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

UNITED STATES OF AMERICA, Plaintiff, v. GLOBAL MARKETING ENTERPRISES, INC., LIFELINE NUTRIENTS, CORP., and PRONTO FOODS COMPANY, corporations, and EDUARDO S. CHUA and HAIDEE V. DAWIS, individuals Defendants.	)	Civil No. _____

COMPLAINT FOR PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned counsel, alleges as follows:

1. Defendants are three related businesses and two individuals that manufacture, package, and label numerous products and distribute them to consumers nationwide from a Chicago warehouse. Many of Defendants' products are dietary supplements and/or drugs under the Federal Food, Drug, and Cosmetic Act ("FDCA" or "Act").

2. Defendants' products are adulterated, misbranded, or unapproved, in violation of the FDCA. Defendants' dietary supplements are prepared, packed, or held under conditions that do not meet the U.S. Food and Drug Administration's ("FDA") current good manufacturing practice regulations for dietary supplements, which are intended to ensure the quality of dietary supplements. Also, the labels on Defendants' dietary supplements do not contain information required by law. Defendants are violating the FDCA by introducing, or causing the introduction of adulterated and misbranded dietary supplements into interstate commerce, and/or causing

dietary supplements to become adulterated or misbranded while they are held for sale after shipment of one or more components in interstate commerce.

3. Certain of Defendants' products are drugs under the FDCA because they are intended for use in diagnosing, curing, mitigating, treating, or preventing disease, such as Alzheimer's disease, diabetes, HIV/AIDS, and Parkinson's disease. Defendants' drugs are "unapproved new drugs" because they are not generally recognized as safe and effective, not approved by FDA, and not exempt from the approval requirements. Also, the labeling of Defendants' drugs fails to bear adequate directions for use. Defendants are violating the FDCA by introducing unapproved new drugs into interstate commerce, by introducing or causing the introduction of misbranded drugs into interstate commerce, and/or by causing drugs to become misbranded while they are held for sale after shipment of one or more components in interstate commerce.

4. Beginning in 2015, FDA repeatedly warned Defendants that they were violating the FDCA. Despite repeated promises to fix the problems, Defendants have not done so. Accordingly, the United States now seeks a permanent injunction to bring Defendants' operations into compliance with the law.

5. This statutory injunction proceeding is brought under the FDCA, 21 U.S.C. § 332(a), and the inherent equitable authority of this Court, to permanently enjoin Global Marketing Enterprises, Inc., Lifeline Nutrients, Corp., and Pronto Foods Company, corporations, and Eduardo Chua and Haidee Dawis, individuals, (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) or misbranded within the meaning of 21 U.S.C. §§ 343(s)(2)(B) or (q)(5)(F);

B. Violating 21 U.S.C. § 331(k), by causing articles of food (dietary supplements, as defined at 21 U.S.C. § 321(ff)) to become adulterated within the meaning of 21 U.S.C. § 342(g)(1) or misbranded within the meaning of 21 U.S.C. §§ 343(s)(2)(B) or (q)(5)(F), while such articles are held for sale after shipment of one or more of their components in interstate commerce;

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(a) nor exempt from approval pursuant to 21 U.S.C. § 355(i);

D. 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 that are misbranded within the meaning of 21 U.S.C. § 352(f)(1); and

E. Violating 21 U.S.C. § 331(k), by causing articles of drug to become misbranded within the meaning of 21 U.S.C. § 352(f)(1), while such articles are held for sale after shipment of one or more of their components in interstate commerce.

Jurisdiction and Venue

6. 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).

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

Defendants

8. Defendant Global Marketing Enterprises, Inc. ("Global Marketing") is an Illinois corporation with its principal place of business at 1801 South Canal Street, Chicago, Illinois (the "South Canal Street Facility"). Global Marketing purchases ingredients in interstate commerce and distributes in interstate commerce numerous finished products, including dietary supplements.

9. Defendant Lifeline Nutrients, Corp. ("Lifeline Nutrients") is an Illinois corporation with its principal place of business at the South Canal Street Facility. Lifeline Nutrients manufactures finished products, including dietary supplements, using ingredients purchased by Global Marketing or Defendant Pronto Foods Company, and distributes these products in interstate commerce.

10. Defendant Pronto Foods Company ("Pronto Foods") is an Illinois corporation with its principal place of business at the South Canal Street Facility. Pronto Foods purchases ingredients used by Lifeline Nutrients to manufacture finished products, including dietary supplements, and distributes these products in interstate commerce.

11. Eduardo S. Chua is the president and owner of Global Marketing and Pronto Foods, and the owner of Lifeline Nutrients. He is the most responsible person at each company with ultimate authority over all operations, including product formulation, manufacturing, labeling, and sales. Chua controls several websites through which Defendants' products are sold, including lifelinenutrients.ecrater.com and lifelinenutrients.com, and he also offers Defendants' products for sale through amazon.com. Chua works at the South Canal Street Facility.

12. Haidee V. Dawis is the operations manager for Global Marketing, Lifeline Nutrients, and Pronto Foods, and she reports directly to Chua. Dawis is responsible for managing food preparation and facility sanitation, maintaining dietary supplement manufacturing records, processing orders, and distributing dietary supplements. Dawis works at the South Canal Street Facility.

Background

13. Many of Defendants' products, including ALCAR Acetyl-L-Carnitine HCL, L-Carnosine Capsules, and L-Phenylalanine are dietary supplements under the FDCA, 21 U.S.C. § 321(ff). The FDCA defines "dietary supplement" 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). 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.*

14. Many of Defendant's products, including ALCAR Acetyl-L-Carnitine HCL, Ampalaya Fruit Bittermelon Powder Extract Capsules, Berberine HCL Powder Extract, Berberine HCL Powder Extract Plus Milk Thistle Capsules, Grape Seed Extract, L-Carnosine Capsules, L-Phenylalanine, L-Lysine HCL, and L-Carnitine meet the FDCA's definition of drug, 21 U.S.C. § 321(g)(1), because they are intended for use in the cure, mitigation, treatment, or prevention of disease.

15. During an inspection conducted in May to July 2015 of Defendants' South Canal Street Facility (the "2015 Inspection"), FDA investigators observed numerous deviations from

FDA's current good manufacturing practice regulations set forth in 21 C.F.R. Part 111 ("Dietary Supplement CGMP"). Among other deficiencies observed by FDA, Defendants failed to conduct at least one appropriate test or examination to verify the identity of a dietary ingredient prior to use; failed to identify product specifications and to verify that such specifications are met; failed to prepare and follow a written master manufacturing record for each unique formulation and batch size; failed to establish and follow written procedures for quality control operation responsibilities; and failed to establish and follow written procedures for maintaining, cleaning, and sanitizing equipment, utensils, and contact surfaces. FDA also identified that Defendants' product labels failed to comply with the Act's dietary supplement labeling requirements.

16. At the close of the 2015 Inspection, FDA investigators issued a List of Inspectional Observations ("Form FDA-483") to Chua and discussed the observed deficiencies with him. Chua promised to correct the deficiencies and respond in writing to FDA within 15 days. Chua did not correct the deficiencies or send a letter to FDA regarding the Form FDA-483 observations.

17. On March 15, 2016, FDA issued a Warning Letter (the "Warning Letter") to Chua and Global Marketing, informing them that they were introducing adulterated and misbranded dietary supplements into interstate commerce in violation of the FDCA, 21 U.S.C. §§ 331(a) and (k). The Warning Letter specifically described five Dietary Supplement CGMP violations observed by FDA and two misbranding violations relating to dietary supplement labels that failed to contain information required by law. On March 30, 2016, Chua sent FDA an email in response to the Warning Letter, which email purported to include links to documents addressing

some of the issues discussed in the Warning Letter. FDA was unable to open the documents and Chua never responded to FDA's request to resend the documents in a different format.

18. During March to June 2017, FDA again inspected Defendants' South Canal Street Facility (the "2017 Inspection"). Among other things, FDA investigators observed seven Dietary Supplement CGMP deviations, five of which were the same or similar to those identified in the Warning Letter: failure to conduct at least one appropriate test or examination to verify the identity of a dietary ingredient prior to use; failure to identify product specifications and to verify that such specifications are met; failure to prepare and follow a written master manufacturing record for each unique formulation and batch size; failure to establish and follow written procedures for quality control operation responsibilities; and failure to establish and follow written procedures for maintaining, cleaning, and sanitizing equipment, utensils, and contact surfaces.

19. During the 2017 Inspection, FDA investigators collected samples of Defendants' product labels. Defendants' dietary supplement labels continued to be deficient in the same ways described in the Warning Letter.

20. At the end of the 2017 Inspection, FDA investigators issued another Form FDA-483 to Chua and discussed the observed deficiencies with him. On June 19, 2017, Chua provided FDA a document estimating that various corrective steps would be taken within 15 days to 2 months. Chua did not provide any documentation to FDA regarding such corrections.

21. On November 13, 2017, FDA sent Chua and Global Marketing a letter requesting documents to demonstrate the corrections that Chua promised on June 19, 2017. Defendants did not respond to this letter and did not otherwise demonstrate they implemented their proposed corrections.

Defendants' Violations of the Act

Adulterated Dietary Supplements

22. A dietary supplement is deemed to be adulterated if it is not prepared, packed, or held in conformance with Dietary Supplement CGMP. 21 U.S.C. § 342(g)(1).

23. Defendants are required to comply with Dietary Supplement CGMP because they manufacture, package, label, and/or hold dietary supplements, including the products identified in paragraph 13 above. Dietary Supplement CGMP requires that Defendants control all aspects of their dietary supplement processes and procedures to ensure compliance with established specifications for identity, purity, strength, composition, and limits on certain types of contamination.

24. Defendants' dietary supplements are prepared, packed, or held in a manner that does not conform to Dietary Supplement CGMP, including but not limited to the following violations:

A. Failure to conduct at least one appropriate test or examination to verify the identity of a component that is a dietary ingredient, prior to use, as required by 21 C.F.R. § 111.75(a)(1)(i);

B. Failure to establish product specifications for the identity, purity, strength, and composition of the finished batch of dietary supplements, and for limits on those types of contamination that may adulterate, or that may lead to the adulteration of, the finished batch of dietary supplements to ensure the quality of dietary supplements, as required by 21 C.F.R. § 111.70(e). Because Defendants do not have the required specifications, they also fail to comply with 21 C.F.R. § 111.75(c), which requires dietary supplement manufacturers to verify that their product specifications have been met;

C. Failure to prepare and follow a written master manufacturing record ("MMR") for each unique formulation and batch size of dietary supplement manufactured that identifies specifications for the points, steps, or stages in the manufacturing process where control is necessary to ensure the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the MMR, as required by 21 C.F.R. §§ 111.205(a) and (b)(1);

D. Failure to establish and follow written procedures for the responsibilities of quality control operations, including written procedures for conducting a material review and making a disposition decision, and for approving or rejecting any reprocessing, as required by 21 C.F.R. § 111.103;

E. Failure to establish and follow written procedures for maintaining, cleaning, and sanitizing, as necessary, all equipment, utensils, and any other contact surfaces that are used to manufacture, package, label, or hold components or dietary supplements, as required by 21 C.F.R. § 111.25(c); and

F. Failure to establish and follow written procedures for reviewing and investigating product complaints, as required by 21 C.F.R. § 111.553.

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

26. Defendants violate 21 U.S.C. § 331(k), by causing articles of food (dietary supplements) to become adulterated within the meaning of 21 U.S.C. § 342(g)(1), while such articles are held for sale after shipment of one or more of their components in interstate commerce.

Misbranded Dietary Supplements

27. A dietary supplement is deemed to be misbranded unless:

A. its label or labeling identifies the product by using the term "dietary supplement," which term may be modified with the name of such an ingredient, as required by 21 U.S.C. § 343(s)(2)(B); and

B. its label or labeling bears nutrition information in a Supplement Facts panel, as required by 21 U.S.C. § 343(q)(5)(F).

28. Defendants' dietary supplements, including but not limited to the following, are misbranded because:

A. the labels for L-Carnosine Capsules, L-Phenylalanine, and ALCAR Acetyl-L-Carnitine HCL fail to identify the products as dietary supplements as part of the statement of identity, as required by 21 U.S.C. § 343(s)(2)(B) and 21 C.F.R § 101.3(g); and

B. the labels for L-Carnosine Capsules, L-Phenylalanine, and ALCAR Acetyl-L-Carnitine HCL fail to bear a Supplement Facts panel, as required by 21 U.S.C. § 343(q)(5)(F) and 21 C.F.R § 101.36.

29. 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 food (dietary supplements) that are misbranded within the meaning of 21 U.S.C. §§ 343(s)(2)(B) and/or (q)(5)(F).

30. Defendants violate 21 U.S.C. § 331(k) by causing articles of food (dietary supplements) to become misbranded within the meaning of 21 U.S.C. §§ 343(s)(2)(B) and/or (q)(5)(F), while such articles are held for sale after shipment of one or more of their components in interstate commerce.

Unapproved New Drugs

31. The FDCA's definition of drug includes products that are "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease." 21 U.S.C. § 321(g)(1)(B).

32. Because a product's intended use may determine whether it is a drug, a product that falls within the FDCA's dietary supplement definition may also meet the FDCA'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).

33. Defendants cause certain of their products to be drugs because they make claims that the products are intended to cure, mitigate, treat, or prevent diseases ("disease claims"). For example, the following claims are disease claims establishing that these products are intended to cure, mitigate, treat, or prevent disease, and therefore, are drugs:

A. Berberine HCL Powder Extract Plus Milk Thistle Capsules: "*Berberine has been tested successfully in human diabetes. It lowers elevated blood total cholesterol, LDL cholesterol… Berberine seems to suppress the growth of a wide variety of tumor cells, including breast cancer… For Type II diabetes, human and animal research shows that 1500mg of berberine, taken in three doses of 500 mg each, is equally effective as taking 1500mg of metformin or 4mg glibenclamide, two pharmaceuticals for treating type II diabetes*";

B. Berberine HCL Powder Extract: "*Berberine has drawn extensive attention towards its antineoplastic effects. It seems to suppress the growth of a wide*

variety of tumor cells, including breast cancer, leukemia, melanoma, epidermoid carcinoma, hepatoma, pancreatic cancer, oral carcinoma, tongue carcinoma, glioblastoma, prostate carcinoma and gastric carcinoma … A new study shows the potential application of berberine as a complementary therapeutic agent for HIV/AIDS";

C. Ampalaya Fruit Bittermelon Powder Extract Capsules: *"Laboratory studies show that bitter melon extracts can kill certain cancer cells and slow the ability of HIV to insert its genes into human chromosomes… It is used for kidney stones, psoriasis and liver disease. It is also used for diabetes as it contails [sic] a chemical that acts like insulin to help reduce blood sugar levels";*

D. L-Carnosine Capsules: *"Carnosine acts as an antiglycating agent, reducing the rate of formation of advanced glycation end-products (AGEs) (substances that can be a factor in the development or worsening of many degenerative diseases, such as diabetes, atherosclerosis, chronic renal failure, and Alzheimer's disease[)] and ultimately reducing development of atherosclerotic plaque build-up";*

E. L-Phenylalanine: *"[L-Phenylalanine] is commonly used in dietary and nutritional supplement [sic] for its reputed analgesic and antidepressant effects. Phenylalanine is used for depression, attention deficit-hyperactivity disorder (ADHD), Parkinson's disease, chronic pain, osteoarthritis, rheumatoid arthritis"*;

F. L-Lysine HCL: "*The most predominant benefit of L-lysine is for treatment of mouth & genital lesions caused by herpes simplex virus, as well as shingles caused by herpes zoster viruses. Taking L-lysine can speed recovery time and reduce the chance of recurrent breakouts of herpes infection. … Good results can be seen by initiating supplementation during the beginning phases of a herpes simplex episode*";

G. ALCAR Acetyl-L-Carnitine HCL: "*[A]cetyl-L-carnitine … has been studied as a possible adjunct treatment for Alzheimer's disease. Acetyl-L-carnitine may also help address symptoms of depression, and may be useful in the treatment of Parkinson's disease, stroke*";

H. Grape Seed Extract: *"A polyphenol contained in grape seeds is resveratrol, which is under study for its possible effect on cancer cell growth, proliferation or apoptosis. Today, standardized extracts of grape seed may be used to treat a range of health problems related to free radical damage, including heart disease, diabetes, and cancer. Grape seed extract has also been shown to protect against bacterial infections, such as Staphylococcus aureus"*; and

I. L-Carnitine: *"L-carnitine is used for conditions of the heart and blood vessels including heart-related chest pain, congestive heart failure (CHF), heart complications of a disease called diphtheria, heart attack, leg pain caused by circulation problems (intermittent claudication), and high cholesterol. Some people use L-carnitine for muscle disorders associated with certain AIDS medications, … diabetes, overactive thyroid, attention deficit-hyperactivity disorder (ADHD), … Lyme disease…*".

34. A drug is a "new drug" if "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 safety and effectiveness. *See* 21 U.S.C. § 355(d).

35. Defendants' drugs, including those listed in paragraph 33 above, lack substantial evidence of safety and effectiveness. There are no published adequate and well-controlled investigations to show that these drugs are GRAS/E for any use and, therefore, qualified experts cannot come to a consensus opinion concerning the effectiveness of these products. Because Defendants' drugs are not GRAS/E, they are new drugs.

36. A drug that is a "new drug" within the meaning of the Act is prohibited from being introduced or delivered for introduction into interstate commerce unless FDA has approved a new drug application or abbreviated new drug application for that drug, or the drug is exempt from approval under an investigational new drug application. *See* 21 U.S.C. §§ 355(a), (b), (i), and (j). There are no new drug applications, abbreviated new drug applications, or investigational new drug applications for Defendants' new drugs listed in paragraph 33 above. Therefore, Defendants' drugs are unapproved new drugs within the meaning of the Act, 21 U.S.C. § 355(a).

37. 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 pursuant to 21 U.S.C. § 355(i).

Misbranded Drugs

38. A drug is misbranded if its labeling fails to bear "adequate directions for use" and it does not fall within a regulatory exemption from that requirement. 21 U.S.C. § 352(f)(1). FDA has defined "adequate directions for use" as "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. Drugs that are unapproved are not exempt from the requirement for adequate directions for use. *See* 21 C.F.R. §§ 201.100(c)(2), 201.115.

39. By definition, a drug that is also a prescription drug cannot have adequate instructions for lay use. 21 U.S.C. § 353(b)(1)(A) (requiring a drug to be dispensed by prescription that, "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"). Because of the purposes for which they are intended, the potential for harmful effect, and/or the collateral measures necessary to their use, many of Defendants' drugs are prescription drugs (including those listed in paragraph 33 above), which, as a matter of law, cannot meet the requirement for "adequate directions for use."

40. In addition, it is not possible to write adequate directions for use for certain of Defendants' drugs, including those listed in paragraph 33 above, because such directions—including dosages, indications, contraindications, warnings, side effects, and necessary collateral measures—are premised on animal and clinical data derived from extensive, scientifically controlled testing. As noted in paragraph 35 above, there are no well-controlled clinical test data for Defendants' drugs.

41. For the reasons identified in paragraphs 38 through 40, 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. These drugs are not exempt from the requirement for adequate directions for use because they are unapproved. *See* 21 C.F.R. §§ 201.100(c)(2), 201.115.

42. 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 drug that are misbranded within the meaning of 21 U.S.C. § 352(f)(1).

43. Defendants violate 21 U.S.C. § 331(k) by causing articles of drug to become misbranded within the meaning of 21 U.S.C. § 352(f)(1), while such articles are held for sale after shipment of one or more of their components in interstate commerce.

Relief

WHEREFORE, the United States respectfully requests that the Court enter judgment in its favor and:

I. Order that 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, cease receiving, manufacturing, preparing, packing, repacking, labeling, holding, or distributing articles of dietary supplement and/or articles of drug, unless and until:

A. Defendants' facilities, methods, processes, and controls used to receive, manufacture, prepare, pack, repack, label, hold, and distribute dietary supplements are established, operated, and administered in conformity with Dietary Supplement CGMP and the FDCA, in a manner acceptable to FDA;

B. Defendants' dietary supplement labeling complies with 21 U.S.C. § 343 and applicable regulations, in a manner acceptable to FDA; and

C. Defendants' claims do not cause any product that they receive, manufacture, prepare, pack, repack, label, hold, or distribute to be a drug within the

meaning of the FDCA, 21 U.S.C. § 321(g)(1)(B), unless and until the product is the subject of an approved new drug application or abbreviated new drug application, or is exempt from approval under an investigational new drug application, 21 U.S.C. §§ 355(a), (b), (i), and (j).

II. Order that 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, be permanently restrained and enjoined under 21 U.S.C. § 332(a) 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, or causing to be introduced or delivered or introduction, into interstate commerce articles of food (including but not limited to dietary supplements and their components) that are adulterated within the meaning of 21 U.S.C. § 342(g)(1) or misbranded within the meaning of 21 U.S.C. § 343;

B. violating 21 U.S.C. § 331(k), by causing articles of food (including but not limited to dietary supplements and their components) to become adulterated within the meaning of 21 U.S.C. § 342(g)(1) or misbranded within the meaning of 21 U.S.C. § 343, which such articles are held for sale after shipment of one or more of their components in interstate commerce;

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(a) nor exempt from approval pursuant to 21 U.S.C. § 355(i);

D. 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 that are misbranded within the meaning of 21 U.S.C. § 352(f)(1); and

E. violating 21 U.S.C. § 331(k), by causing articles of drug to become misbranded within the meaning of 21 U.S.C. § 352(f)(1), which such articles are held for sale after shipment of one or more of their components in interstate commerce.

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. Order that Plaintiff be awarded costs incurred in pursuing this action and such other equitable relief as the Court deems just and proper.

DATED this 26th day of July, 2018.

Respectfully submitted,

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