

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%.	lomed, 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under these findings, approval of the NDAs listed in table 1 and all amendments and supplements thereto are hereby withdrawn as of March 17, 2020.<sup>1</sup>

Dated: March 12, 2020.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2020–05498 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–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) debaring 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](mailto: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(j)(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)

<sup>1</sup> 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.

of the FD&C Act that Mr. Dailey's felony convictions for introducing misbranded drugs into interstate commerce and importing merchandise contrary to law were for conduct relating to the importation into the United States of any drug or controlled substance because he illegally imported kratom, a misbranded drug, for repackaging, sale, and distribution to U.S. consumers. 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. Dailey's offenses, and concluded that each of these felony offenses independently warranted a 5-year period of debarment, and proposed that these debarment periods be served consecutively under section 306(c)(2)(A)(iii) of the FD&C Act.

The proposal informed Mr. Dailey of the proposed debarment and offered Mr. Dailey 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. Dailey received the proposal and notice of opportunity for a hearing on October 7, 2019. Mr. Dailey 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. Dailey has been convicted of two felony counts under Federal law for conduct relating to the importation into the United States of any drug or controlled substance. FDA finds that each offense should be accorded a debarment period of 5 years. Under section 306(c)(2)(A)(iii) of the FD&C Act, in the case of a person debarred for multiple offenses, FDA shall determine whether the periods of debarment shall run concurrently or consecutively. FDA has concluded that the 5-year period of debarment for each of the 2 offenses of conviction needs to be served consecutively, resulting in a total debarment period of 10 years.

As a result of the foregoing finding, Mr. Dailey is debarred for a period of 10

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, the importing or offering for import into the United States of any drug or controlled substance by, with the assistance of, or at the direction of Mr. Dailey is a prohibited act.

Any application by Mr. Dailey for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA-2019-N-3310 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(j).

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-2019-P-4523]

#### **Determination That Potassium Chloride in 5% Dextrose and 0.225% Sodium Chloride Injection, 5 Milliequivalents, 10 Milliequivalents, 15 Milliequivalents, 20 Milliequivalents, 30 Milliequivalents, and 40 Milliequivalents, in Plastic Containers, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) has determined that the potassium chloride drug products listed in this notice were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) that refer to these drug products, if all other legal and regulatory requirements are met.

**FOR FURTHER INFORMATION CONTACT:** Linda Jong, Center for Drug Evaluation

and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6288, Silver Spring, MD 20993-0002, 301-796-3977, [Linda.Jong@fda.hhs.gov](mailto:Linda.Jong@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is known generally as the "Orange Book." Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

The drug products listed in table 1 of this notice are no longer being marketed. All the products listed in table 1 are the subject of NDA 018365, held by ICU Medical, Inc., and initially approved on May 29, 1980. The products are indicated in patients requiring parenteral administration of potassium chloride with minimal carbohydrate calories and sodium chloride.