IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF OKLAHOMA

1.	UNITED STATES OF AMERICA,	
	Plaintiff,	
v.		
1.	250,000 filled bottles of liquid product, more or less, of finished product, containing kratom, labeled in part: "Botanic Tonics Feel Free Plant Based Herbal Supplement",	Case No. 23-cv-168-JFH-CDL
2.	1.5 tanks of liquid product, more or less, containing kratom,	
3.	1,200 cartons of capsules, more or less, of kratom, labeled in part: "Botanic Tonics Feel Free Plant Based Herbal Supplement",	
4.	Undetermined quantities of bulk powder kratom, labeled in part: "Green Nano",	
	and	
5.	All other quantities of the aforesaid articles of food with any lot number and in any size or type container that are labeled or otherwise appear to contain, or are, kratom, located at 13105 East 61st Street, Suites A&B Broken Arrow, Oklahoma 74012-1191,	
	Defendant Articles.	

First Amended Verified Complaint for Forfeiture In Rem

NOW COMES the United States of America, by its attorneys, Clinton J.

Johnson, United States Attorney for the Northern District of Oklahoma, and Kristin

Harrington, Assistant United States Attorney, respectfully stating as follows:

NATURE OF THE ACTION

1. This is a civil forfeiture action *in rem* brought by the United States of

America pursuant to 21 U.S.C. § 334 to seize and condemn the Defendant Articles in

rem ("Defendant Articles") identified in the caption that are property involved in or

facilitating violations of the Federal Food, Drug, and Cosmetic Act ("Act"), 21

U.S.C. § 301 et seq, and are located on the premises of Botanic Tonics, LLC,

("Botanic Tonics"), 13105 East 61st Street, Suites A&B Broken Arrow, Oklahoma

74012-1191.

The Property In Rem

- 2. The Defendant Articles consist of:
 - a) 59 pallets and four partial pallets said to contain 225,048 bottles, each bottle filled with 20z of liquid finished product containing kratom;
 - b) One partial pallet said to contain 616 bottles of 90 count capsules of finished product containing kratom;
 - c) 1,237 cartons each said to contain 72 count capsules of finished product containing kratom;
 - d) Contents of one full tank of in-process liquid product containing kratom said to contain an estimated volume sufficient to fill 125,000 bottles with 2oz each of liquid finished product containing kratom;
 - e) Two mixed pallets of three finished products containing kratom that were packaged with shipping labels ready for distribution containing: 2oz liquid; 90 count capsules bottles; and 72 count capsules cartons; and
 - f) Sixty-five cases said to contain, in total, 1,300 kg of bulk powder kratom.

A warrant *in rem* was duly issued by this Court pursuant to Supplemental Rule G(3)(b) and the United States executed the warrant upon the Defendant Articles on April 26, 2023.

JURISDICTION AND VENUE

3. This Court has jurisdiction over seizures brought by the United States under 28 U.S.C. § 1345 and under 21 U.S.C. § 334.

4. The Defendant Articles are articles of food, within the meaning of 21 U.S.C. §§ 321(f) and 321(ff), located on the premises of Botanic Tonics, 13105 East 61st Street, Suites A&B Broken Arrow, Oklahoma 74012-1191, in the Northern District of Oklahoma.

5. This Court has *in rem* jurisdiction over the Defendant Articles, and venue is proper in this district pursuant to 28 U.S.C. § 1355(b)(1) because the acts or omissions giving rise to the forfeiture occurred in this district, and pursuant to 28 U.S.C. § 1395 and 21 U.S.C. § 334(a)(1), because the seized Defendant Articles are located in this district.

6. The Defendant Articles consist in whole or in part of components that were shipped in interstate commerce from outside the state of Oklahoma.

FACTS

7. Botanic Tonics manufactures, holds, and distributes dietary supplements, labeled as Botanic Tonics Feel Free Plant Based Herbal Supplement that contain *Mitragyna speciosa*, also known as kratom, in liquid form and packaged in bottles, in capsule form and packaged in sealed pouches, and Botanic Tonics receives

bulk powder kratom that is used in its production of dietary supplements.

8. As a plant, kratom is a botanical and, therefore, a dietary ingredient within the meaning of 21 U.S.C. § 321(ff)(1)(C). Because kratom was not marketed as a dietary ingredient in the United States prior to October 15, 1994, it is a new dietary ingredient within the meaning of 21 U.S.C. § 350b(d). The Defendant Articles are dietary supplements within the meaning of 21 U.S.C. § 321(ff)(3)(B).

9. Investigators from the United States Food and Drug Administration ("FDA") conducted an inspection of the premises of Botanic Tonics, 13105 East 61st Street, Suites A&B Broken Arrow, Oklahoma 74012-1191, between October 17, and November 17, 2022. During the inspection, FDA investigators observed large quantities of products similar to the Defendant Articles, including bottles of Feel Free Plant Based Herbal Supplement, labeled as containing kratom and as a dietary supplement; and large quantities of bulk kratom powder, used by Botanic Tonics to manufacture its dietary supplements.

10. On or around January 2023, FDA documented that Botanic Tonics' social media webpage (facebook.com/botanictonics) advertised packages of Feel Free Plant Based Herbal Supplement capsules. FDA then purchased Botanic Tonics' Feel Free Plant Based Herbal Supplement capsules on or around February 2023, from https://botanictonics.com. FDA received a shipment from Botanic Tonics, located in Broken Arrow, Oklahoma, of Botanic Tonics' Feel Free Plant Based Herbal Supplement capsules on or around March 2023. Botanic Tonics' Feel Free

Plant Based Herbal Supplement capsules were labeled as containing kratom and as a dietary supplement.

11. Investigators from FDA conducted an inspection of Botanic Tonics on April 26, 2023. During the inspection, FDA investigators observed large quantities of products similar to the Defendant Articles, including large quantities of Feel Free Plant Based Herbal Supplement liquid, labeled as containing kratom and as a dietary supplement; large quantities of Botanic Tonics' Feel Free Plant Based Herbal Supplement capsules labeled as containing kratom and as a dietary supplement; and large quantities of bulk kratom powder, used by Botanic Tonics to manufacture its dietary supplements.

12. Serious safety concerns exist regarding the effect of kratom on multiple organ systems. Consumption of kratom can lead to a number of negative health impacts, including respiratory depression, vomiting, nervousness, weight loss, and constipation. Kratom consumption has been linked to neurologic, analgesic and sedative effects, addiction, and liver toxicity.

13. Mitragynine, the major alkaloid identified in kratom, has been reported as a partial opioid agonist, producing effects that are similar to morphine. Furthermore, a minor alkaloid of kratom, 7-hydroxymitragynine, has been reported to be even more potent than morphine. *Mitragyna speciosa* preparations have significant effects on cognition in humans.

14. *Mitragyna speciosa* has been indicated to have both narcotic and stimulant-like effects, which substantiates its potential for abuse. Chronic exposure to

Mitragyna speciosa preparations can be followed by withdrawal symptoms in humans, some typical withdrawal symptoms include hostility, aggression, excessive tearing, inability to work, arching of muscle, bones, and jerk limb movements.

BASIS FOR FORFEITURE

15. The allegations in the preceding paragraphs are re-alleged and incorporated by reference.

16. The Defendant Articles are dietary supplements and dietary ingredients within the meaning of the Act, 21 U.S.C. §§ 321(ff) and 321(ff)(1), that may not be introduced or delivered for introduction into interstate commerce pursuant to 21 U.S.C. § 331(a) because they are adulterated within the meaning of 21 U.S.C. § 342(f)(1)(B).

17. The Defendant Articles 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 of injury.

18. Based on the foregoing, the Defendant Articles are held illegally within the jurisdiction of this Court and are liable to seizure, forfeiture, and condemnation pursuant to 21 U.S.C. § 334.

CLAIM FOR RELIEF

WHEREFORE, the United States requests that judgment be entered declaring that the Defendant Articles be condemned and disposed of according to law, and that the United States be granted such other and further relief as this Court may

deem just and proper, together with costs and disbursement of this action in rem.

DATED: May 10, 2023.

RESPECTFULLY SUBMITTED,

CLINTON J. JOHNSON UNITED STATES ATTORNEY

By: ____

KRISTIN F. HARRINGTON, OBA No. 21185 Assistant United States Attorney 110 West 7th Street, Suite 300 Tulsa, Oklahoma 74119 T: (918) 382-2785 | F: (918) 560-7938 Email: Kristin.Harrington@usdoj.gov

VERIFICATION

I, Chad J. Whitwell, Compliance Officer for the Food and Drug Administration, U.S. Department of Health and Human Services, declare under penalty of perjury that I have read the foregoing First Amended Verified Complaint for Forfeiture *In Rem* in this action and state that the allegations it contains are true and correct to the best of my knowledge, information, and belief.

The sources of my knowledge and information and the grounds of my belief are the official files and records of the United States, as well as my investigation of this case, together with others, as a Compliance Officer, Division 3 West, United States Food and Drug Administration.

Executed on the 10th day of May, 2023, in Dallas, Texas.

CHAD J. WHITWELL Compliance/Consumer Safety Officer Food and Drug Administration U.S. Department of Health and Human Services

CERTIFICATE OF SERVICE

I hereby certify that on May 10, 2023, the foregoing document was electronically transmitted to the Clerk of Court using the ECF System for filing and transmittal of a Notice of Electronic Filing to counsel of record.

<u>/s/ Shawna Carter</u> SHAWNA CARTER Paralegal Specialist