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.

[FR Doc. 2020–05443 Filed 3–16–20; 8:45 am]

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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.

TABLE 1—APPROVED NDAS FOR WHICH REQUIRED REPORTS HAVE NOT BEEN SUBMITTED

Application No.	Drug	NDA holder
NDA 014217 ...	Maolate (chlorphenesin carbamate) Tablet, 400 milligrams (mg).	Pan American Laboratories, LLC, 4099 Highway 190, Covington, LA 70433.
NDA 020530 ...	Iontocaine (epinephrine and lidocaine hydrochloride (HCl)) Topical Solution, 0.01 mg/milliliter; 2%.	Iomed, Inc., 2441 South 3850 West, Suite A, Salt Lake City, UT 84120–9941.
NDA 021504 ...	LidoSite Topical System: LidoSite Patch (lidocaine HCl and epinephrine topical iontophoretic patch) 10%/0.1% and LidoSite Controller.	Vyteris, Inc., 13–01 Pollitt Dr., Fair Lawn, NJ 07410.

FDA finds that the holders of the NDAs listed in table 1 have repeatedly failed to submit reports required by § 314.81. In addition, under § 314.200, FDA finds that the holders of the NDAs have waived any contentions concerning the legal status of the drug products. Therefore, under these findings, approval of the NDAs listed in table 1 and all amendments and supplements thereto are hereby withdrawn as of March 17, 2020.[1]

Dated: March 12, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–05498 Filed 3–16–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3310]

Matthew Dailey: 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 Matthew Dailey for a period of 10 years from importing or offering for import any drug into the United States. FDA bases this order on a finding that Mr. Dailey was convicted, as defined in the FD&C Act, of one felony count under Federal law for introducing misbranded drugs into interstate commerce and one felony count of importing merchandise contrary to law. The factual basis supporting both felony convictions, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Mr. Dailey was given notice of the proposed debarment and was given an opportunity to request a hearing within the timeframe prescribed by regulation to show why he should not be debarred. As of November 8, 2019 (30 days after receipt of the notice), Mr. Dailey had not responded. Mr. Dailey'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, Room 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa (ELEM–4029), Division of Enforcement, Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 240–402–8743 or at *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 the 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 May 8, 2019, Mr. Dailey was convicted as defined in section 306(*l*)(1) of the FD&C Act, in the U.S. District Court for the Eastern District of Michigan, when the court accepted his plea of guilty and entered judgment against him for the offenses of introducing misbranded drugs into interstate commerce in violation of section 301(a) of the FD&C Act (21 U.S.C. 331(a)) and importing merchandise contrary to law in violation of 18 U.S.C. 545.

The FDA's finding that debarment is appropriate is based on the felony convictions referenced herein. The factual basis for these convictions is as follows: As contained in the Stipulation of Facts incorporated into the Plea Agreement, filed on January 8, 2019, from on or about March 2011 through November 2016, Mr. Dailey imported hundreds of shipments of kratom into the United States. To evade the lawful regulatory authority of FDA, he instructed his foreign suppliers to label shipments of bulk kratom with materially false statements that described the kratom as ''incense,'' ''paint pigment,'' and other substances not regulated by the FDA. Mr. Dailey also provided the FDA (sometimes through import brokers) materially false written descriptions of his bulk kratom imports. After receiving the kratom, Mr. Dailey then apportioned bulk shipments of kratom into smaller portions and repackaged the kratom into smaller plastic bags at a location not registered as a facility that manufactures, prepares, propagates, compounds, and processes drugs. Mr. Dailey then sold kratom products to hundreds of consumers through the United States through a website he managed. The labeling of his kratom products did not include any directions for use, such as indications, dosage instructions, methods of administration, or contraindications. In selling his kratom product, Mr. Dailey intended that consumers use his kratom products as a ''drug'' within the meaning of section 201(g)(1) of the FD&C Act (21 U.S.C. 321(g)(1)). Specifically, Mr. Dailey intended that consumers use the kratom he imported to treat and mitigate diseases, including but not limited to chronic pain, fibromyalgia, opiate withdrawal, and Lyme disease, and to affect the structure and function of the human body by taking the kratom products as substitutes for drugs of abuse and prescription pills. As stated in the Stipulation of Facts, Mr. Dailey's actions were in violation of section 301(a) of the FD&C Act and 18 U.S.C. 545.

As a result of this conviction, FDA sent Mr. Dailey by certified mail on October 2, 2019, a notice proposing to debar him for 2 consecutive 5-year periods (10 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)

[1] Although it was not a factor in FDA's determination, we note that all three drugs covered by these NDAs are in discontinued marketing status.