UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. SALUD NATURAL ENTREPRENEUR, INC., a corporation and HECTOR PABLO OLIVA, MICHEL MONFORT, and CAROLINA L. GIRAL, individuals, Defendants.	)	No. 22 C 1123 Judge

COMPLAINT FOR PERMANENT INJUNCTION

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

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act ("FDCA" or "the Act"), 21 U.S.C. § 332(a), and this court's inherent equitable authority to enjoin and restrain Salud Natural Entrepreneur, Inc., a corporation, and Hector Pablo Oliva, Michel Monfort, and Carolina L. Giral, individuals (collectively, "Defendants") from violating:

A. 21 U.S.C. § 331(a), by introducing or delivering for introduction, and/or causing to be introduced or delivered for introduction, into interstate commerce:

(1) 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 ("Dietary Supplement CGMP");

(2) articles of food (dietary supplements, as defined by 21 U.S.C. § 321(ff)) that are misbranded within the meaning of 21 U.S.C. §§ 343(f), (i)(2), (q)(1)(A), (q)(5)(F), (r)(1)(A), and/or (s)(2)(C); and

(3) articles of drug (as defined by 21 U.S.C. § 321(g)(1)(B)) 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;

B. 21 U.S.C. § 331(k), by causing:

(1) articles of food (dietary supplements, as defined by 21 U.S.C. § 321(ff)) that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(g)(1);

(2) articles of food (dietary supplements, as defined by 21 U.S.C. § 321(ff)) that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become misbranded within the meaning of 21 U.S.C. §§ 343(f), (i)(2), (q)(1)(A), (q)(5)(F), (r)(1)(A), and/or (s)(2)(C); and

(3) articles of drug that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(f)(1);

C. 21 U.S.C. § 331(d), by introducing or delivering for introduction, and/or causing to be introduced or delivered, 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.

Jurisdiction and Venue

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

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

Defendants

4. Defendant Salud Natural Entrepreneur, Inc. ("Salud Natural") is incorporated under the laws of the State of Illinois. Salud Natural is a dietary supplement manufacturer and own-label distributor of dietary supplements. Salud Natural does business at 1120 Glen Rock Avenue, Waukegan, Illinois (the "Facility"), within the jurisdiction of this court.

5. Defendant Hector Pablo Oliva is the President and owner of Salud Natural. He is the most responsible person at the company. He has ultimate authority over all the company's operations, including product formulation, manufacturing, labeling, and sales. Defendant Oliva also owns and controls at least one website through which Defendants' products are sold, www.nopalinaonline.com, and bears ultimate responsibility for the content of this website. Defendant Oliva performs his duties at the Facility.

6. Defendant Michel Monfort is Salud Natural's production manager for the Facility. He is responsible for overseeing daily operations and the production and distribution schedule for Salud Natural's products. Defendant Monfort reports directly to Defendant Oliva. Defendant Monfort performs his duties at the Facility.

7. Defendant Carolina L. Giral is Quality Control Manager for Salud Natural. She is responsible for quality control operations, including creating and implementing procedures; completing batch production records for each batch of dietary supplements; managing raw material and finished product third-party testing; releasing finished products to the warehouse manager for

distribution; and training new employees on Dietary Supplement CGMP requirements. Defendant Giral reports directly to Defendant Oliva. Defendant Giral performs her duties at the Facility.

8. Defendants have been and are now engaged in the business of manufacturing and distributing:

A. Dietary supplements within the meaning of the Act, which defines "dietary supplement," in part, as "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). Dietary supplements are deemed to be "food" under the Act, except for purposes of 21 U.S.C. §§ 321(g) and 350f. 21 U.S.C. § 321(ff). Among other requirements, dietary supplements also 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." 21 U.S.C. § 321(ff); and

B. Products that meet the definition of "drug" under the Act, 21 U.S.C. § 321(g)(1)(B), because they are intended for use in the cure, mitigation, treatment, or prevention of disease, and meet the definition of "new drug" under the Act, 21 U.S.C. § 321(p), because their composition is such that 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 the[ir] labeling."

9. Defendants manufacture their products from components shipped to them from outside the State of Illinois, including, among other places, India. Defendants distribute their

products in interstate commerce to customers outside the state of Illinois, including, but not limited to, locations in California, Colorado, Georgia, Pennsylvania, and Texas.

Defendants' Violations of the Act

Defendants Distribute 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 supplements set forth at 21 C.F.R. Part 111. 21 U.S.C. § 342(g)(1).

11. The Dietary Supplement CGMP regulations are designed to ensure the quality of dietary supplements. These regulations apply to any person who manufactures, packages, labels, or (subject to an exception not relevant here) holds dietary supplements. These 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 inspected Defendants' Facility between May 10, 2021, and May 21, 2021 (the "2021 inspection"). This inspection established that the dietary supplements Defendants manufacture and 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 requirements. Defendants' significant deviations from Dietary Supplement CGMP include, but are not limited to, the following:

A. Failure to establish identity and component specifications for every ingredient Defendants use in the manufacture of their dietary supplements, as required by 21 C.F.R. § 111.70(b). For example, Defendants have not established any specifications for Senna Leaves, Glycerin, and Vitamins B1, B6, and B12.

B. Failure to establish specifications for the identity, purity, strength, and composition for each dietary supplement Defendants manufacture, as required by 21 C.F.R.

§ 111.70(e). For example, the finished product specifications for Defendants' Buzz Recovery (33.81 fl. Oz.) and Nopalina Flax Seed Plus Fiber (1 lb.) contain only organoleptic specifications, *i.e.*, aroma and taste, texture, visual, and physical properties, but do not contain chemical specifications; and although Defendants' product label for Buzz Recovery claims nutrition value for vitamin B1, B6, and B12, the product's specifications do not establish acceptance criteria for vitamins B1 and B12 and do not mention vitamin B6.

C. Failure to conduct at least one appropriate test or examination to verify the identity of any component that is a dietary ingredient, confirm the identity of other components, and determine whether other applicable component specifications are met; and, for a subset of finished dietary supplement batches that the firm identified through a sound statistical sampling plan (or for every finished batch), verify that the firm's finished batch of the dietary supplement meets product specifications for identity, purity, strength, composition, and for limits on those types of contamination that may adulterate or that may lead to adulteration of the finished batch of the dietary supplement, as required by 21 C.F.R. § 111.75. For example, Defendants did not test hydrolyzed bovine collagen and Vitamin C before using these dietary ingredients in their dietary supplement Collagen + Vitamin C capsules and have never tested their Vitamin C capsules for strength.

D. Failure of quality control personnel to reject a component or a dietary supplement when a specification established in accordance with 21 C.F.R. § 111.70 is not met, as required by 21 C.F.R. § 111.113(b)(2). For example, Defendants failed to reject a lot of flax seed powder despite third-party laboratory testing demonstrating a total yeast level of 2,000 colony forming units per gram (CFU/g) when Defendant's specification for this ingredient is less than 10 CFU/g Total Yeast. Defendants used this lot of flaxseed

powder in the manufacture of Nopalina Flax Seed, a finished dietary supplement. In further example, Defendants failed to reject a lot of Grapefruit Powder with failing mold levels and released for distribution Psyllium Husk Powder when total aerobic plate count and yeast exceeded specifications. During a prior inspection conducted from August 20, 2019, to January 22, 2020, FDA discovered that Defendants had failed to reject a lot of Senna Leaves Powder that tested positive for *Salmonella*. *Salmonella* is a foodborne pathogen that, when ingested, can cause serious illness, including gastroenteritis, hospitalization, and even death. Despite this, in callous disregard of the public health, Defendants re-tested the lot without justification and then used it in the production of finished dietary supplements, which they shipped to customers. Despite FDA testing that confirmed the presence of *Salmonella*, Defendant Oliva initially refused to conduct a voluntary recall, falsely claiming that he did not use the implicated lot of Sienna Leaves Powder in the manufacture of dietary supplements. Only after FDA issued a Safety Alert did Defendants initiate a voluntary recall.

E. Failure to establish and follow written procedures for the responsibilities of quality control operations, as required by 21 C.F.R. § 111.103. For example, Defendants' procedure, "Responsibilities of the Quality Control Operations," states that the Quality Control Unit will review and approve all product labels for compliance with 21 C.F.R. 101. Despite this, Defendants do not perform this review. For example, the label for Defendants' Buzz Recovery product does not declare glycerin and Uva as ingredients but they are part of the product's formulation and are added during manufacture; the label for Defendants' Aloe Vera Juice does not declare glycerin as an ingredient, but it is part of the product's formulation and is added during manufacture; and the label for UrCran declares

Saw Palmetto and Uva Ursi as ingredients but these two ingredients are not part of the product's formulation and do not appear on batch production records.

F. Failure to prepare a written master manufacturing record ("MMR") for each unique formulation and each batch size of dietary supplement that Defendants manufacture, to ensure uniformity in the finished batch and from batch to batch, that includes the information required by 21 C.F.R. § 111.205. For example, Defendants have not prepared MMRs for each product, and its MMRs for powder and capsule products and for liquid products are templates that do not include product-specific information, including product names, formulas, in-process specifications, or labeling.

G. Failure to create and follow batch production records ("BPR") that include all information relating to the production and control of each batch, as required by 21 C.F.R. § 111.260. For example, various of Defendants' BPRs do not contain, *inter alia*, documentation at the time of performance of:

(1) the identity and weight or measure of each component used, *e.g.*, the number of capsules used in production, as required by 21 C.F.R. § 111.260(e);

(2) blending that occurs during processing, as required by 21 C.F.R. § 111.260(j);

(3) the initials of operators and individuals verifying the operator's actions at the time of performance such as the initials of the person responsible for weighing or measuring each component used in the batch and the initials of the person responsible for verifying the weight or measure of each component used in the batch, as required by 21 C.F.R. § 111.260(j)(2);

(4) the steps performed during packaging and labeling operations, as required by 21 C.F.R. § 111.260(k), including documenting (i) the unique identifier

that Defendants assigned to packaging and labels used, the quantity of the packaging and labels used, and, when label reconciliation is required, reconciliation of any discrepancies between issuance and use of labels in accordance with 21 C.F.R. § 111.260(k)(1); and (ii) an actual or representative label, or a cross-reference to the physical location of the actual or representative label specified in the MMR, as required by 21 C.F.R. § 111.260(k)(2); and.

(5) any required material review or disposition decision, as required by 21 C.F.R. § 111.260(m). For example, Defendants' batch production records show that Terma Serrano, an ingredient in Defendants' formulation of their Buzz Recovery product, was not added in a number of batches, in violation of 21 C.F.R. § 111.260(m).

H. Failure to maintain equipment to protect components and dietary supplements from being contaminated by any sources, as required by 21 C.F.R. § 111.27(a)(3)(v). For example, the bonds on the Facility hopper were not smooth, and there were dents on the auger screw, both of which are used in manufacturing dietary supplements.

I. Failure to hold components and dietary supplements under appropriate conditions of temperature, humidity, or light so that the identity, purity, strength, and composition of the components and dietary supplements are not affected, as required by 21 C.F.R. § 111.455(a). For example, Defendants' temperature and humidity monitoring records demonstrate that measured temperature and relative humidity were higher than the acceptable range listed in the monitoring records.

13. For the foregoing reasons, Defendants violate

A. 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) 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.

B. 21 U.S.C. § 331(k) by causing articles of food (dietary supplements) that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(g)(1).

Defendants Distribute Misbranded Dietary Supplements

14. Certain of Defendants' products are misbranded food (dietary supplements, as defined at 21 U.S.C. § 321(ff)), within the meaning of:

A. 21 U.S.C. § 343(f) because the product labels contain information in two languages but do not repeat all required information in both languages, as required by 21 C.F.R. § 101.15(c)(2). For example, the product labels for Defendants' Aloe Vera Juice, Buzz Recovery, Nopalina Flax Seed Fiber capsules, Nopalina Flax Seed Fiber powder (1 lb., Urinary Cleanse Tea, Slim Fiber Mix Moringa (1 lb.), and Slim Fiber Mix Garcinia (1 lb.) are misbranded because the nutrition labeling information, *i.e.*, the Supplement Facts label, and statement of identity are not repeated in Spanish, the foreign language used on the labels.

B. 21 U.S.C. § 343(i)(2) because the product labels fail to declare the common or usual name of each ingredient, as required by 21 C.F.R. §§ 101.4(h) and 101.36. For example, the product label for Defendants' Buzz Recovery declares the dietary ingredients carqueja and poleo mint instead of the Latin binomial or the standardized common names Baccharis trimera and European pennyroyal, respectively and canchalagua incayuyo and vira instead of the Latin binomial of the plant.

C. 21 U.S.C. § 343(q)(1)(A) because the serving size declared on product labels is incorrect. Serving size for a dietary supplement is the maximum amount

consumed per eating occasion as recommended on the product label. 21 C.F.R. §101.9(b)(1); 21 C.F.R. § 101.12(b), Table 2. The serving sizes declared on the product labels for Defendants' Aloe Vera Juice and Buzz Recovery, for example, do not comply with the requirements set forth in 21 C.F.R. § 101.9(b) and 21 C.F.R. § 101.12(b), Table 2. The directions of use for Aloe Vera Juice recommend the consumer drink two to four fluid ounces per day but the serving size incorrectly lists two fluid ounces instead of four; and the directions of use for Buzz Recovery recommend the consumer drink four to eight fluid ounces before and/or after a night of drinking, but the serving size incorrectly lists four fluid ounces instead of eight.

D. 21 U.S.C. § 343(q)(5)(F) because the presentation of the nutrition information on the product label does not comply with the requirements set forth in 21 C.F.R. § 101.36. For example:

(1) the product labels for Defendants' Slim Fiber Mix Moringa (1 lb.) and Slim Fiber Mix Garcinia (1 lb.) improperly declare 78% Daily Value for Omega-3 but no Daily Value has been established for this dietary ingredient;

(2) the product label for Defendants' Nopalina Flax Seed Fiber powder (1 lb.) declares a quantitative amount of zero for saturated fat and added sugars; the product labels for Defendants' Slim Fiber Mix Moringa (1 lb.) and Slim Fiber Mix Garcinia (1 lb.) declare a quantitative amount of zero for saturated fat, trans fat, and cholesterol; the product labels for Defendants' Nopalina Flax Seed Fiber capsules, Aloe Vera Gel, and Aloe Vera and Nopal each declare a quantitative amount of zero for total sugars and added sugars; and the product label for Aloe Vera Juice declares a quantitative amount of zero for total fat, protein, and sugars, but these "(b)(2)-nutrients" (nutrients identified within the meaning of 21 C.F.R.

§ 101.36(b)(2)) are not permitted to be declared if they are present in amounts that can be declared as zero in accordance with 21 C.F.R. § 101.9(c), as required by 21 C.F.R. § 101.36(b)(2).

(3) the product label for Defendants' Aloe Vera Juice declares 0% Daily Value for (b)(2)-dietary ingredients with established Daily Reference Values where the declared amount is greater than zero. For dietary ingredients for which Daily Reference Values have been established, "Less than 1%" or "<1%" must be used to declare the % Daily Value when the quantitative amount of the dietary ingredient by weight is great enough to require that the dietary ingredient be listed but the amount is so small that the % Daily Value when rounded to the nearest percent is zero, as required by 21 C.F.R. § 101.36(b)(2)(iii);

(4) the product label for Defendants' Buzz Recovery declares the dietary ingredients iron and grape juice concentrate but fails to list the quantitative amount by weight for each, as required by 21 C.F.R. §§ 101.36(b)(2)(ii) and 101.36(b)(3)(ii), respectively;

(5) the product labels for Defendants' Buzz Recovery and Aloe Vera Juice list sodium in the wrong order. The quantitative amount by weight per serving and percent of the daily value should be listed after iron on the Buzz Recovery label and after protein on the Aloe Vera Juice label, as required by 21 C.F.R. § 101.36(b)(2)(i)(B); and

(6) the product label for Defendants' Slim Fiber Mix Garcinia (1 lb.) lists an incorrect % Daily Value (DV) for dietary fiber. The %DV must be based on Reference Daily Intake or Daily Reference Values and expressed to the nearest whole percent, as required by 21 C.F.R. § 101.36(b)(2)(iii)(C).

E. 21 U.S.C. § 343(r)(1)(A) because the product labels bear nutrient content claims when the products do not meet the requirements for making such claims. For example, the product labels for Defendants' Slim Fiber Mix Moringa (1 lb.) and Slim Fiber Mix Garcinia (1 lb.) bear the claim "Excellent source of dietary fiber" but do not contain 20 percent or more of fiber to meet the definition of "excellent source," as required by 21 C.F.R. § 101.54(b) for making such "excellent source of" claims. Further, the product label for Defendants' Slim Fiber Mix Moringa (1 lb.) bears an "antioxidant" nutrient content claim when it does not meet the requirements of 21 C.F.R. § 101.54(g) for making such a claim because there is no established Reference Daily Intake for moringa, as required by 21 C.F.R. § 101.54(g)(1), and moringa has no recognized antioxidant activity, as required by 21 C.F.R. § 101.54(g)(2).

F. 21 U.S.C. § 343(s)(2)(C) because Defendants' product labels do not identify the part of the plant from which each botanical dietary ingredient contained in them is derived, as required by 21 C.F.R. § 101.4(h)(1). For example, the product label for Defendants' Urinary Cleanse Tea fails to include the part of the plant from which horsetail is derived; the product labels for Defendants' Nopalina Flax Seed Fiber capsules, Nopalina Flax Seed Fiber powder (1 lb.), Slim Fiber Mix Moringa (1 lb.), and Slim Fiber Mix Garcinia (1 lb.) fail to include the part of the plant from which psyllium is derived; the product label for Aloe Vera Juice fails to include the part of the plant from which aloe vera is derived; and the product label for Buzz Recovery fails to include the parts of the plant from which carqueja, poleo mint, thyme, chamomile, vira, canchalaugua, and blessed thistle are derived.

15. For the foregoing reasons, Defendants violate

A. 21 U.S.C. § 331(a), by introducing or delivering for introduction, and/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 misbranded within the meaning of 21 U.S.C. §§ 343(f), (i)(2), (q)(1)(A), (q)(5)(F), (r)(1)(A), and/or (s)(2)(C).

B. 21 U.S.C. § 331(k), by causing articles of food (dietary supplements, as defined at 21 U.S.C. § 321(ff)) that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become misbranded within the meaning of 21 U.S.C. §§ 343(f), (i)(2), (q)(1)(A), (q)(5)(F), (r)(1)(A), and/or (s)(2)(C).

Defendants Distribute Unapproved New Drugs

16. Under the Act, 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. 21 C.F.R. § 201.128.

17. Because a product's intended use determines whether it is a drug, a product that falls within the Act's dietary supplement definition may also meet the Act's drug definition if it is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease. *See* 21 U.S.C. § 321(ff).

18. 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). The labeling includes anything that explains the uses of the drug, whether or not it is physically attached to the product itself. *See Kordel v. United States,* 335 U.S. 350 (1948).

19. Defendants cause certain of their products to be drugs under the Act because they make claims establishing that the products are intended to cure, mitigate, treat, or prevent diseases ("disease claims"). The intended uses in Defendants' labeling include the following product(s) and disease claim(s) observed on the product labels and/or the Defendants' website, https://www.nopalinaonline.com:

A. Aloe Vera Gel: "useful treating Type II diabetes";

B. Aloe Vera Juice: "Antiviral";

C. Aloe Vera Nopal Juice: "Used for: . . . Ulcers and Gastritis";

D. Blood Purifier Tea: "Used for . . . skin infections"; "constipation"; "improve blood circulation";

E. Buzz Recovery: "Psoriasis";

F. Collagen C: "osteoporosis";

G. Golden Milk: "anti-inflammatory . . . and antiseptic properties";

H. Liver Detox Tea: "alcoholism . . . gallbladder pain";

I. Moringa Capsules: "Anti-inflammatory support";

J. Nopalina Flax Seed Fiber capsules: "can help reduce levels of cholesterol . . . , which reduces the risk of cardiovascular disease";

K. Nopalina Flax Seed Fiber powder: "can help reduce levels of cholesterol . . ., which reduces the risk of cardiovascular disease";

L. Obesy-Tea: "High Cholesterol";

M. Slim Fiber Mix Moringa (2 lb.) and Slim Fiber Mix Garcinia (2 lb.): "lower risk of heart disease and some cancers";

N. Urcran Cranberry: "Helps with Urinary tract infections . . . kidney stones"; and

O. Urinary Cleanse Tea: "urinary tract infections, stones (calculations)"; "High blood pressure."

20. The claims set forth in paragraph 19 above are disease claims and demonstrate that the products are intended to cure, mitigate, treat, and/or prevent disease; therefore, these products are drugs within the meaning of the Act, 21 U.S.C. § 321(g)(1)(B).

21. Under the Act, a drug is a "new drug" if its "composition . . . 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 "generally recognized as safe and effective" (GRAS/E), three conditions must be satisfied. First, there must be substantial evidence of its effectiveness. The Act defines "substantial evidence" as "evidence consisting of adequate and well-controlled investigations, including clinical investigations . . . on the basis of which it could fairly and responsibly be concluded by . . . [qualified] experts that the drug will have the effect it purports or is represented to have . . . ." 21 U.S.C. § 355(d). Second, the investigations must be published in the scientific literature so that they are made generally available to the community of qualified experts and thereby subject to peer evaluation, criticism, and review. *See Weinberger v. Bentex Pharms., Inc.*, 412 U.S. 645, 652 (1973). Third, there must be a consensus among the experts, based on those published investigations, that the product is safe and effective under the conditions prescribed, recommended, or suggested in its labeling. *Id.*

22. Defendants' drugs listed in paragraph 19 lack substantial evidence of safety and effectiveness. There are no published, adequate, and well-controlled investigations to show that they are GRAS/E for their labeled indications and, therefore, qualified experts cannot come to a consensus opinion concerning the safety and effectiveness of these products.

23. Because Defendants' drugs listed in paragraph 19 are not GRAS/E, they are new drugs.

24. 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 FDA nor exempt from approval. 21 U.S.C. § 331(d). Specifically, 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 or an abbreviated new drug application with respect to such drug, or such drug is exempt from approval under an investigational new drug application. 21 U.S.C. §§ 331(d) and 355(a), (b), (i), and (j).

25. FDA searched its records and none of Defendants' drugs listed in paragraph 19 above are the subject of an FDA-approved new drug application, abbreviated new drug application, or investigational new drug application. Therefore, Defendants' products are unapproved new drugs within the meaning of the Act, 21 U.S.C. § 355(a).

26. 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 unapproved new drugs.

Defendants Distribute Misbranded Drugs

27. Under the Act, a drug is deemed to be misbranded if its labeling does not bear "adequate directions for use," 21 U.S.C. § 352(f)(1), and it is not exempt from that requirement. *See* 21 C.F.R. §§ 201.100-125, 201.129 (establishing exemptions from the adequate directions for use requirement in 21 U.S.C. § 352(f)(1)). 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.

28. Certain of Defendants' drugs are misbranded within the meaning of 21 U.S.C. § 352(f)(1) because they fail to bear adequate directions for use and the drugs do not fall within a regulatory exemption from that requirement.

29. Under the Act, a prescription drug is defined as "[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, a drug that is also a prescription drug cannot have adequate instructions for lay use. Many of Defendants' drugs are prescription drugs for which, by definition, adequate directions for lay use cannot be written.

30. In addition, adequate directions for use of these drugs, whether or not prescription drugs, cannot be written because such directions — including indications, contraindications, dosages, routes of administration, warnings, side effects, and necessary collateral measures — are necessarily premised on animal and clinical data derived from extensive, scientifically controlled testing. *United States v. Undetermined Quantities of Articles of Drug . . . Street Drug Alt.*, 145 F. Supp. 2d 692, 701–702 (D. Md. 2001) (in the absence of investigations or clinical data demonstrating the safety and efficacy of the drugs there can be no adequate instruction for their safe use); *United States v. Miami Serpentarium Labs.*, [1981-1982 Transfer Binder] Food Drug Cosm. L. Rep. (CCH) ¶ 38,164 at 38,931 (S.D. Fla. 1982) ("Without such test data, [a] drug cannot be labeled for any use and, *a fortiori*, lacks adequate directions for use."). Because there are no well-controlled clinical test data for Defendants' drugs, adequate directions under which a layperson can safety use these drugs cannot be written.

31. Because these drugs are neither approved nor the subject of an effective investigational new drug application, as described above, they cannot qualify for an exemption

from the requirement for adequate directions for use. 21 C.F.R. §§ 201.100(c)(2), 201.115. Thus, those drugs are misbranded under 21 U.S.C. § 352(f)(1).

32. Defendants violate 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 misbranded drugs.

33. Defendants violate 21 U.S.C. § 331(k) by causing their drugs to become misbranded while they are held for sale after shipment of one or more of their components in interstate commerce.

Defendants' History of Violative Conduct

34. Defendants have a history of noncompliance and are aware that their practices violate the Act. FDA has repeatedly warned Defendants about their violative conduct and that continued violations could lead to enforcement action, including an injunction.

35. At the close of the 2021 inspection, the FDA investigators issued an FDA Form 483 listing 20 Inspectional Observations and discussed the observed deviations with Defendants Monfort and Giral. Despite promises to respond in writing to the Inspectional Observations, Defendants have not done so.

36. At the close of an inspection at Defendants' prior manufacturing facility conducted from May to July 2015 (the "2015 inspection"), the FDA investigator issued an FDA Form 483 listing 11 Inspectional Observations and discussed the observed deviations with a representative of Defendant Salud Natural. FDA subsequently received a partial response to the FDA Form 483 that did not adequately address the identified violations.

37. Because of the seriousness of the Dietary Supplement CGMP, product labeling, and unapproved new drug violations identified during the 2015 inspection, on April 8, 2016, FDA issued a Warning Letter to Defendants Oliva and Salud Natural informing them that their products

were adulterated and misbranded dietary supplements, unapproved new drugs, and misbranded drugs, the introduction of which into interstate commerce is prohibited by the Act. The Warning Letter addressed:

A. Dietary Supplement CGMP deviations that were the same as or similar to the observations made during FDA's 2021 inspection, including failure to establish and follow written procedures for the responsibilities of the quality control operations; failure to identity test each batch of ingredient prior to manufacturing; failure to prepare and follow a written master manufacturing record for each unique formulation and batch size; failure to include complete information relating to the production and control of each batch; and failure to maintain equipment to protect components and dietary supplements from being contaminated;

B. Product labels that failed to comply with the labeling requirements for dietary supplements, including violations that were the same as ones identified during the 2021 inspection, and

C. Labeling that established that Defendants were manufacturing and distributing unapproved new drugs, including the same products with the same disease claims set forth in paragraph 19. A-D and I-O above that were identified during the 2021 inspection.

38. Defendants promised to take corrective action following the 2015 inspection and Warning Letter but failed to do so.

39. At the close of an inspection conducted from July 31 to August 28, 2018 (the "2018 inspection") at Defendants' current Facility, the FDA investigator issued an FDA Form 483 listing four Inspectional Observations and discussed the observed deviations with Defendants Oliva, Monfort, and Giral. The identified violations included similar observations made during FDA's

2021 inspection, *i.e.*, failure to test for identity verification of dietary ingredients prior to use; and failure to establish product specifications for the identity, purity, strength, and composition of the finished dietary supplements. The inspection also identified labeling that continued to make disease claims.

40. On November 19, 2018, after Defendants failed to respond to the FDA Form 483, FDA held a regulatory meeting with Defendants Oliva and Monfort in an effort to assist Defendants in coming into compliance with the Dietary Supplement CGMP and labeling requirements of the Act and its implementing regulations. During the meeting, Defendant Oliva stated that new labels were being designed and promised to send them to FDA when completed. Defendant Monfort stated that all labels containing disease claims would be removed from Salud Natural's website. Defendants Oliva and Monfort were informed that future noncompliance could lead to enforcement action, including an injunction. Despite their promises, Defendants did not submit any corrective action documentation in response to the Inspectional Observations or regulatory meeting.

41. At the close of an inspection conducted from August 20, 1019 and January 22, 2020 (the "2020 inspection") at Defendants' current Facility, the FDA investigator issued an FDA Form 483 listing 28 Inspectional Observations and discussed the observed deviations with Defendants Monfort and Giral. The identified violations included similar observations made during FDA's 2021 inspection, such as failure to reject a component or dietary supplement when an established specification is not met; failure to establish and follow written procedures for the responsibilities of quality control operations; failure to prepare and follow a written master manufacturing record for each dietary supplement; failure to create batch production records to include all required information; failure to maintain equipment to protect components and dietary supplements from being contaminated; and failure to hold components and dietary supplements under appropriate

conditions of temperature, humidity, or lights. The inspection also identified labeling that did not comply with dietary supplement labeling requirements and labeling that continued to make disease claims. On February 14 and 24, 2020, following the close of the inspection, Defendant Giral in two emails provided perfunctory and incomplete responses to two of the 28 Inspectional Observations and promised to send more information. Despite these promises, FDA has not received from Defendants any further response to the 2020 FDA Form 483.

42. As noted above, a number of the violations identified during the 2021 inspection had been identified during the 2015, 2018, and 2020 inspections.

43. Defendants have not followed through on their repeated written and oral promises to correct their Dietary Supplement CGMP deficiencies and labeling violations, including promises made in discussions with FDA investigators during the 2015, 2018, 2020, and 2021 inspections, and at the 2018 regulatory meeting. Nor have Defendants submitted any corrective action plan addressing how to prevent violations from recurring. And they have used tainted ingredients in their products and resisted recall, as evidenced by the example involving *Salmonella* set forth in paragraph 12.C. above.

44. Based on the foregoing, despite repeated notifications, Defendants remain unable or unwilling to comply with the Act. 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), and the inherent equitable authority of the court, Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, from directly or indirectly 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, and/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 under 21 U.S.C. § 342(g)(1), and/or misbranded under 21 U.S.C. § 343;

B. Violating 21 U.S.C. § 331(k) by causing articles of food (dietary supplements, as defined at 21 U.S.C. § 321(ff)), that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become adulterated under 21 U.S.C. § 342(g)(1) and/or misbranded under 21 U.S.C. § 343;

C. Violating 21 U.S.C. § 331(d) by introducing or delivering for introduction, and/or causing to be introduced or delivered 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;

D. Violating 21 U.S.C. § 331(a) by introducing or delivering for introduction, and/or causing to be introduced or delivered, into interstate commerce drugs that are misbranded under 21 U.S.C. § 352(f)(1); and

E. Violating 21 U.S.C. § 331(k) by causing drugs that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become misbranded under 21 U.S.C. § 352(f)(1).

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. manufacturing, preparing, processing, packing, labeling, holding, and distributing food (dietary supplements, as defined at 21 U.S.C. § 321(ff)) at or from the Facility, or at or from any other location(s) at which Defendants manufacture, prepare, process, pack, label, hold, and/or

distribute food (dietary supplements), now or in the future, unless and until Defendants bring their manufacturing, preparing, processing, packing, labeling, holding, 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; and

B. introducing or delivering for introduction, or causing to be introduced or delivered for introduction into interstate commerce, any drug unless and until an approved new drug application, abbreviated new drug application, or investigational new drug application 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' place(s) of business and all records relating to the receipt, manufacture, preparing, packing, labeling, holding, and distribution of all of Defendants' products, including dietary supplements and drugs and their components, 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.

IV. Award Plaintiff its costs incurred in pursuing this action and such other and further relief as the court deems just and proper.

Dated March 3, 2022.

Respectfully Submitted,

OF COUNSEL

DANIEL J. BARRY
Acting General Counsel
Department of Health and Human Services

PERHAM GORJI
Deputy Chief Counsel for Litigation
Food and Drug Division

LESLIE COHEN
Associate Chief Counsel
Office of the Chief Counsel
Food and Drug Administration
5630 Fishers Lane, Rm. 2207
Rockville, Maryland 20857
leslie.cohen@hhs.fda.gov

BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General

ARUN G. RAO
Deputy Assistant Attorney General

GUSTAV W. EYLER
Director, Consumer Protection Branch

ALAN PHELPS
Assistant Director

JOHN R. LAUSCH, Jr.
United States Attorney

By: s/Donald R. Lorenzen
DONALD R. LORENZEN
Special Assistant U.S. Attorney
Senior Litigation Counsel
Consumer Protection Branch
U.S. Department of Justice
450 Fifth Street, N.W., Suite 6400
Washington, D.C. 20530
(312) 353-5330
donald.lorenzen@usdoj.gov