject to a 5-year period of debarment. The proposal also offered Mr. Dong 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 a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Dong failed to respond within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and waived any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(b)(1)(C) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. Dong has been convicted of a felony count under Federal law for conduct relating to the importation into the United States of an article of food and that he is subject to a 5-year period of debarment.

As a result of the foregoing finding, Mr. Dong is debarred for a period of 5 years from importing articles of food or offering such articles for import into the United States, effective (see DATES). Pursuant to section 301(cc) of the FD&C Act (21 U.S.C. 331(cc)), the importing or offering for import into the United States of an article of food by, with the assistance of, or at the direction of Mr. Dong is a prohibited act.

Any application by Mr. Dong for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA-2019-N-3474 and sent to the Dockets Management Staff (see ADDRESSSES). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20.

Publicly available submissions will be placed in the docket and will be viewable at http://www.regulations.gov or at the Dockets Management Staff (see ADDRESSES) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 11, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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