



## I. BACKGROUND

The Federal Food, Drug, and Cosmetic Act (“FDCA” or the “Act”), 21 U.S.C. §§ 301, *et seq.*, sets forth a comprehensive regulatory scheme to protect the public health by, among other things, prohibiting the introduction or delivery for introduction into interstate commerce of adulterated dietary supplements. *See* 21 U.S.C. §§ 331(a) (prohibited act), 342(f) (adulteration provision). Manufacturers are responsible for evaluating the safety of their dietary supplements before marketing to ensure that they meet the Act’s requirements, and FDA has the authority to take enforcement action, including seizure, against adulterated dietary supplements. *See id.* § 334(a)(1).

In furtherance of its public health mission, FDA has warned the public not to use products containing *Mitragyna speciosa*, a plant commonly known as “kratom” that grows naturally in parts of Southeast Asia. FDA’s warnings have emphasized serious concerns regarding kratom, including that kratom appears to have properties that expose users to the risks of addiction, abuse, and dependence.<sup>1</sup> *See* Complaint ¶ 14. Consumption of kratom can lead to respiratory depression, vomiting, nervousness, weight loss, and constipation; and kratom consumption has been linked to neurologic, analgesic, and sedative effects, addiction, and liver toxicity. *Id.* ¶ 12. As kratom has gained popularity, consumer complaints and adverse event reports to

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<sup>1</sup> *See* FDA and Kratom, <https://www.fda.gov/news-events/public-health-focus/fda-and-kratom>. Kratom affects the same opioid brain receptors as morphine, and kratom is often taken recreationally by users for its euphoric effects. *See id.*; *see also* Complaint ¶¶ 12-14.

FDA regarding kratom have increased.<sup>2</sup> FDA is aware of reports of at least 36 deaths associated with the use of kratom-containing products.<sup>3</sup> There are no FDA-approved therapeutic uses of kratom.<sup>4</sup>

Because of FDA's safety concerns associated with kratom's use, *see* Complaint ¶¶ 12, 14, FDA has issued public health advisories,<sup>5</sup> and an import alert to detain without physical examination shipments of kratom being imported into the United States.<sup>6</sup> FDA also has conducted numerous *in rem* seizures of kratom and kratom-containing products.<sup>7</sup>

Here, the United States filed a verified forfeiture complaint following FDA's multiple inspections of Botanic Tonics' Broken Arrow, Oklahoma facility. (Dkt. 9).

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<sup>2</sup> *See* Statement from FDA Commissioner Scott Gottlieb, M.D. on FDA advisory about deadly risks associated with kratom, <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-fda-advisory-about-deadly-risks-associated-kratom>.

<sup>3</sup> *Id.*

<sup>4</sup> *Id.*

<sup>5</sup> *See* FDA and Kratom, <https://www.fda.gov/news-events/public-health-focus/fda-and-kratom>.

<sup>6</sup> *See* Import Alert 54-15, [https://www.accessdata.fda.gov/cms\\_ia/importalert\\_1137.html](https://www.accessdata.fda.gov/cms_ia/importalert_1137.html).

<sup>7</sup> *See, e.g., United States v. 286,161 bottles, 209 dietary supplement cookie packs, and 45,521 packs, boxes, or granules, more or less, of an article of food, specifically various herbal supplement capsules, tablets, cookies, and teas*, No. 19-C-3876, 2020 WL 550598 (N.D. Ill. Feb. 3, 2020); *United States v. 101 Cases, More or Less, Containing Bottles & Pouches of Articles of Drug Labeled in Part as Kratom Therapy*, No. CV-16-05138, 2016 WL 11002541 (C.D. Cal. Dec. 21, 2016); *see also* FDA Announces Seizure of Adulterated Dietary Supplements Containing Kratom, <https://www.fda.gov/news-events/press-announcements/fda-announces-seizure-adulterated-dietary-supplements-containing-kratom>; FDA and Kratom, <https://www.fda.gov/news-events/public-health-focus/fda-and-kratom>.

FDA inspected Botanic Tonics between October 17 and November 17, 2022.

Complaint ¶ 9. During that inspection, FDA investigators observed large quantities of Botanic Tonics' kratom products, including bottles of "Feel Free Plant Based Herbal Supplement," labeled as a dietary supplement and as containing kratom. *Id.* During that inspection, FDA also observed large quantities of bulk kratom powder, used by Botanic Tonics to manufacture its "Feel Free" kratom-containing products. *Id.* Between February and March 2023, FDA purchased and received several capsules of Botanic Tonics' "Feel Free" products, labeled as containing kratom and as a dietary supplement. *Id.* ¶ 10. On April 26, 2023, FDA again inspected Botanic Tonics' Broken Arrow, Oklahoma facility and again observed large quantities of "Feel Free" kratom-containing products (in liquid and capsule form) and bulk kratom powder. *Id.* ¶ 11.

As a result of FDA's latest inspection of Botanic Tonics' facility, the United States filed a verified forfeiture complaint to seize the Defendant Articles pursuant to 21 U.S.C. § 334. (Dkt. 2). The Complaint alleges that these articles are dietary supplements and dietary ingredients, within the meaning of 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).

## **II. ARGUMENT**

The Court should deny Botanic Tonics' motion to dismiss because the Complaint

clearly satisfies the pleading requirements under Rules G and 12(b)(6).

Rule G governs the requirements for *in rem* forfeiture complaints arising from a federal statute, such as the FDCA. *See* Fed. R. Civ. P. Suppl. R. G(1)-(2). Under Rule G(2)(f), a complaint need only “state sufficiently detailed facts to support a reasonable belief that the government will be able to meet its burden at trial.” While a higher standard than notice pleading, Supplemental Rule G is a “low bar.” *See United States v. 17 Bank Accounts Containing Various Amounts of United States Currency Identified in Exhibit A*, No. 18-CV-189-ABJ, 2019 WL 13225955, at \*5 (D. Wyo. Mar. 29, 2019) (quoting *United States v. Aguilar*, 782 F.3d 1101, 1109 (9th Cir. 2015)).

Supplemental Rule G(2) governs the pleading standard for civil asset forfeiture complaints but the well-known standards for *in personam* complaints enunciated in the Supreme Court’s holdings in *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007) and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009) also provide guidance to the extent they do not conflict with Supplemental Rule G(2). *See 17 Bank Accounts*, 2019 WL 13225955, at \*5 (citations and quotations omitted); *see also* Fed. R. Civ. P. Suppl. R. A(2).

Accordingly, in considering a Rule 12(b)(6) motion to dismiss a complaint for forfeiture, the pleading requirements are satisfied when the United States’ complaint includes “a short and plain statement of the claim showing that the pleader is entitled to relief,” *17 Bank Accounts*, 2019 WL 13225955, at \*4 (citations and quotations omitted), and “it suffices for the government to simply allege enough facts so that the claimant may understand the theory of forfeiture, file a responsive pleading, and

undertake an adequate investigation.” *United States v. One Gulfstream G-V Jet Aircraft*, 941 F. Supp. 2d 1, 14 (D.D.C. 2013). “Likewise, the plaintiff must be afforded every favorable inference that may be drawn from the allegations of fact set forth in the [forfeiture] complaint” and “the plaintiff’s factual allegations must be presumed true and should be liberally construed in his or her favor.” *Id.* Contrary to Botanic Tonics’ view that detailed evidence and legal argument is required under Rule G, Rule G(2)(f) simply requires the government to sufficiently plead facts to enable a claimant, “without moving for a more definitive statement,” which Botanic Tonics has not done here, “to commence an investigation of the facts and to frame a responsive pleading.” Supplemental Rule E(2)(A); *see id.* at G(2) advisory committee’s note to 2006 enactment. The United States has easily met its burden here.

While Botanic Tonics only appears to dispute whether the complaint meets Rule G(2)(f)’s “reasonable belief” standard, the complaint meets all of the requirements of Rule G(2)(a) through (f). As required by Rule G(2)(a), the complaint is verified under penalty of perjury by an FDA compliance officer who declares that the allegations are true and correct and based on the official files and records of the United States and his investigation of the matter. Complaint at 8 (verification signed by Chad J. Whitwell, FDA Compliance/Consumer Safety Officer). The Complaint states the statutory basis for forfeiture and explains the factual basis for FDA’s determination that the Defendant Articles are adulterated and therefore subject to forfeiture, thus satisfying Rule G(2)(b). *See id.* ¶¶ 3-6. Rule G(2)(c) is satisfied because the Complaint

identifies with reasonable particularity the Defendant Articles and identifies that each article is or contains kratom. *See id.* ¶¶ 2, 11. And Rules G(2)(d) and (e) are met because the Complaint states the location of the seized property and identifies the statute under which the forfeiture action is brought. *See id.* ¶ 1 (citing 21 U.S.C. § 334).

Rule G(2)(f) is also satisfied. Paragraphs 4, 8, and 16-18 of the Complaint provide the legal framework and factual predicates that inform Botanic Tonics of the basis for forfeiture of the Defendant Articles. Specifically, those paragraphs allege that Defendant Articles are articles of food, within the meaning of 21 U.S.C. §§ 321(f), 321(ff); that kratom is a botanical and, therefore, a dietary ingredient within the meaning of 21 U.S.C. § 321(ff)(1)(C); that kratom is a new dietary ingredient within the meaning of 21 U.S.C. § 350b(d); that the Defendant Articles are dietary supplements within the meaning of 21 U.S.C. § 321(ff); and that the Defendant Articles 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). Paragraph 17 explains 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 or injury; and paragraphs 12 through 14 provide further details regarding FDA' safety concerns, supporting the adulteration charge and the seizure. Because all of these facts must be presumed true and should

be liberally construed in the United States' favor, *One Gulfstream G-V Jet Aircraft*, 941 F. Supp. 2d at 14, there can be no serious contention that the United States has failed to adequately plead a plausible basis for forfeiture of the Defendant Articles. Indeed, Botanic Tonics' memorandum in support of its motion shows that it understands the basis for forfeiture and that the Complaint provides sufficient details to allow Botanic Tonics "to commence an investigation of the facts and to frame a responsive pleading."

To be clear, the United States need not, at this point, prove its case by a preponderance of the evidence, its burden of proof at trial. *United States v. \$144,210.77 in Funds Seized from Suntrust Bank Account XXXXX6875*, 63 F. Supp. 3d 1387, 1389 (N.D. Ga. 2014). Rather, at the pleading stage, the United States "is merely required to establish the reasonable belief that [it] can meet its burden at trial." *Id.*

Botanic Tonics' additional arguments are also unavailing. Its assertion that the United States erred by not citing to 21 U.S.C. § 350b(a) in the Complaint, (Dkt. 12 at 8-10), is legally unsupportable. Citation to 21 U.S.C. § 350b(a) is not necessary to establish an article is adulterated under 21 U.S.C. § 342(f)(1)(B). As discussed above, the United States has alleged that the Defendant Articles are adulterated under 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. *See* Complaint ¶ 17. The Complaint cites 21 U.S.C. § 350b(d) to establish that kratom is a new dietary ingredient, *id.* ¶ 8, and explains that because the Defendant Articles are



adulterated under 21 U.S.C. § 342(f)(1)(B), they are subject to seizure, forfeiture, and condemnation pursuant to 21 U.S.C. § 334. *Id.* ¶¶ 17-18. Section 350b(a) provides the circumstances when manufacturers or distributors of new dietary ingredients or dietary supplements that contain new dietary ingredients may be required to submit a new dietary ingredient notification to FDA before introducing the product into interstate commerce. To the extent Botanic Tonics intends to defend against this action based on 21 U.S.C. § 350b(a), such arguments are inappropriate at the motion to dismiss stage.

Further, Botanic Tonics' assertion that the Complaint should be dismissed for lack of evidence, (Dkt. 12 at 10-14), distorts the Rule G standard which requires a complaint plead facts, not evidence. *See, e.g., United States v. All Assets Held at Bank Julius Baer & Co.*, 571 F. Supp. 2d 1, 16 (D.D.C. 2008) (denying motion to dismiss, stating that the government "need not plead evidence, it must plead facts to support its allegations."). The notion that the United States was required to "critique any specific information about the safety of kratom," (Dkt. 12 at 10), "identify the amount of kratom that must be consumed in a particular time period in order to have any negative effect on the body," (*id.* at 11), "cite adverse events," (*id.* at 3), explain why FDA has seized kratom but not "sugar, red meat, artificial sweeteners, diet soda, and high fructose corn syrup," (*id.* at 11), or cite "testing analysis of the Defendant Articles," (*id.* at 12), are all improper assertions that the United States must include exhaustive detail and supporting evidence in its complaint instead of "sufficiently detailed facts to support a reasonable belief that the government will be

able to meet its burden at trial.” Rule G(2)(f); *see also United States v. 5208 Los Franciscos Way*, 385 F.3d 1187, 1193 (9th Cir. 2004) (“While [claimants] assert that the [forfeiture] complaint was not supported at the time of filing by evidence sufficient to meet the preponderance standard, the government is not required to prove its case simply to get in the courthouse door”). Similarly, Botanic Tonics’ allegation that the Complaint fails to adequately explain what constitutes a “significant or unreasonable risk of illness or injury,” (Dkt. 12 at 10-11), is undermined by the safety concerns associated with kratom, including respiratory depression, sedative effects, addiction, liver toxicity, and aggression, which were in fact alleged in the Complaint. *See, e.g.,* Complaint ¶¶ 12, 14.<sup>8</sup>

It is no surprise that many courts have denied motions to dismiss complaints under Rule G. *See, e.g., United States v. 286,161 bottles, 209 dietary supplement cookie packs, and 45,521 packs, boxes, or granules*, No. 19- C-3876, 2020 WL 550598, at \*2 (N.D. Ill. Feb. 3, 2020) (denying motion to dismiss under 12(b)(6) FDA’s complaint for forfeiture of dietary supplements containing kratom). The one case Botanic Tonic cites in which a court granted a motion to dismiss a forfeiture complaint, *United*

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<sup>8</sup> Botanic Tonics makes several other arguments that have no bearing on whether the Complaint meets Rule G’s or Rule 12(b)(6)’s pleading standards. For example, Botanic Tonics argues that FDA should provide evidence of testing samples of “Feel Free” products that FDA purchased in advance of the second inspection and subsequent seizure. (Dkt. 12 at 4). Similarly, Botanic Tonics argues that the United States should have explained the basis for its emergency ex parte order, (*id.* at 4), and why FDA did not seek to use its administrative detention authority before executing the seizure. (*id.* at 11). These arguments are irrelevant to whether the complaint satisfies Rule G.

*States v. One Gulfstream G-V Jet Aircraft*, is inapposite because the court’s dismissal was for failure to allege sufficient facts that connected the seized good (a jet) to the alleged illicit activity (extortion, misappropriation, theft, or embezzlement of public funds by a public official). 941 F. Supp. 2d at 5, 14. In contrast, the Complaint does not involve property allegedly subject to forfeiture because it is “traceable” to unlawful activity; instead, the Complaint alleges that the seized kratom articles are themselves unlawful and subject to forfeiture under 21 U.S.C. § 334(a) because the articles are adulterated dietary supplements and bulk dietary ingredients. Complaint ¶¶ 15-18.

### III. CONCLUSION

Because the Complaint clearly meets the Rule G(2)(f) pleading standard, especially when viewed, as required, in the light most favorable to the United States, the United States respectfully requests that the court deny Botanic Tonics’ motion to dismiss the Complaint.

DATED: June 7, 2023.

RESPECTFULLY SUBMITTED,

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### **Certificate of Service**

I hereby certify that on the 7th day of June, 2023, I electronically transmitted the foregoing document to the Clerk of Court using the ECF System for filing and transmittal of a Notice of Electronic Filing to the following ECF recipient:

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