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UNITED STATES DISTRICT COURT

DISTRICT OF UTAH

UNITED STATES OF AMERICA, Plaintiff, v. EVIG, LLC d/b/a BALANCE OF NATURE, a corporation, and DOUGLAS LEX HOWARD, an individual, Defendants.	**COMPLAINT FOR PERMANENT INJUNCTION** Case No. 4:23-cv-00089-DN Judge David Nuffer

Plaintiff, the United States of America, by its undersigned counsel, and on behalf of the United States Food and Drug Administration ("FDA"), respectfully represents to this Court as follows:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), and the inherent equitable authority of this Court, to permanently enjoin Evig, LLC doing business as Balance of Nature, Corp. ("Evig"), and Douglas Lex Howard, an individual, (collectively, "Defendants") from:

A. Violating 21 U.S.C. § 331(a), by introducing or delivering for introduction or causing to be introduced or delivered for introduction into interstate commerce articles of food (dietary supplements, as defined at 21 U.S.C. § 321(ff)) that are adulterated within the meaning of 21 U.S.C. § 342(g)(1) in that they have been prepared, packed, or held in violation of the Current Good Manufacturing Practice regulations for dietary supplements set forth in 21 C.F.R. Part 111; and

B. Violating 21 U.S.C. § 331(a), by introducing or delivering for introduction or causing to be introduced or delivered for introduction into interstate commerce articles of drug, as defined in 21 U.S.C. § 321(g)(1) that are misbranded within the meaning of 21 U.S.C. § 352(f)(1) in that their labeling fails to bear adequate directions for use; and

C. Violating 21 U.S.C. § 331(d), by introducing or delivering for introduction or causing to be introduced or delivered for introduction into interstate commerce new drugs, as defined by 21 U.S.C. § 321(p), that are neither approved pursuant to 21 U.S.C. § 355 nor exempt from approval.

JURISDICTION AND VENUE

2. This Court has jurisdiction over the subject matter and all parties to this action under 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331, 1337, and 1345.

3. Venue in this district is proper under 28 U.S.C. §§ 1391(b) and (c).

DEFENDANTS

4. Defendant Evig is a limited liability company incorporated in Nevada and in Utah as a foreign limited liability company with its principal place of business at 1568 S River Rd., St.200, St. George, UT 84790 (“Defendants’ Establishment”), within the jurisdiction of this

Court. Defendant Evig, an own-label distributor, sells and promotes three products labeled as dietary supplements under the brand name Balance of Nature: (1) Whole Food Fiber & Spice, a powder, (2) Whole Produce Fruits, capsules, and (3) Whole Produce Veggies, capsules. These products are manufactured by Premium Production, LLC using freeze dried fruits and vegetables, spices, and other botanicals in powder form. Defendant Evig handles all consumer complaints related to these products.

5. Defendant Douglas Lex Howard is the CEO/Manager of Evig. Mr. "Lex" Howard is the sole owner of the company and most responsible individual at the firm. He is responsible for product safety, product formulation, and raw component and finished product specifications. He has the authority to make operational decisions and to hire and fire employees.

DEFENDANTS' OPERATIONS

6. Defendants have been and are now engaged in the business of distributing articles of food, namely dietary supplements within the meaning of the Act, 21 U.S.C. § 321(ff). These products also meet the definition of drug under the Act, 21 U.S.C. § 321(g)(1), from Defendants' Establishment.

7. Defendants operate a website, www.balanceofnature.com, which is used to sell and promote their products. Consumers can purchase Defendants' products directly from this website. Defendants further promote their products on their social media accounts.

DEFENDANTS' VIOLATIONS OF THE ACT

Defendants Distribute Adulterated Dietary Supplements

8. It is a violation of the Act to introduce or deliver for introduction, or cause to be introduced or delivered for introduction, into interstate commerce articles of food (dietary

supplements) that are adulterated within the meaning of 21 U.S.C. § 342(g)(1), in that they have been prepared, packed, or held under conditions that do not meet the Dietary Supplement CGMP regulations, 21 C.F.R. Part 111. 21 U.S.C. § 331(a).

Defendants' Products are Dietary Supplements

9. A product is a dietary supplement within the meaning of the Act, if, among other things, it is "a product (other than tobacco) intended to supplement the diet" that contains one or more of the following dietary ingredients: a vitamin; a mineral; an herb or other botanical; an amino acid; a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract or combination of any of them. 21 U.S.C. § 321(ff). In addition, a dietary supplement must not be "represented for use as a conventional food or as a sole item of a meal or the diet" and must be "labeled as a dietary supplement." *Id.*

Defendants' Products are Adulterated Dietary Supplements

10. The Act deems a dietary supplement to be adulterated if it is not prepared, packed, or held in conformance with current good manufacturing practice regulations for dietary for dietary supplements set forth at 21 C.F.R. Part 111 ("Dietary Supplement CGMP"). 21 U.S.C. § 342(g)(1).

11. The Dietary Supplement CGMP regulations are designed to ensure the quality of dietary supplements. The regulations apply to any person who manufactures, packages, labels, or (subject to an exception not relevant here) holds dietary supplements. The regulations require such persons to control all aspects of their processes and procedures to ensure compliance with

established specifications for identity, purity, strength, composition, and limits on certain types of contamination.

12. FDA investigators most recently inspected Defendants' Establishment in May 2022 (the "2022 inspection"). This inspection established that the dietary supplements Defendants distribute are adulterated within the meaning of 21 U.S.C. § 342(g)(1), in that they are prepared, packed, and/or held in a manner that does not conform to Dietary Supplement CGMP. Defendants' significant deviations from Dietary Supplement CGMP include, but are not limited to, the following:

A. Failure to establish and follow written procedures to fulfill the requirements for product complaints, as required by 21 C.F.R. § 111.553. In addition, failure to ensure product complaints are reviewed and investigated as required by 21 C.F.R. § 111.560 and written records of every product complaint that is related to good manufacturing practice and subsequent investigations are made and kept, as required by 21 C.F.R. § 111.570(b)(2). Specifically, the Evig Defendants have not established or followed adequate complaint procedures. During the 2022 inspection, FDA reviewed Defendant Evig's complaint log and determined that it did not demonstrate that the listed complaints were being adequately investigated. Following the inspection, the Evig Defendants provided FDA with a draft complaint procedure and example of a complaint that it purportedly had investigated. However, the complaint procedure did not contain any substantive information or description of procedures, such as how to determine the root causes of received consumer complaints, and it was neither approved nor signed by quality control personnel. To date, Evig has not demonstrated that it has conducted any complaint investigations.

13. For the foregoing reasons, Defendants' products are adulterated dietary supplements.

Defendants Distribute Unapproved New Drugs

14. It is a violation of the Act to introduce or deliver for introduction, or cause to be introduced or delivered for introduction, into interstate commerce a "new drug" that is neither approved by the United States Food and Drug Administration ("FDA") nor exempt from approval. 21 U.S.C. § 331(d).

Defendants' Products are Drugs

15. A product is a drug if, among other things, it is "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease[.]" 21 U.S.C. § 321(g)(1)(B). The intended use of a product may be determined from any relevant source, including product labeling and the circumstances surrounding the distribution of the article.

16. The Act defines "label" as, among other things, "a display of written, printed, or graphic matter upon the immediate container of any article," 21 U.S.C. § 321(k); and "labeling" as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m).

17. Defendants' products are intended for use to diagnose, cure, mitigate, treat, and/or prevent numerous diseases, including, but not limited to, cancer, heart disease, cirrhosis, diabetes, and asthma. Defendants have stated such intended uses on their product labeling, including on their website, www.balanceofnature.com, and on their social media accounts. Defendants' intended use claims for their products include, but are not limited to, the following:

A. On Defendants' website for Evig, www.balanceofnature.com:

i. Fruits and Veggies: "Here are some studies that specifically document the health benefits of Balance of Nature Fruits & Veggies: A study conducted by Pavlov State Medical University (St. Petersburg, Russia) on the anticarcinogenic [cancer] effects of Balance of Nature: [and] The effect of Balance of Nature on patients with cirrhosis (clinical trial)[.]"

ii. Fruits and Veggies: "Fruits and vegetables are known for positively impacting a myriad of conditions and diseases. To name a few [] Heart disease [:] Research from the United States, United Kingdom, and the Netherlands suggests that the role of fruits and vegetables in preventing heart disease is a protective one. Risk reduction was estimated as high as 20-40 percent among individuals who consumed substantial amounts of fruits and vegetables. People who were already diagnosed with coronary heart disease were able to reduce blockage modestly through exercise and an extremely low-fat, vegan-like diet rich in fruits and vegetables. [] Cancer . . . Studies involving patients who were taking dietary supplements in place of fruits and vegetables ended early due to a high mortality rate among the supplement users. Researchers concluded that dietary supplements (vitamin supplementation) do not have the same positive effects as eating real fruits and vegetables. Balance of Nature is real, whole fruits and vegetables!"

iii. Fruits: ". . . papayas may help protect against various health conditions including [. . .] Age-related macular degeneration . . . Asthma . . . Cancer . . Bone fractures [. . .] Diabetes [. . .] Constipation [. . .] Heart Disease [. . .]"

B. On Defendants' Facebook page for Evig, www.facebook.com/balanceofnature:

i. Fiber & Spice: "Fiber & Spice may help with arthritis, may lower cholesterol [Hypercholesterolemia] . . ."

ii. Fruits: "[C]onsuming papaya[1] can help reduce the risk of heart disease, diabetes, and cancer. It can also aid in . . . blood glucose control, lowering blood pressure [Hypertension], and healing wounds . . . Papaya also contains the phytochemicals alpha- and beta carotene, lutein, zeaxanthin, and lycopene. Phytochemicals have . . . anti-inflammatory, anticancer properties . . . the seeds contain isothiocyanate, which works against leukemia as well as colon, lung, breast, and prostate cancer . . . "

iii. Fruits: "Lycopene . . . works to protect you from disease . . . Lycopene . . . to protect against life threatening diseases such as cancer and cardiovascular disease." Lycopene is a phytonutrient found in tomatoes[2]

iv. Fruits and Veggies: "We offer a free set of Fruits & Veggies with our customer's 4th and 8th orders . . . I personally have seen some incredible results from this product. My mom's diabetes is under control, my Dad doesn't take blood pressure medication, and I no longer suffer from the pain of IBS [Irritable Bowel Syndrome] . . . "

v. Fiber & Spice, Fruits, and Veggies: "Gerniol . . . This phytonutrient has shown anti-inflammatory, anticancer, antibacterial, antifungal . . . anti-cancer . . . "

C. On Defendants' YouTube channel for Evig, https://www.youtube.com/c/BalanceOfNatureHealth/videos:

i. Fruits and Veggies: *Father Takes Balance of Nature- Doesn't Get Sick for 2 Years* video[3]: "For myself, the two years that I've been on it, I don't even think I've had a cold,

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[1] Papaya is a listed ingredient in the Fruits product.

[2] Tomato is a listed ingredient in the Fruits product.

[3] The Fruits and Veggies products are shown in the video.

never mind the flu. Nothing close to the flu."

ii. Fruits and Veggies: *Balance of Nature Customer Review- "Balance of Nature has impacted my life"*[4]: "It's been a Godsend, I'm telling you. I mean I'm a pharmacist and for two years I haven't had a cold."

D. On the TrustPilot page for Defendants' company, Evig, www.trustpilot.com/review/balanceofnature.com:[5]

i. Fiber & Spice: "I noticed an improvement from diabetes medicine side effects as a result taking the fiber and spice mix." Defendant Evig replied: "Thank you for leaving a review! We are so happy to hear that you like our products and that you're seeing results from taking them!"

ii. Fruits: "Balance of nature fruit veg tablets are great . . . I received these capsules the day I was diagnosed with the Covid-19 . . . virus and I started takin [sic] them immediately and without a doubt in my mind they really helped keep my symptoms to that of less than a common cold which [sic] is exactly what this virus is !" Defendant Evig replied: "Thank you for your review. We're glad you have felt healthier since taking Balance of Nature."

iii. Fruits and Veggies: "Balance of Nature has helped me with my asthma problems. When I started getting sick I just doubled up on the Fruits and Veggies. It costs less than asthma

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[4] The Fruits and Veggies products are shown in the video.

[5] Trustpilot Group, PLC operates a website wherein consumers post reviews of companies on a dedicated webpage. There is a Trustpilot webpage for Defendant Evig under the name Balance of Nature. Defendant Evig's personnel have replied to all of the posts listed herein, effectively acknowledging and appropriating the consumer's statements.

medication." Defendant Evig replied: "Thank you for sharing your success with us! We are so glad you love Balance of Nature."

iv. Fruits and Veggies: "i [sic] had cancer last year . . . after a massive surgery . . . I just resigned by myself to the daily pain...I decided to try your fruits and veggies and I've been using your products for about 2 weeks and today I realized that I had ZERO pain . . . don't take pain meds so it was all the supplements . . . you have soy beans in the veggie supplement . . . worried that this is estrogenic . . . " Defendant Evig replied: "That is amazing to hear that Balance of Nature has helped you so much!...soy used in our products . . . doesn't have the high Estrogen levels . . . We use whole fermented soy . . . beneficial . . . lower rates of heart disease and may even help lower cholesterol [Hypercholesterolemia] . . . "

v. Fruits and Veggies: "I have been taking Fruits and Veggies for at least 5 years . . . Post Covid Infection helped in my recovery. My hair were [sic] falling and now they are back and strong again[.]" Defendant Evig replied: "That is amazing that you have been taking Fruits & Veggies for 5 years! We are so glad to hear that it has been working well for you . . . "

E. On the *Reinventing your Health with Dr. Howard* Podcast:[6]

i. Balance of Nature products, generally: *Episode 16: Your Immune System is Important*: [On Covid-19] "It's a virus . . . what we can do is build our own immune systems . . . If your immune system is strong, you build immunity . . . I do take Balance of Nature, that what I take..."

[6] *Available at* https://podcasts.apple.com/us/podcast/reinventing-your-health-with-dr-howard/id1486978168 *and* https://shows.acast.com/the-balance-of-nature-podcast/episodes/your-immune-system-and-the-coronavirus.

18. The claims described in Paragraph 17 above are disease claims and demonstrate that the products are intended to cure, mitigate, treat, and/or prevent disease; therefore, Defendants' products are drugs within the meaning of the Act, 21 U.S.C. § 321(g)(1)(B).

Defendants' Drugs are Unapproved New Drugs

19. A "new drug" is defined as any drug "the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. § 321(p)(1). For a product to be deemed "generally recognized as safe and effective" ("GRAS/E"), it must have substantial evidence of effectiveness. *See* 21 U.S.C. § 355(d).

20. Defendants' drugs are "new drugs" as defined in 21 U.S.C. § 321(p)(1) because they are not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in their labeling.

21. A "new drug" may not be introduced or delivered for introduction, or caused to be introduced or delivered for introduction, into interstate commerce unless FDA has approved a new drug application ("NDA") or an abbreviated new drug application ("ANDA") with respect to such drug, or such drug is exempt from approval. 21 U.S.C. §§ 331(d) and 355(a), (b), and (j).

22. FDA has conducted a search of its records for NDA and ANDA submissions and found no approved NDAs or ANDAs for Defendants' drug products. Additionally, FDA has confirmed that Defendants' drug products do not qualify for an exemption from the new drug approval requirement.

23. Accordingly, Defendants' drug products are unapproved new drugs within the meaning of 21 U.S.C. § 355(a). Defendants' products are unapproved new drugs within the meaning of the Act, 21 U.S.C. § 355(a), because FDA searched its records and none of Defendants' drugs is the subject of an FDA-approved NDA or ANDA, or an effective IND.

24. Defendants violate 21 U.S.C. § 331(d) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce new drugs, as defined by 21 U.S.C. § 321(p), that are neither approved pursuant to 21 U.S.C. § 355(a) nor exempt from approval.

Defendants Distribute Misbranded Drugs

25. A drug is deemed to be misbranded under 21 U.S.C. § 352(f)(1) if its labeling fails to bear "adequate directions for use" and the drug does not fall within a regulatory exemption from that requirement. *See*, *e.g.*, 21 C.F.R. § 201.115. Adequate directions for use "means directions under which the layman can use a drug safely and for the purposes for which it is intended." 21 C.F.R. § 201.5.

26. A prescription drug is "[a] drug intended for use by man which because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug." 21 U.S.C. § 353(b)(1)(A). By definition then, a drug that is also a prescription drug cannot have adequate directions for lay use and is *per se* misbranded under 21 U.S.C. § 352(f)(1), unless such prescription drug qualifies for a regulatory exemption from the requirement to bear adequate directions for use. *See, e.g.*, 21 C.F.R. § 201.100. In addition, a prescription drug that is also subject to the new drug approval

requirements in 21 U.S.C. § 355 is not exempt from the requirements to bear adequate directions for use unless it bears labeling approved by FDA. *Id.* at 201.100(c).

27. Because the Defendants' drugs are intended to treat one or more diseases, as described in Paragraph 19, that are not amenable to self-diagnosis or treatment without the supervision of a licensed practitioner, they are prescription drugs, which, as a matter of law, cannot meet the requirement for "adequate directions for use.

28. Because Defendants' prescription drugs are also unapproved new drugs, as described above, they do not bear FDA-approved instructions for use and thus cannot qualify for an exemption from the requirement to bear adequate directions for use. 21 C.F.R. §§ 201.100(c)(2), 201.115. Moreover, it would be impossible to write adequate instructions for use for Defendants' drugs because adequate instructions for use (including indications, contraindications, dosages, routes of administration, warnings, side effects, and necessary collateral measures) are premised on animal and clinical data derived from extensive, scientifically controlled testing. *See* 21 U.S.C. § 355(d). As described in Paragraph 22 above, there are no well-controlled clinical test data for Defendants' drugs.

29. Accordingly, Defendants' drugs are misbranded within the meaning of 21 U.S.C. § 352(f)(1) because they fail to bear adequate directions for use.

30. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction, or causing the introduction or delivery for introduction, into interstate commerce of misbranded drugs within the meaning of 21 U.S.C. § 352(f)(1).

DEFENDANTS ENGAGE IN INTERSTATE COMMERCE

31. Defendants primarily sell their products through their website, www.balanceofnature.com. Defendants distribute approximately 85% of their finished product to customers out of state, including to Pennsylvania and California. Such shipments constitute the introduction or delivery for introduction into interstate commerce, of adulterated dietary supplements and misbranded drugs under 21 U.S.C. § 331(a) as well as unapproved new drugs under 21 U.S.C. § 331(d).

DEFENDANTS' HISTORY OF VIOLATIVE CONDUCT

32. Defendants have a long history of failing to comply with the Act. FDA has documented a pattern of continued violative conduct during multiple inspections of Defendants' Establishment and have repeatedly warned Defendants that such conduct could lead to enforcement action.

33. FDA conducted the most recent inspection of the Defendants' Establishment in May 2022. As a result of the inspection, FDA issued a List of Inspectional Observations ("Form FDA 483") to Defendant Evig on May 26, 2022.[7] The Dietary Supplement CGMP observation included in the 2022 Form FDA 483 described in Paragraph 14 was a repeat violation from a previous Form FDA 483. The violative drug claims described in Paragraph 19 were first cited to Defendant Evig in a 2019 Warning Letter and again, verbally, during the 2021 and 2022 inspections. Defendant Evig responded to the Form FDA 483 on June 16, July 7, August 8, September 9, and October 14, 2022. FDA found all of Defendant Evig's responses to be

[7] FDA issued an Amended Form FDA 483 to Defendant Evig the same day.

inadequate in addressing FDA's Dietary Supplement CGMP concerns. For example, Defendant Evig's responses lacked appropriate corrective actions to the issues identified by FDA, if they were addressed at all, as described in Paragraph 14. Defendant Evig addressed the drug claims in four of their 2022 Form FDA 483 responses, which FDA found to be inadequate. Defendant Evig indicated it removed and modified the content of their website and social media sites and was developing a product claims policy but the claims listed in Paragraph 19 were never removed.

34. FDA previously conducted inspections of Defendants' Establishment in March 2021. As a result of the inspection, FDA issued a Form FDA 483 to Defendant Evig on April 13, 2021. The Form FDA 483 included the observation in the 2022 Form FDA 483 that was described in Paragraph 14. of the same CGMP and drug violations Defendant Evig responded to the Form FDA 483 on May 31, June 8, August 9, and September 24, 2021. FDA found all of Defendant Evig's responses to be inadequate.

35. FDA also previously conducted an inspection of Defendants' Establishment in 2019. As a result of the inspection, FDA issued a Warning Letter to Defendant Evig on April 20, 2019. The Warning Letter issued to Defendant Evig included unapproved new drugs violations due to disease claims in its labeling. Defendant Evig responded to the Warning Letter on September 19, 2019, which FDA deemed to be inadequate. The Evig Defendants stated that they corrected the drug claims in their Warning Letter response but FDA found that the corrections were not made at that time. As noted above, the Evig Defendants later addressed the drug claims in the 2022 Form FDA 483 responses but FDA deemed their responses to be inadequate as well.

Further, after receiving the Warning Letter, Defendants began to promote their products as a treatment or Covid-19 in addition to the previously documented disease claims.

36. Defendants continue to operate their business in a state of non-compliance. Defendant Evig's responses to FDA's issued Form FDA 483s have all been inadequate. Defendants' significant Dietary Supplement CGMP violation was a repeat from the 2021 inspection and the drug claim violations were largely repeats to the ones listed in the 2019 Warning Letter.

37. Based on the foregoing, Plaintiff believes that, unless restrained by this Court, Defendants will continue to violate the Act in the manner set forth above.

WHEREFORE, Plaintiff respectfully requests that the Court:

I. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them, from doing or causing to be done, any of the following acts:

A. Violating 21 U.S.C. § 331(a), by introducing or delivering for introduction, or causing to be introduced or delivered or introduction, into interstate commerce articles of food (namely dietary supplements and their components) that are adulterated within the meaning of 21 U.S.C. § 342(g)(1); and

B. Violating 21 U.S.C. § 331(a), by introducing or delivering for introduction, or causing the introduction or delivery for introduction, into interstate commerce of any drug that is misbranded under 21 U.S.C. § 352(f)(1); and

C. Violating 21 U.S.C. § 331(d), by introducing or delivering for introduction, or causing the introduction or delivery for introduction, into interstate commerce new drugs, as defined in 21 U.S.C. § 321(p), that are neither approved pursuant to 21 U.S.C. § 355 nor exempt from approval.

II. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them, from:

A. Preparing, labeling, and distributing food (dietary supplements, as defined at 21 U.S.C. § 321(ff)) at or from the Establishment, or at or from any other location(s) at which Defendants prepare, label, and/or distribute food (dietary supplements), now or in the future, unless and until Defendants bring their preparation, labeling, and distributing operations into compliance with the Act and dietary supplement CGMP regulations in a manner that has been found acceptable by FDA, and unless and until Defendants have otherwise brought their operations into compliance with the Act;

B. Introducing or delivering for introduction, or causing the introduction or delivery for introduction into interstate commerce, of any drug unless and until an approved new drug application, abbreviated new drug application, or investigational new drug application is filed pursuant to 21 U.S.C. § 355(b), (j), or (i) is in effect for such drug;

III. Order that FDA be authorized pursuant to this injunction to inspect Defendants' places of business, and all records relating to introducing or delivering for introduction, or causing the introduction or delivery for introduction, into interstate commerce of any dietary supplement or drug, to ensure continuing compliance with the terms of the injunction, with the

costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished; and that Plaintiff be granted judgment for its costs herein, and that this Court grant such other and further relief as it deems just and proper.

Dated this 11th day of October, 2023.

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Office of the General Counsel
Food and Drug Division

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

United States of America

(b) County of Residence of First Listed Plaintiff _____
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Sarah Williams
US Department of Justice, Civil Division
450 5th St NW, Washington, DC 20001

DEFENDANTS

Evig LLC and Douglas Lex Howard

County of Residence of First Listed Defendant Washington Co., Utah
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*
Scott Kaplan, Rebecca Wood and William Levi, Sidley Austin LLP
Kurt Harris, Esq.

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- [x] 1 U.S. Government Plaintiff
- [ ] 2 U.S. Government Defendant
- [ ] 3 Federal Question *(U.S. Government Not a Party)*
- [ ] 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	[ ] 1	[ ] 1	Incorporated *or* Principal Place of Business In This State	[ ] 4	[ ] 4
Citizen of Another State	[ ] 2	[ ] 2	Incorporated *and* Principal Place of Business In Another State	[ ] 5	[ ] 5
Citizen or Subject of a Foreign Country	[ ] 3	[ ] 3	Foreign Nation	[ ] 6	[ ] 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- [ ] 110 Insurance
- [ ] 120 Marine
- [ ] 130 Miller Act
- [ ] 140 Negotiable Instrument
- [ ] 150 Recovery of Overpayment & Enforcement of Judgment
- [ ] 151 Medicare Act
- [ ] 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- [ ] 153 Recovery of Overpayment of Veteran's Benefits
- [ ] 160 Stockholders' Suits
- [ ] 190 Other Contract
- [ ] 195 Contract Product Liability
- [ ] 196 Franchise

TORTS

PERSONAL INJURY
- [ ] 310 Airplane
- [ ] 315 Airplane Product Liability
- [ ] 320 Assault, Libel & Slander
- [ ] 330 Federal Employers' Liability
- [ ] 340 Marine
- [ ] 345 Marine Product Liability
- [ ] 350 Motor Vehicle
- [ ] 355 Motor Vehicle Product Liability
- [ ] 360 Other Personal Injury
- [ ] 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- [ ] 365 Personal Injury - Product Liability
- [ ] 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- [ ] 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
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- [ ] 371 Truth in Lending
- [ ] 380 Other Personal Property Damage
- [ ] 385 Property Damage Product Liability

REAL PROPERTY
- [ ] 210 Land Condemnation
- [ ] 220 Foreclosure
- [ ] 230 Rent Lease & Ejectment
- [ ] 240 Torts to Land
- [ ] 245 Tort Product Liability
- [ ] 290 All Other Real Property

CIVIL RIGHTS
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- [ ] 443 Housing/ Accommodations
- [ ] 445 Amer. w/Disabilities - Employment
- [ ] 446 Amer. w/Disabilities - Other
- [ ] 448 Education

PRISONER PETITIONS

Habeas Corpus:
- [ ] 463 Alien Detainee
- [ ] 510 Motions to Vacate Sentence
- [ ] 530 General
- [ ] 535 Death Penalty

Other:
- [ ] 540 Mandamus & Other
- [ ] 550 Civil Rights
- [ ] 555 Prison Condition
- [ ] 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- [ ] 625 Drug Related Seizure of Property 21 USC 881
- [ ] 690 Other

LABOR
- [ ] 710 Fair Labor Standards Act
- [ ] 720 Labor/Management Relations
- [ ] 740 Railway Labor Act
- [ ] 751 Family and Medical Leave Act
- [ ] 790 Other Labor Litigation
- [ ] 791 Employee Retirement Income Security Act

IMMIGRATION
- [ ] 462 Naturalization Application
- [ ] 465 Other Immigration Actions

BANKRUPTCY
- [ ] 422 Appeal 28 USC 158
- [ ] 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- [ ] 820 Copyrights
- [ ] 830 Patent
- [ ] 835 Patent - Abbreviated New Drug Application
- [ ] 840 Trademark
- [ ] 880 Defend Trade Secrets Act of 2016

SOCIAL SECURITY
- [ ] 861 HIA (1395ff)
- [ ] 862 Black Lung (923)
- [ ] 863 DIWC/DIWW (405(g))
- [ ] 864 SSID Title XVI
- [ ] 865 RSI (405(g))

FEDERAL TAX SUITS
- [ ] 870 Taxes (U.S. Plaintiff or Defendant)
- [ ] 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- [ ] 375 False Claims Act
- [ ] 376 Qui Tam (31 USC 3729(a))
- [ ] 400 State Reapportionment
- [ ] 410 Antitrust
- [ ] 430 Banks and Banking
- [ ] 450 Commerce
- [ ] 460 Deportation
- [ ] 470 Racketeer Influenced and Corrupt Organizations
- [ ] 480 Consumer Credit (15 USC 1681 or 1692)
- [ ] 485 Telephone Consumer Protection Act
- [ ] 490 Cable/Sat TV
- [ ] 850 Securities/Commodities/ Exchange
- [x] 890 Other Statutory Actions
- [ ] 891 Agricultural Acts
- [ ] 893 Environmental Matters
- [ ] 895 Freedom of Information Act
- [ ] 896 Arbitration
- [ ] 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- [ ] 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

- [x] 1 Original Proceeding
- [ ] 2 Removed from State Court
- [ ] 3 Remanded from Appellate Court
- [ ] 4 Reinstated or Reopened
- [ ] 5 Transferred from Another District *(specify)*
- [ ] 6 Multidistrict Litigation - Transfer
- [ ] 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301-392

Brief description of cause:
FDCA Civil Enforcement Action for a Permanent Injunction

VII. REQUESTED IN COMPLAINT:

- [ ] CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: [ ] Yes [x] No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE David Nuffer DOCKET NUMBER 23-cv-88

DATE
Oct 11, 2023

SIGNATURE OF ATTORNEY OF RECORD
SARAH WILLIAMS
Digitally signed by SARAH WILLIAMS
Date: 2023.10.11 09:20:21 -04'00'

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) **Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) **County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) **Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. **Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below**; NOTE: federal question actions take precedence over diversity cases.**)

III. **Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. **Nature of Suit.** Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: Nature of Suit Code Descriptions.

V. **Origin.** Place an "X" in one of the seven boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statue.

VI. **Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service.

VII. **Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. **Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.