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

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"**,

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 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.

Case No. 23-CV-168-JFH-CDL

CLAIMANT BOTANIC TONICS, LLC'S MOTION TO DISMISS FIRST AMENDED VERIFIED COMPLAINT

Claimant Botanic Tonics, LLC ("Botanic" or "Claimant"), by and through undersigned counsel, moves to dismiss the complaint,1 pursuant to Fed. R. Civ. P. Supp. R. G(8)(b)(i) and Fed. R. Civ. P. 12(b)(6), because it fails to even reference, let alone allege non-compliance with, the specific statute addressing whether new dietary ingredients are deemed adulterated. Further, the complaint and its boilerplate language are bereft of facts that support the government's conclusory allegations about the safety of kratom. Accordingly, and as set forth more fully below, the complaint must be dismissed.

Factual Background and Allegations

On April 26, 2023, investigators from the Food and Drug Administration ("FDA") conducted an inspection of Botanic Tonics, LLC, located in Broken Arrow, Oklahoma. (Doc. 9, First Amended and Verified Complaint, ¶¶ 1, 11). The government alleges that Botanic Tonics makes and distributes dietary supplements, labeled as Botanic Tonics Feel Free Plant Based Herbal Supplements that contain Mitragyna speciosa, also known as kratom, and that Botanic Tonics received bulk powder kratom that is used in its production of dietary supplements. (FAC, ¶ 7).

According to the government, kratom is a "botanical and, therefore, a dietary ingredient." (FAC, ¶ 8). It is also a "food," and, specifically, a dietary supplement. (FAC, ¶4). The government alleges that kratom was not marketed as a dietary ingredient in the United States prior to October 15, 1994, so it is a "new dietary ingredient." (FAC, ¶ 8). The government claims that "serious safety concerns exist regarding the effect of kratom on

[1] The government filed its initial complaint on April 26, 2023, (Doc. 2), and a First Amended Verified Complaint on May 10, 2023. (Doc. 9).

multiple organ systems." (FAC, ¶ 12). According to the government, "[m]itragynine, the major alkaloid identified in kratom, has been reported as a partial opioid agonist," and that "a minor alkaloid of kratom, 7-hydroxymitragynine, has been reported to be even more potent than morphine." (FAC, ¶ 13).

The government does not cite to or reference any scientific data, studies, or reports to support its sweeping claims, nor does the government provide any data, studies, or reports assessing how much of this "food" must be consumed in order to have any adverse effect. And the government does not identify any adverse events resulting from the use of kratom, generally, or Feel Free, specifically. In fact, the government simply notes that consumption of kratom "can lead to a number of negative health impacts," but not that such negative health impacts are even probable or likely, just that they are possible. (FAC, ¶ 12). Further, the FDA Compliance Officer who verified the complaint does not include any specific basis for his sworn assertion that the complaint is true and correct. Based on his job title, "Compliance Officer, Division 3 West," he does not appear to have special knowledge about kratom. (FAC at p. 8).

During the inspection on April 26, 2023, FDA investigators claimed to have seen "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." (FAC, ¶ 11).

That very same day, FDA filed an "Emergency Application for Warrant to Arrest in Rem." (Doc. 4). The Magistrate Judge signed an "Order Granting Emergency Application for Warrant of Arrest in Rem," (Doc. 6), and signed the warrant at 5:23 p.m. on April 26, 2023, the same day as the inspection. (Doc. 7). Notably, no document filed by the government explained why an emergency ex parte order was necessary or justified. To the contrary, the government specifically alleged that it observed similar products at the same Botanic Tonics location five and six months prior to seeking the "emergency" warrant, (FAC, ¶ 9), and that FDA conducted a secret purchase of Botanic Tonic's products in February 2023, two months before the "emergency" warrant application. (FAC, ¶ 10). Notably, even though the government received "a shipment from Botanic Tonics … of Feel Free Plant Based Herbal Supplement capsules on or around March 2023," the complaint makes no mention of whether those products actually contained kratom. (FAC, ¶ 10). Logically, it would seem that either that the products did not contain kratom or that the government did not even bother to test the product in the month or more that it had them prior to filing the "emergency" complaint.

In seeking seizure and forfeiture of the Defendant Articles, the government provides a single paragraph alleging that the Defendant Articles are adulterated. Specifically, the government alleges:

> 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 or injury.

(FAC, ¶ 17).

Botanic Tonics, LLC filed a claim to the Defendant Articles contemporaneously with this motion to dismiss. As noted in the verified claim to the Defendant Articles, Botanic Tonics is the owner of those articles, which establishes standing to contest the government's efforts to forfeit the property.

Argument and Citation of Authority

In rem actions such as the present case apply the Supplemental Rules for Admiralty or Maritime Claims and Asset Forfeiture Actions. Pursuant to Rule G(2)(f), the complaint must "state sufficiently detailed facts to support a reasonable belief that the government will be able to meet its burden of proof at trial." Fed. R. Civ. P. Supp. R. G(2)(f). A claimant who has standing to contest forfeiture may move to dismiss the action under Federal Rule of Civil Procedure 12(b). Fed. R. Civ. P. Supp. R. G(8)(b)(i).

"To survive a motion to dismiss [under 12(b)(6)], a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009); see also Clinton v. Sec. Benefit Life. Ins. Co., 63 F.4th 1264, 1274 (10th Cir. 2023). To state a plausible claim for relief, a complaint's factual allegations must "allow the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Iqbal, 556 U.S. at 678; Clinton, 63 F.4th at 1275. While a court must accept a complaint's factual allegations as true in response to a motion to dismiss, it is not required to accept the plaintiff's legal conclusions. Iqbal, 556 U.S. at 678. "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." Iqbal, 556 U.S. at 678; Clinton, 63 F.4th at 1275. See also U.S. v. $134,972.34 Seized from FNB Bank, Account No.-5351, 94 F. Supp. 3d 1224, 1230

(N.D.Ala. 2015) ("[T]he court should determine the sufficiency of the complaint by first separating the factual and conclusory allegations, and then applying the standard of Supplemental Rule G(2)(f)."). "An allegation is conclusory where it states an inference without stating underlying facts or is devoid of any factual enhancement." Clinton, 63 F.4th at 1275.

The requirement in Supplemental Rule G that in rem forfeiture complaints must "state sufficiently detailed facts to support a reasonable belief that the Government will be able to meet its burden of proof at trial," creates a heightened burden for pleading on the plaintiff above that of Iqbal. See Fed. R. Civ. P. Supp. R. G(2)(f); $134,972.34 Seized from FNB Bank, Account No.-5351, 94 F. Supp. 3d at 1229-30 (applying heightened pleading standard but noting that Iqbal and Twombly may provide guidance if not in conflict with Supplemental Rule G(2)); United States v. All Assets Held at Bank Julius Baer & Co., 571 F. Supp. 2d 1, 16-17 (D.D.C. 2008). This heightened particularity requirement "is designed to guard against the improper use of seizure proceedings and to protect property owners against the threat of seizure upon conclusory allegations." United States v. One Gulfstream G-V Jet Aircraft, 941 F. Supp. 2d l, 14 (D.D.C. 2013). Failure to satisfy the more exacting pleading requirements of a civil forfeiture action warrants dismissal of an in rem complaint. Id. at 16 (finding government failed to state a claim under standards set forth in Supplemental Rules G and E and granting claimant's 12(b)(6) motion to dismiss in rem forfeiture action).

None of the Defendant Articles are subject to forfeiture under the laws of the United States. Dietary supplements, including those manufactured, produced, marketed, distributed, and sold by Botanic Tonics, are regulated pursuant to the Dietary Supplement

Health and Education Act (DSHEA), Pub. L. No. 103-417, 108 Stat. 4325 (1994), which amended the Federal Food, Drug and Cosmetic Act (FDCA). See Nutraceutical Corp. v. Von Eschenbach, 459 F.3d 1033, 1035 (10th Cir. 2006).

As alleged in the First Amended Complaint, the United States claims that 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." (FAC, ¶ 17).

Under DSHEA, a dietary ingredient is a "new dietary ingredient" (NDI), if it was not marketed as a dietary ingredient in the United States before October 15, 1994. 21 U.S.C. § 350b(d); see also Debernadis v. IQ Formulations, LLC, 942 F.3d 1076, 1081 (11th Cir. 2019). The United States claims that kratom is a new dietary ingredient. (FAC, ¶ 8). "[K]ratom constitutes food within the meaning of the law." See In re Spa & Organic Essentials of Penn., LLC, No. 1:18-MC-546, 2019 WL 1651607, at *1 (M.D. Penn. Apr. 17, 2019).

Because dietary supplements are classified as foods, manufacturers and producers are not required to provide evidence of product safety or regulatory status before distributing dietary supplement products. Dietary supplements are legally presumed to be safe. See United States v. Undetermined Quantities of All Articles of Finished and In-Process Foods, 936 F.3d 1341, 1348 (11th Cir. 2019) ("Congress thought it better to have a clear, administrable rule—dietary supplements are presumed safe, subject only to a contrary

showing—than to require a particularized inquiry in every case." (citing Sen. Rep. No. 103-410, at 21-22 (1994)).

In any proceeding under DSHEA, the "United States shall bear the burden of proof on each element to show that a dietary supplement is adulterated." 21 U.S.C. 342(f)(1)(B). See also NVE, Inc. v. Dep't of Health and Hum. Servs., 436 F.3d 182, 186 (3d Cir. 2006) ("It is well-established that the government bears the burden of proving that a food is adulterated in enforcement actions brought directly under the FDCA."). Neither FDA nor the United States has made any attempts to meet that burden.

The Government Fails to State a Claim that the Defendant Articles Are Adulterated Because It Does Not Address 21 U.S.C. § 350b.

The government admits that kratom is a food, (FAC ¶ 4), but claims the Defendant Articles are adulterated, under 21 U.S.C. § 342(f)(1)(B), because they contain kratom and there is "inadequate information to provide reasonable assurances that [kratom] does not present a significant or unreasonable risk of illness or injury." (FAC ¶ 17).

Pursuant to the FDCA, 21 U.S.C. § 350b(a), a dietary supplement containing an NDI is considered adulterated under 21 U.S.C. § 342(f) unless it satisfies one of the following:

1. The dietary supplement contains only dietary ingredients which have been present in the food supply as an article used for food in a form in which the food has not been chemically altered.
2. There is a history of use or other evidence of safety establishing that the dietary ingredient when used under the conditions recommended or suggested in the labeling of the dietary supplement will reasonably be expected to be safe and, at least 75 days before being introduced or delivered for introduction into interstate commerce, the manufacturer or distributor of the dietary ingredient or dietary supplement provides the Secretary with information, including any citation to published articles,

> which is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe.

As noted, the government has the "burden of proof on each element to show that a dietary supplement is adulterated." 21 U.S.C. § 342(f). 21 U.S.C. § 350b(a) provides specific statutory instances when a product is not considered adulterated. The government must show that none of these situations apply in order to meet its burden. However, the government fails to even reference 21 U.S.C. § 350b(a) let alone allege that these elements are not met, which is fatal to its complaint. It fails to specifically allege that kratom has not been present in the food supply as an article used for food in a form in which the food has not been chemically altered. 21 U.S.C. § 350b(a)(1). Nor could it argue this because FDA representatives have previously stated under oath that kratom is a "food" and "used for food or drink for humans or used as a component of such food or drink. In re Admin. Establishment Inspection of Spa & Organic Essentials of Penn., LLC, 2019 WL 1651607, at *1 -2. In fact, kratom has been in the food supply for years and is legal in 44 states, including Oklahoma. See, e.g., Oklahoma Kratom Consumer Protection Act, Oklahoma Statutes § 63-1-1432.4 (2021); Georgia O.C.G.A. § 16-13-122 (2019); Arizona Revised Statutes § 36-795 (2019); Utah Code Annotated 4-45-101 et seq. (2019); see also Undetermined Quantities of All Articles…, 936 F.3d at 1348 ("A fair inference [under DSHEA] is that herbs and other botanicals and their constituents made the list of favored dietary ingredients because consuming them is ordinarily safe.").

The government also fails to allege that there is no history of use establishing that kratom when used under the recommended or suggested labeling and conditions will be

reasonably expected to be safe and that the required notice providing evidence forming the basis that the manufacturer has concluded that it will reasonably be expected to be safe has not been submitted to FDA. 21 U.S.C. § 350b(a)(2). In fact, there is no allegation in the complaint that the government even reviewed the Feel Free product labels, even though the government alleges that it has seen and possessed those labels for months. (FAC, ¶¶ 9-11).

The government's First Amended Verified Complaint is simply silent on 21 U.S.C. § 350b, which specifically provides instances where a new dietary ingredient will not be deemed adulterated. Because the government has the burden of proving that a dietary supplement is adulterated, the complaint does not properly state a claim upon which relief can be granted and therefore must be dismissed.

The Government's Boilerplate and Conclusory Allegation That the Defendant Articles Are Adulterated Is Insufficient to State a Claim.

The government's single, blanket statement that there is "inadequate information to provide reasonable assurances that [kratom] does not present a significant or unreasonable risk of illness or injury," pursuant to 21 U.S.C. § 342(f)(1)(B), is insufficient to support its claim that the seized product is adulterated. (FAC ¶ 17). See Ashcroft v. Iqbal, 556 U.S. 662 (2009). It is simply a conclusory allegation which should be discounted by the Court. See $134,972.34 Seized from FNB Bank, Account No.-5351, 94 F. Supp. 3d at 1230. The complaint does not "state sufficiently detailed facts to support a reasonable belief that the government will be able to meet its burden of proof at trial." Fed. R. Civ. P. Supp. R. G(2)(f).

The United States does not attempt to critique any specific information about the safety of kratom but merely asserts it is inadequate without explaining why. The government

does not explain or even attempt to explain, what a "significant or unreasonable risk of illness or injury" is. And the government does not attempt to identify the amount of kratom that must be consumed in a particular time period in order to have any negative effect on the body, either because it does not know or because it does not like the answer. In its complaint, the government cites no adverse events and makes no mention of any exigent circumstances justifying the need for an emergency seizure warrant six months after initially identifying the product at Botanic Tonic's facility. Also, although not specifically required, the government does not explain why FDA did not seek an Administrative Detention Order, which would have allowed the government to seize the product but also provide an immediate avenue for Claimant to appeal such an order. See 21 U.S.C. §334(h).

Instead, the United States broadly claims that there are "safety concerns" regarding the effect of kratom on the body. (FAC ¶ 12). However, the failure to provide any factual allegation about kratom to support a blanket statement that kratom can be harmful is insufficient. See Hall v. Bellmon, 935 F.2d 1106, 1110 (10th Cir. 1991) ("[C]onclusory allegations without supporting factual averments are insufficient to state [a] claim on which relief can be based." (citing Dunn v. White, 880 F.2d 1188, 1197 (10th Cir. 1989)); G&W Labs., Inc. v. Laser Pharms., LLC, No. 3:17-cv-3974, 2018 WL 3031943, at *5 (D.N.J. 2018) ("[The complaint] must include 'factual enhancements' and not just conclusory statements …."); Dyck v. Albertelli L., 98 Fed. Cl. 624, 630 (2011) ("[C]onclusory allegations unsupported by any factual assertions will not withstand a motion to dismiss.").

To state the obvious, there are "safety concerns" with many different foods such as sugar, red meat, artificial sweeteners, diet sodas, and high fructose corn syrup, but FDA has

not sought to seize those food items, and certainly not on an emergency basis. Simply alleging that consumption of kratom "can" (i.e., "could possibly") lead to health problems without alleging that it is "probable" or "likely" and without specifically alleging what amount would be required to be ingested in a specific time period in order to possibly have health problems is fatal to the complaint. (FAC, ¶ 12). See Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007) (requiring enough facts to "nudge" the claim "across the line from conceivable to plausible" in order to survive a motion to dismiss); see also Robbins v. Oklahoma, 519 F.3d 1242, 1247 (10th Cir. 2008); Smith v. U.S., 561 F.3d 1090, 1098 (10th Cir. 2009).

Critically, the government also cites no testing analysis of the Defendant Articles or even testing analysis of the alleged anonymous purchase which FDA made months before seeking an ex parte seizure to determine if these products even contain kratom and, if so, in what amounts. (FAC ¶ 10). If the government wants to assert that "serious safety concerns" exist around kratom use, in seeking an emergency seizure warrant and filing a verified complaint, it should be required to actually confirm that the product contains kratom, and in an amount scientifically shown to likely cause harm. And, if there was such a serious safety concern around kratom that required an emergency ex parte seizure motion, why did the government wait six months to pursue a seizure when it claimed it saw products similar to the Defendant Articles during an inspection in October and November 2022? (See FAC, ¶ 9). Moreover, for many of the products seized, the government does not even specifically allege that the product contains kratom. Instead, it says the products seized are "said to contain…finished product containing kratom." (FAC ¶ 2(a, b, c)). The seizure occurred on

April 26, 2023, (FAC ¶ 2), and the government filed the First Amended Complaint fourteen days later on May 10, 2023, yet either did not test the products it seized or is withholding from the Court what amount of kratom, if any, is contained in the seized products. The failure to affirmatively allege that each of the Defendant Articles contain kratom renders the FAC insufficient to state a claim.

The government's complaint is further deficient because it does not allege what amount of kratom, if any, is contained in Botanic Tonics' Feel Free Plant Based Herbal Supplement, and then to connect that amount, if any, to alleged "safety concerns" regarding the use of kratom. How can the government allege that there is "inadequate information to provide reasonable assurances that [kratom] does not present a significant or unreasonable risk of illness or injury" if did not even bother to test the product that allegedly contains kratom to see how much kratom it contains or whether it even contains a detectible amount of the "minor alkaloid of kratom, 7-hydroxymytragynine," that the government claims "has been reported to be even more potent than morphine"? (FAC, ¶ 13).

Between October 17 and November 17, 2022, inspectors from the FDA conducted an inspection of the same Botanic Tonics' facility from which it is now seeking an ex parte seizure of Botanic Tonic's products and property. (FAC, ¶ 9). Presuming this was a valid inspection that followed established FDA rules and protocols, FDA collected documents that Botanic Tonics is required to have under the Good Manufacturing Practices regulations applicable to the manufacture of dietary supplements. 21 C.F.R. Part 111. Included in these documents that must have been collected by FDA are copies of the Master Manufacturing Record (MMR) for Botanic Tonic's Feel Free. In accordance with regulatory requirements,

Botanic Tonics' MMR for Feel Free would have had to include "the strength, concentration, weight, or measure of each dietary ingredient for each batch size" of Feel Free manufactured by Botanic Tonics, as well as "[t]he identity and weight or measure of each dietary ingredient that will be declared on the Supplement Facts label and the identity of each ingredient that will be declared on the ingredients list of the dietary supplement." (21 C.F.R. § 111.210(a, d)). The government does not allege Botanic Tonics failed to comply with this requirement so, presumably, FDA had all the information required to determine if the amount of kratom, mitragynine, and 7-hydroxymitragynine, if any, in each serving of Feel Free causes the product to be adulterated under U.S.C. § 342(f)(1)(B). However, the complaint is silent on this critically necessary information. The government bears the burden of proof on each element to show that a dietary supplement is adulterated and to do so with "sufficiently detailed facts to support a reasonable belief that the government will be able to meet its burden of proof at trial," but failed to do so. Fed. R. Civ. P. Supp. R. G(2)(f).

CONCLUSION

At its core, the government's forfeiture complaint fails to connect the dots legally and factually. It does not even cite the relevant statute or explain why the Defendant Articles are allegedly adulterated pursuant to that statute. And, while it admits that kratom is a food, it does not allege how much kratom must be consumed to result in any alleged adverse health issues. Nor does it then complete the circle by alleging that the Defendant Articles all contain kratom and in amounts that could result in significant or unreasonable risk of illness or injury. Accordingly, the case must be dismissed.

DATED: 17 May 2023

Respectfully submitted,

s/ John D. Russell

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CERTIFICATE OF SERVICE

I hereby certify that on 17 May 2023 I caused to be filed the above and foregoing pleading with the Clerk of Court via the Court's ECF system, which served a true copy on all counsel of record via the ECF system.

s/ John D. Russell
John D. Russell