been convicted of a felony for conduct relating to the importation into the United States of any drug or controlled substance.

On December 20, 2018, Mr. Lewicki was convicted as defined in section 306(l)(1)(B) of the FD&C Act, in the United States District Court for the Eastern District of Virginia, when the court accepted his plea of guilty for the offense of conspiracy to distribute HGH imported from China for unapproved purposes in violation of 18 U.S.C. 371 and 21 U.S.C. 333(e) (section 303(e) of FD&C Act).

The FDA's finding that debarment is appropriate is based on the felony conviction referenced herein. The factual basis for this conviction is as follows: As contained in the Stipulation of Facts incorporated into the Plea Agreement, filed on December 20, 2018, from on or about January 2017 to February 2018, Mr. Lewicki conspired with certain other known and unknown individuals to unlawfully distribute HGH imported from China. Specifically, Mr. Lewicki submitted periodic orders, and gave money, for HGH to co-conspirators, for the purchase of HGH from manufacturers based in China. In addition, Mr. Lewicki set up various post office boxes at private carriers in the Eastern District of Virginia. The Chinese based manufacturers delivered vials of HGH from China to Mr. Lewicki at post office boxes he set up. Mr. Lewicki received approximately 90 packages from Chinese manufacturers, each containing 200 vials of HGH. Mr. Lewicki would then sell these vials to individual customers throughout the United States for bodybuilding and other unapproved purposes. Mr. Lewicki's actions were in violation of 18 U.S.C. 371 and 21 U.S.C. 333(e) (section 303(e) of the FD&C Act).

As a result of this conviction FDA sent Mr. Lewicki, by certified mail on September 25, 2019, a notice proposing to debar him for 5 years from importing or offering for import any drug into the United States. The proposal was based on a finding under section 306(b)(3)(C) of the FD&C Act that Mr. Lewicki's felony conviction for conspiracy in violation of 18 U.S.C. 371 and section 303(e) of the FD&C Act was for conduct relating to the importation into the United States of any drug or controlled substance because on multiple occasions, he imported HGH from China and conspired to distribute it within the United States. In proposing a debarment period, FDA weighed the considerations set forth in section 306(c)(3) of the FD&C Act that it considered applicable to Mr. Lewicki's offense and, for the reasons detailed in the notice, concluded that his offense warranted a 5-year period of debarment under section 306(c)(2)(A)(iii).

The proposal informed Mr. Lewicki of the proposed debarment and offered Mr. Lewicki 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. Lewicki received the proposal and notice of opportunity for a hearing on September 28, 2019. Mr. Lewicki failed to request a hearing 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)(3)(C) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. Lewicki 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. FDA finds that the offense should be accorded a debarment period of 5 years.

As a result of the foregoing finding, pursuant to section 306(b)(1)(D) of the FD&C Act, Mr. Lewicki is debarred for a period of 5 years from importing or offering for import any drug 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 any drug by, with the assistance of, or at the direction of, Mr. Lewicki is a prohibited act.

Any application by Mr. Lewicki for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA–2019–N–3131 and sent to the Dockets Management Staff (see **ADDRESSES**). 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.

[FR Doc. 2020–05449 Filed 3–16–20; 8:45 am]

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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 March 17, 2020.

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 **ADDRESSES**). 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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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0419]

Pan American Laboratories, LLC, et al.; Withdrawal of Approval of Three New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of three new drug applications (NDAs) from multiple holders of those NDAs. The basis for the withdrawal is that these NDA holders have repeatedly failed to file required annual reports for those NDAs.

DATES: Approval is withdrawn as of March 17, 2020.

FOR FURTHER INFORMATION CONTACT: Kimberly S. Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993–0002, 301–796–3137.

SUPPLEMENTARY INFORMATION: The holder of an approved application to market a new drug for human use is required to submit annual reports to FDA concerning its approved application in accordance with § 314.81 (21 CFR 314.81).

In the **Federal Register** of November 18, 2019 (84 FR 63661), FDA published a notice offering an opportunity for a hearing (NOOH) on a proposal to withdraw approval of these NDAs because the holders of those NDAs had repeatedly failed to submit the required annual reports for those NDAs. The holders of the NDAs identified in table 1 did not respond to the NOOH. Failure to file a written notice of participation and request for hearing as required by § 314.200 (21 CFR 314.200) constitutes an election by those holders of the NDAs not to make use of the opportunity for a hearing concerning the proposal to withdraw approval of their NDAs and a waiver of any contentions concerning the legal status of the drug products. Therefore, FDA is withdrawing approval of the three applications listed in table 1 of this document. FDA notes that the NOOH also proposed to withdraw approval of NDA 018663, but FDA has decided not to pursue withdrawal of approval of this NDA at this time.