

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
FORT MYERS DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

Case No. 2:21-cv-336-FtM-38NPM

DEFENDANT ARTICLES IDENTIFIED
IN PARAGRAPH ONE OF
THE AMENDED VERIFIED
COMPLAINT,

Defendants.

CONSENT DECREE OF CONDEMNATION AND DESTRUCTION

On May 7, 2021, the United States filed an Amended Verified Complaint for Forfeiture against the Defendant Articles, articles of food. The Amended Verified Complaint alleges that the Defendant Articles are articles of food, namely dietary supplements and dietary ingredients, that are adulterated within the meaning of the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 342(f)(1)(B), in that they contain or are a new dietary ingredient, kratom, for which there is inadequate information to provide reasonable assurance that this ingredient does not present a significant or unreasonable risk of illness or injury.

Pursuant to the Amended Warrant of Arrest *In Rem* issued by this Court, the United States Marshals Service seized the Defendant Articles on May 21, 2021. The United States published notice of this action on www.forfeiture.gov in accordance with Rule G(4) of the Supplemental Rules for Admiralty or Maritime Claims and Asset Forfeitures Actions of the Federal Rules of Civil Procedure (hereinafter,

GOVERNMENT
EXHIBIT

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“Supplemental Rule G”). On May 12, 2021, BioBotanical LLC, a Florida Limited Liability Company, intervened and filed a statement of interest or right to the Defendant Articles. Specifically, Claimant BioBotanical LLC claims all Defendant Articles that are bulk kratom powder. On May 12, 2021, MT Brands LLC, a Florida Limited Liability Company, also intervened and filed a statement of interest or right to the Defendant Articles. Specifically, Claimant MT Brands LLC claims all Defendant Articles that are packaged food. Collectively, BioBotanical LLC and MT Brands LLC (hereafter, “Claimants”) assert an interest or right to all the Defendant Articles seized by the United States.

Claimants affirm that they have an interest in the seized articles, and that no other party has an interest in the articles. Further, Claimants affirm that they will hold Plaintiff harmless should any other party or parties hereafter file or seek to file a statement of interest or right to intervene in this action, or seek to defend or to obtain any part of the seized Defendant Articles subject to this Consent Decree of Condemnation and Destruction (“Decree”). Claimants now consent that a Decree, as sought in the Complaint, be entered condemning the seized Defendant Articles.

Claimants, without admitting or denying the allegations in the Amended Verified Complaint, having appeared and voluntarily consented to the entry of this Decree without contest, before any testimony has been taken, and the United States having consented to the entry of this Decree, it is now

ORDERED, ADJUDGED, AND DECREED that:

1. This Court has jurisdiction over this action pursuant to 28 U.S.C.

§ 1345 and 21 U.S.C. § 334.

2. The Amended Verified Complaint states a claim for relief under the Act.

3. The seized Defendant Articles are articles of food, within the meaning of 21 U.S.C. §§ 321(f) and 321(ff), that are adulterated within the meaning of 21 U.S.C. § 342(f)(1)(B), in that they contain or are a new dietary ingredient, kratom, for which there is inadequate information to provide reasonable assurance that this ingredient does not present a significant or unreasonable risk of illness or injury.

4. The seized Defendant Articles are condemned pursuant to 21 U.S.C. § 334(a) and forfeited to the United States.

5. Claimant shall pay to the United States all court costs, fees, storage, and other proper expenses, and such further costs for which Claimant is liable pursuant to 21 U.S.C. § 334(e). Claimant shall pay these costs within 20 calendar days of receiving notice from FDA of such costs.

6. Within 20 calendar days of the entry of this Decree, Claimants shall execute and file with the Clerk of this Court a \$175,252.32 penal bond in a form acceptable to the Clerk of this Court, and payable to Clerk, United States District Court, and conditioned on Claimants' abiding by and performing all of the terms and conditions of this Decree, and of such further orders and decrees as may be entered in this proceeding.

7. After filing the bond with this Court pursuant to paragraph 6 of this Decree, and paying the costs pursuant to paragraph 5 of this Decree, Claimants shall

give written notice to the United States Food and Drug Administration ("FDA"), 555 Winderley Place Suite 200, Maitland, Florida 32751, that Claimants, at their own expense, are prepared to destroy all the seized Defendant Articles under the supervision of a duly authorized FDA representative at a time mutually agreed upon by the parties. Claimants shall notify FDA of the proposed date, place, and method of destruction for all the Defendant Articles. Claimants have already notified FDA of a proposed place and method of destruction, to which FDA has no opposition.

8. Upon receipt of the notice under paragraph 7, FDA will notify the United States Marshals Service to release seized Defendant Articles to the custody of Claimants for the sole purpose of destroying the seized Defendant Articles pursuant to the notice submitted in paragraph 7. Claimants shall not commence attempting to destroy the seized Defendant Articles until Claimants have received written authorization to commence with the destruction from FDA. All seized Defendant Articles shall be destroyed at Claimants' expense under the supervision of FDA. Claimants shall pay all costs incurred in supervising the destruction at the rates specified in paragraph 16 of this Decree.

9. Claimants shall at all times, until the seized Defendant Articles have been destroyed, retain the seized articles intact for examination or inspection by FDA in a place made known to and approved in writing by FDA, and shall retain the records or other proof necessary to identify the articles to the satisfaction of FDA.

10. Claimants shall not destroy or dispose of, permit another person to destroy or dispose of, or cause another person to destroy or dispose of the seized

Defendant Articles in a manner contrary to the provisions of the Act, or other laws of the United States, or of any State or Territory (as defined in the Act) in which they are disposed of.

11. Claimants shall, within 20 days of the date of its notification under paragraph 7 and at its own expense, complete the process of destroying the seized articles under the supervision of FDA, to the extent that FDA deems such supervision to be necessary. Claimants shall reimburse the United States for the costs of supervising the destruction of the seized articles within ten days of receiving an invoice(s) for such costs.

12. The United States Attorney, upon being advised by FDA that the conditions of this Decree have been performed, shall transmit such information to the Clerk of this Court, whereupon the bond given in this proceeding shall be cancelled and discharged.

13. If Claimants fail to abide by and perform all the terms and conditions of this Decree, or of the penal bond, or of such further order or decree as may be entered in this proceeding, then the bond shall, on the United States' motion, be forfeited in its entirety and judgment entered for the United States. If Claimants breach any term or condition of this Decree, then Claimants, at their own expense, shall immediately return the seized Defendant Articles to the United States Marshals Service or otherwise dispose of them pursuant to an order of this Court. In the event that return of the seized Defendant Articles becomes necessary pursuant to this paragraph, Claimants shall be responsible for all costs of storage and disposition that

are incurred by the United States.

14. If Claimants fail to abide by or perform any of the terms or conditions of this Decree, or such further order or decree as may be entered in this proceeding, and is found in civil or criminal contempt thereof, Claimants shall, in addition to other remedies, reimburse the United States for its attorney's fees, all investigational expenses, and court costs relating to such violation and contempt proceedings.

15. All communications required to be sent to FDA under this Decree shall be prominently marked "Decree Correspondence" and shall be sent to Pearl Lopina, HAFE4 Compliance Officer, United States Food and Drug Administration, 555 Winderley Place Suite 200, Maitland, Florida 32751.

16. Claimants shall reimburse Plaintiff for the costs of all FDA supervision, including inspections, examinations, analyses, document reviews, and supervision of destruction, that FDA deems necessary to evaluate Claimants' compliance with any part of this Decree, at the standard rates prevailing at the time the activities are accomplished. As of the date that this Decree is signed by the parties, these rates are: \$102.39 per hour or fraction thereof per representative for supervision, except analytical work; \$122.71 per hour or fraction thereof per representative for analytical work; 56 cents per mile for travel expenses; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per day per representative for subsistence expenses, where necessary. In the event that the standard rates applicable to FDA's supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the

Court.

17. All decisions conferred upon FDA in this Decree shall be vested in the discretion of FDA. Claimants shall abide by the decisions of FDA, and FDA's decisions shall be final. FDA's decisions under this Decree shall be reviewed by this Court, if necessary, under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

18. This Court shall retain jurisdiction to issue such further decrees and orders as may be necessary and appropriate to the proper disposition of this proceeding.

Dated this _____ day of _____, 2021.

SHERI POLSTER CHAPPELL
UNITED STATES DISTRICT JUDGE

We hereby consent to the entry of the foregoing:

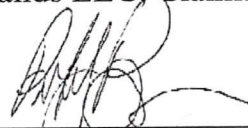
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BioBotanical LLC, Claimant




JAMES MORRISSETTE
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