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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, Plaintiff, v. BETHEL NUTRITIONAL CONSULTING, INC., a corporation, FELIX V. RAMIREZ, and KARINY C. RAMIREZ, individuals, Defendants.	)	Civil No. _____ COMPLAINT FOR PERMANENT INJUNCTION

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 Bethel Nutritional Consulting, Inc., a corporation, and Felix V. Ramirez and Kariny C. Ramirez, 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) 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 (dietary supplements) that Defendants hold for sale after shipment in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(g)(1);

C. 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;

D. Violating 21 U.S.C. § 331(k) by causing articles of drug that Defendants hold for sale after shipment in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352; and

E. 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).

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 Bethel Nutritional Consulting, Inc., is incorporated under the laws of the state of New York. Bethel Nutritional Consulting distributes dietary supplements and drugs under its own label. Bethel Nutritional Consulting does business at 599 West 190th Street, Suite 1, New York, New York (the "Facility"). Defendants also use a storage locker at Extra Space Storage, 1415 Bergen Boulevard, Fort Lee, New Jersey 07024, within the jurisdiction of this court, to warehouse additional product inventory.

5. Defendant Felix V. Ramirez is the president of Bethel Nutritional Consulting. Mr. Ramirez is the most responsible person at the firm. He has ultimate authority over all of the firm's operations, including all major financial decisions and the content of the firm's website, www.bethel30.com. He also has the authority to hire and fire employees. Defendant Felix Ramirez performs his duties at Bethel Nutritional Consulting, 599 West 190th Street, Suite 1, New York, New York, and at 1415 Bergen Boulevard, Fort Lee, New Jersey, within the jurisdiction of this court.

6. Defendant Kariny C. Ramirez is the vice president of Bethel Nutritional Consulting. Ms. Ramirez is responsible for regulatory affairs, customer relations, and ordering products from the firm's suppliers. She also has the authority to hire and fire employees. Defendant Kariny Ramirez performs her duties at Bethel Nutritional Consulting, 599 West 190th Street, Suite 1,

New York, New York, and at 1415 Bergen Boulevard, Fort Lee, New Jersey, within the jurisdiction of this court.

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

A. Dietary supplements within the meaning of the Act, which 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, and that "is labeled as a dietary supplement" and "is not represented for use as a conventional food or as a sole item of a meal or the diet." 21 U.S.C. § 321(ff). (Except for purposes of 21 U.S.C. §§ 321(g) and 350f, dietary supplements are deemed to be food under the Act. 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), because Defendants' claims establish that the products are intended to cure, mitigate, treat, or prevent disease and/or affect the structure or function of the body.

8. Defendants' products have been shipped to them by their suppliers from outside the state of New Jersey, including China, California, and Florida. Defendants distribute their products to customers in locations throughout the United States, including California, Texas, Florida, and Connecticut.

Defendants' Violations of the Act

Adulterated Dietary Supplements

9. The Act deems a dietary supplement to be adulterated if it is not prepared, packed, and held in conformance with regulations for current good manufacturing practice for dietary

supplements ("Dietary Supplement CGMP"). 21 U.S.C. § 342(g)(1). The Dietary Supplement CGMP regulations, set forth at 21 C.F.R. Part 111, 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.

10. FDA investigators inspected Defendants' Facility on December 17-18, 22-23, 2014, January 5, 7, and 13, 2015 (the "2014/2015 inspection"). The 2014/2015 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, or held in a manner that does not conform to Dietary Supplement CGMP regulations. FDA investigators documented significant deviations from Dietary Supplement CGMP regulations, including but not limited to:

A. Failure to establish and follow written procedures for the responsibilities of the quality control operations, including but not limited to rejecting or approving incoming dietary supplement shipments (pursuant to 21 C.F.R. § 111.105), and reviewing and approving decisions about whether to investigate a product complaint (pursuant to 21 C.F.R. § 111.135), as required by 21 C.F.R. § 111.103;

B. Failure to establish and follow written procedures for holding and distribution operations, including but not limited to written procedures for establishing and monitoring temperature and relative-humidity ranges in product storage facilities, as required by 21 C.F.R. § 111.453; and

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

11. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering 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 Dietary Supplement CGMP regulations, 21 C.F.R. Part 111.

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

Misbranded Dietary Supplements

13. The Act deems a dietary supplement to be misbranded unless:

A. If it is a dietary supplement in package form, its label bears the place of business (city, state, ZIP) of the manufacturer, packer, or distributor, as required by 21 U.S.C. § 343(e)(1);

B. Its label or labeling bears nutrition information that provides the serving size in the manner required by 21 U.S.C. § 343(q)(1)(A), and the number of servings or other units of measure per container, as required by 21 U.S.C. § 343(q)(1)(B);

C. Its label or labeling identifies the product by using the term "dietary supplement," as required by 21 U.S.C. § 343(s)(2)(B);

D. In the case of a dietary supplement that contains an herb or other botanical, its label or labeling identifies the part of the plant (e.g., root, leaves) from which the ingredient is derived, as required by 21 U.S.C. § 343(s)(2)(C); and

E. If it is a dietary supplement marketed in the United States, the label includes a domestic address or domestic telephone number through which the responsible person (as described in 21 U.S.C. § 379aa-1) may receive a report of a serious adverse event with the product, as required by 21 U.S.C. § 343(y).

14. During the 2014/2015 inspection, FDA investigators photographed the inventory of Defendants' labeled products warehoused at two locations - the Facility and Defendants' storage

locker at Extra Space Storage in Fort Lee, New Jersey. FDA evaluated the product labels and determined that Defendants cause many of their dietary supplements to be misbranded within the meaning of 21 U.S.C. § 343 as follows:

A. The labels for Bethel Plus, B-Thinner Caffeine Free, Bronchial & Respiratory, CLA, Dong Quai, Garlic & Parsley, M.A.G., Nutrigland, and V.H.P. fail to list the place of business of the manufacturer, packer, or distributor, as required by 21 U.S.C. § 343(e)(1) and 21 C.F.R. § 101.5;

B. The label for Bethel Plus also fails to list the correct serving size, as required by 21 U.S.C. § 343(q)(1)(A) and 21 C.F.R. §§ 101.9(b), 101.12(b);

C. The labels for Bethel Plus, B-Thinner Caffeine Free, CLA, Dong Quai, Garlic & Parsley, M.A.G., and V.H.P. fail to identify the product by using the term "dietary supplement," as required by 21 U.S.C. § 343(s)(2)(B) and 21 C.F.R. § 101.3(g);

D. The labels for Bethel Plus, B-Thinner Caffeine Free, Bronchial & Respiratory, Dong Quai, K-Cleanser, M.A.G., Nutrigland, and V.H.P. fail to identify the part of the plant (e.g., root, leaves) from which each botanical dietary ingredient in the product is derived, as required by 21 U.S.C. § 343(s)(2)(C) and 21 C.F.R. § 101.4(h)(1); and

E. The label for V.H.P. also fails to list the correct servings per container, as required by 21 U.S.C. § 343(q)(1)(B) and 21 C.F.R. § 101.36(b)(1)(ii), and a domestic address or domestic telephone number through which the responsible person (as described in 21 U.S.C. § 379aa-1) may receive a report of a serious adverse event with the product, as required by 21 U.S.C. § 343(y).

15. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce articles of food (dietary supplements) that are misbranded within the meaning of 21 U.S.C. § 343.

Unapproved New Drugs

16. The Act's definition of drug includes products that are "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" or "intended to affect the structure or any function of the body." 21 U.S.C. §§ 321(g)(1)(B), (C).

17. 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).

18. 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 or intended to affect the structure or function of the body. *See* 21 U.S.C. § 321(ff).

19. Defendants cause 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") or intended to affect the structure or function of the body ("structure/function claims").

20. FDA reviewed Defendants' website, www.bethel30.com, on January 13, 2015, and identified the following claims (italicized below):

A. Milk Thistle: *"Helps Protect the liver from the effects of alcohol, viruses, toxics and certain chemotherapy drugs...Helps Slow down the growth of certain forms of cancer"*

B. Omega Max Epa: *"Studies indicate that increasing the intake of EPA may provide added protection against coronary heart disease, high blood pressure and inflammatory diseases such as rheumatoid arthritis"*; *"May help decrease depression, Alzheimer's in adults and ADHD in children."*

C. Valerian Root: *"Presently it may help alleviate...migraines, to alleviate the irritable bowel syndrome and to help with disorders of attention deficit hyperactivity. It may also beneficial [sic] in helping in cases of ulcers, mucus in cases of colds, hypertension...."*

D. Ginkgo Biloba Plus: *"May help slowing the progression of Alzheimer's disease, decrease senility, and improve memory...May help lower blood sugar levels in Type 2 diabetics...Assist preventing cardiovascular disease..."*

E. Diabetes Formula: *"Helps balance blood sugar levels...Helps cut down on the body's need for insulin..."*

F. Energy B with DHEA: *"ENERGY-B with DHEA may help reduce...anxiety and depression"*; *"Recommended for...Reducing...anemia..."*

G. Black Cohosh: *"Recommended for helping with...Reducing depression... Reducing arthritis...pain"*

H. V.H.P.: *"...DEPRESSION..."*

I. St. John's Wort: *"May help relieve depression, anxiety and insominia [sic]...May help fight certain infections caused by viruses and bacteria"*

J. Sweet Sleep: *"Sweet Sleep...eases depression"*; *"Additionally Sweet Sleep acts as a mild tranquilizer for people experiencing...mild depression"*; *"May help...reducing migraines..."*

K. Dong Quai: *"Dong Quai...is sometimes prescribed to women suffering from endometriosis."*

L. Garlic & Parsley: *"Garlic is a powerful herb may be helpful for treating numerous medical conditions, including fungus, bacteria, and viruses, as well as high cholesterol and plaque build up. Garlic can help reduce heart disease through the reduction of plaque, a benefit which in turn reduces the risk of blood clots and arteriosclerosis. A study in 2003 revealed that garlic even can reduce the risk of heart attack....This formulation also includes Parsley oil to help reduce...arthritis, heart and liver problems and inflammation of the kidneys and bladder."*

M. Red Clover: *"Recommended for...Helping prevent osteoporosis and reducing possibility of forming blood clots and arterial plaques"*

N. Colostrum: *"Recommended for...Fighting against infections"*

O. Eagle Eye: *"May help treat retinopathy"*

P. Flex-Maxx: *"Advanced Arthristis [sic] Formula - Relieves Joint Discomfort."*

Q. Alfalfa: *"Helps Alleviate arthritis pain..."*; *"May help in Normalizing blood pressure, and reducing cholesterol levels helping insulin work more effectively."*

R. Aloe Vera: *"Aloe contains anti-bacterial and anti-fungal properties, helping to prevent the onset of disease in the body"*; *"Aloe Vera may help for...defending the body against bacteria, healing internal tissue damage, healing ulcers...."*

S. Cranberry Extract: *"Recommended for...Assist preventing urinary tract infections caused by bacteria...Helps reducing the risk of heart disease...Helping to prevent the development of kidney stones...May help fight stomach ulcers"*

T. Liquid Chlorophyll: *"Chlorophyll may be beneficial as an anti-inflammatory and for wound healing.... It can also assist in the break up of kidney stones."*

U. HCG: *"WEIGHT-LOSS DROPS"*; *"The HCG Diet has also been used for weight loss in obese persons…."* [The label instructs that Defendants' HCG product is "meant to be used while following the standard Dr. Simeons HCG diet protocol, 500 calorie diet."]

21. The claims described in paragraph 20 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).

22. On December 12, 2014, FDA reviewed Defendants' website, www.bethel30.com, and identified the following claims for Defendants' Slim-K and B-Lipo products:

A. Slim-K:
Appetite Suppressant, Fat Burner and speeds up metabolic rate. SLIM-K is an exclusive formula that includes a combination of ingredients recognized for helping control appetite and burn fat effectively while increasing energy. It was especially developed to help burn calories….

B. B-Lipo:
B-LIPO is a Fat-burner and an appetite suppressant. Its more concentrated in increasing energy. Its great for those who need the extra help to burn fat. LOSE WEIGHT QUICKLY FROM 15 TO 25 POUNDS IN ONE MONTH!!! Your package includes a free laxative and a Diet Menu that will help you lose those stubborn extra pounds!!

OUR B-LIPO HELPS INCREASE YOUR METABOLISM AND REDUCES FAT.

23. The claims described in paragraph 22 above are structure/function claims and demonstrate that Defendants' Slim-K and B-Lipo are intended to affect the structure or function of the body; therefore, these products are drugs within the meaning of the Act, 21 U.S.C. § 321(g)(1)(C).

24. The term "dietary supplement" excludes an article that is "approved as a new drug under [21 U.S.C. § 355]" or "authorized for investigation as a new drug . . . for which substantial clinical investigations have been instituted and for which the existence of such investigations has

been made public," if the article "was not before such approval . . . or authorization marketed as a dietary supplement or as a food." 21 U.S.C. § 321(ff)(3)(B).

25. In October 2014, FDA visited Defendants' website, www.bethel30.com, and made an undercover purchase of Slim-K. FDA's laboratory analysis detected sibutramine and phenolphthalein, at an average, respectively, of 25.7 milligrams (mg) and 51.9 mg per capsule, in Slim-K (Lot # 140430). Because Slim-K contains sibutramine, it is excluded from the definition of dietary supplement pursuant to 21 U.S.C. § 321(ff)(3)(B)(ii).

26. Sibutramine is the active pharmaceutical ingredient in Meridia, a new drug that had been approved by FDA at three doses (5 mg, 10 mg, and 15 mg, administered once daily) for marketing in 1997 for prescription treatment of obesity. Meridia was removed from the market in October 2010 because of data indicating that its use was associated with an increased risk of serious adverse cardiovascular events, including heart attack and stroke. Meridia (sibutramine) became authorized for investigation as a new drug under an investigational new drug application in January 1986, and clinical investigations were instituted thereafter. The existence of substantial clinical investigations of sibutramine became public no later than Meridia's approval date in 1997. Sibutramine was not marketed as a dietary supplement or as a food before Meridia was authorized for investigation as a new drug in January 1986. Thus, sibutramine is an article that was "authorized for investigation as a new drug . . . for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public" and "was not before such . . . authorization marketed as a dietary supplement or as a food," which means that sibutramine is excluded from the dietary supplement definition. *See* 21 U.S.C. § 321(ff)(3)(B)(ii). Therefore, any product that contains sibutramine is not a dietary supplement.

27. In October 2014, FDA visited Defendants' website, www.bethel30.com, and made an undercover purchase of B-Lipo. FDA's laboratory analysis detected lorcaserin, at an average of

7.9 mg per capsule, in B-Lipo (Lot # 20213). Because B-Lipo contains lorcaserin, it is excluded from the definition of a dietary supplement pursuant to 21 U.S.C. § 321(ff)(3)(B)(i).

28. Lorcaserin is the active pharmaceutical ingredient in Belviq, a new drug approved by FDA at a twice-daily dose of 10 mg of lorcaserin on June 27, 2012, as a prescription drug for chronic weight management in some overweight or obese adults. Lorcaserin was not marketed as a dietary supplement or as a food before FDA's approval of Belviq. Thus, lorcaserin is an article that is "approved as a new drug under [21 U.S.C. § 355]" and "was not before such approval . . . marketed as a dietary supplement or as a food," which means that lorcaserin is excluded from the dietary supplement definition. *See* 21 U.S.C. § 321(ff)(3)(B)(i). Therefore, any product that contains lorcaserin is not a dietary supplement.

29. 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 or, if it is an over-the-counter ("OTC") drug, it must comply with a monograph established by FDA regulation. *See* 21 U.S.C. § 355(d); 21 C.F.R. § 330.1.

30. Defendants' drugs lack substantial evidence of safety and effectiveness. There are no published adequate and well-controlled investigations to show that Defendants' drugs are GRAS/E for any use and, therefore, qualified experts cannot come to a consensus of opinion concerning the effectiveness of these products.

31. FDA regulations contain OTC monographs that provide a mechanism for certain OTC drugs to be categorized as GRAS/E and thus exempt from the Act's definition of a new drug.

See 21 C.F.R. § 330.1. An OTC product manufactured and labeled in accordance with an OTC monograph can be marketed without the submission and approval of a new drug application or an abbreviated new drug application. Any drug that does not strictly conform to each of the conditions contained in an applicable monograph, however, is subject to the new drug provisions of the Act.

32. Defendants' drugs do not conform to any OTC monograph and, thus, are not GRAS/E by regulation.

33. Because Defendants' drugs are not GRAS/E, they are new drugs.

34. FDA searched its records and found no new drug applications, abbreviated new drug applications, or investigational new drug applications for Defendants' new drugs. Therefore, Defendants' products are unapproved new drugs within the meaning of the Act, 21 U.S.C. § 355(a).

35. 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

36. A drug is misbranded within the meaning of 21 U.S.C. § 352(f)(1) if its labeling fails to bear "adequate directions for use" and it does not fall within a regulatory exemption from that requirement. FDA has defined "adequate directions for use" as "directions under which the layman can use a drug safely and for the purpose for which it is intended." 21 C.F.R. § 201.5(a).

37. 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").

38. 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. It is not possible to write adequate directions for use for Defendants' drugs 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 30 above, there are no well-controlled clinical test data for Defendants' drugs.

40. In addition, because of the purposes for which they are intended and/or the potential for serious adverse effects, many of Defendants' drugs are prescription drugs, which, as a matter of law, cannot meet the requirement for "adequate directions for use." *See* 21 U.S.C. § 352(f)(1); 21 C.F.R. § 201.5(a).

41. Defendants' drugs are misbranded within the meaning of 21 U.S.C. § 352(f)(1) because they fail to bear adequate directions for use. Defendants' 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. A drug is misbranded if its "labeling is false or misleading in any particular." 21 U.S.C. § 352(a). The Act provides that, "in determining whether the labeling . . . is misleading there shall be taken into account . . . not only representations made or suggested . . . but also the extent to which the labeling . . . fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which

the labeling . . . relates under the conditions of use prescribed in the labeling." 21 U.S.C. § 321(n).

43. A drug is misbranded within the meaning of 21 U.S.C. § 352(j) if "it is dangerous to health when used in the dosage or manner; or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof."

44. As noted in paragraph 25 above, analytical testing of Slim-K (Lot # 140430) detected sibutramine (25.7 mg) and phenolphthalein (51.9 mg).

A. Sibutramine in the dosage range that had been approved in Meridia (5 mg - 15 mg per day) was associated with an unacceptable level of serious health risks, such as heart attack and stroke, and the product was subsequently withdrawn from the market. While Meridia was on the market, the prescribing information included warnings against use in certain populations, including people with a major eating disorder (anorexia or bulimia), and warnings about the potential for developing serotonin syndrome, a potentially life-threatening drug interaction.

B. Phenolphthalein was an ingredient in some OTC laxative drug products until 1999 when FDA re-classified the drug as "not generally recognized as safe and effective" (*see* 21 C.F.R. § 310.545(a)(12)(iv)(B)) after studies indicated that phenolphthalein posed a potential carcinogenic risk. Prior to this reclassification, the dose of phenolphthalein permitted in certain OTC laxative products was 30 mg - 270 mg per day.

45. Sibutramine and phenolphthalein, in the amounts detected in Slim-K, cause the product to pose a risk of serious adverse health effects, including heart attack and stroke (from sibutramine), as well as a potential carcinogenic risk (from phenolphthalein).

46. The labeling for Slim-K is false or misleading because does not declare that it contains sibutramine and phenolphthalein or reveal the consequences that may result from using the

product containing these ingredients. Therefore, Slim-K is misbranded within the meaning of 21 U.S.C. § 352(a).

47. For the reason described in paragraph 45 above, Slim-K is also dangerous to health when used as prescribed, recommended, or suggested in its labeling. Therefore, Slim K is misbranded within the meaning of 21 U.S.C. § 352(j).

48. As noted in paragraph 27 above, analytical testing of B-Lipo (Lot # 20213) detected lorcaserin (7.9 mg). The prescribing information for Belviq (lorcaserin) at the approved twice-daily dose of 10 mg bears warnings about, among other things, the risk of developing serotonin syndrome or hypoglycemia.

49. Lorcaserin, in the amount detected in B-Lipo, has a potential to pose serious adverse health risks in certain patient populations.

50. The labeling for B-Lipo is false or misleading because it does not declare that it contains lorcaserin or reveal the consequences that may result from using a product containing this ingredient. Therefore, B-Lipo is misbranded within the meaning of 21 U.S.C. § 352(a).

51. 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(a), (f)(1), and/or (j).

52. Defendants violate 21 U.S.C. § 331(k) by causing articles of drug that Defendants hold for sale after shipment in interstate commerce to become misbranded within the meaning of 21 U.S.C. §§ 352(a), (f)(1), and/or (j).

Previous Violations

53. Defendants have previously violated the Act, as documented by FDA investigators during an inspection of Defendants' Facility conducted on June 10-11 and 14, 2013. During the 2013 inspection, FDA investigators:

A. Observed Dietary Supplement CGMP deviations that were the same or similar to some of the observations made during FDA's most recent inspection (described in paragraph 10 above). For example, FDA investigators documented Defendants' failure to establish and follow written procedures for reviewing and investigating product complaints, as required by 21 C.F.R. § 111.553;

B. After reviewing Defendants' website, www.bethel30.com, identified many claims that established that Defendants' products were intended to be used to cure, mitigate, treat, or prevent diseases;

C. Observed that Defendants' inventory contained an HCG product not approved for OTC use;

D. Informed Defendant Kariny Ramirez that FDA analyzed Bethel 30 (Lot #120514), an undercover purchase from www.bethel30.com, and detected the presence of sibutramine and phenolphthalein (respectively, at an average of 84.2 mg and 88.9 mg per capsule); and

E. Collected product samples for laboratory analyses. FDA's post-inspection testing revealed that Defendant's Quick Thin (Lot #10032011) contained sibutramine and phenolphthalein (respectively, at an average of 22 mg and 60 mg per capsule) and Bethel Advance (Lot #10092011) contained N-di-desmethylsibutramine, an analog of sibutramine (at an average of 11.9 mg per capsule).

54. FDA has warned Defendants about their ongoing violations. At the close of the 2014/2015 inspection, FDA investigators issued a List of Inspectional Observations ("Form FDA-483") to, and discussed each of the observed Dietary Supplement CGMP deviations with, Defendant Kariny Ramirez. FDA investigators also spoke with Defendant Kariny Ramirez about Defendants' website claims that cause their products to be drugs within the meaning of the Act. In addition, the investigators explained to Ms. Ramirez that Defendants' HCG product is an unapproved new drug. Furthermore, the investigators informed Ms. Ramirez that FDA's analyses found that Slim-K (Lot #140430) contained sibutramine and phenolphthalein, and B-Lipo (Lot #20213) contained lorcaserin.

55. After FDA completed its laboratory analyses of Defendants' product samples collected during the 2013 inspection, FDA informed Defendants that testing detected the presence of sibutramine and phenolphthalein in Quick Thin (Lot #10032011) and N-di-desmethylsibutramine in Bethel Advance (Lot #10092011).

56. At the close of the 2013 inspection, FDA investigators issued a Form FDA-483 to Defendant Kariny Ramirez and discussed each observed Dietary Supplement CGMP deviation with her. The investigators also informed Defendant Kariny Ramirez that: Defendants' website claims cause their products to be drugs within the meaning of the Act; Defendants' HCG product is an unapproved new drug; and FDA's analysis of Defendants' Bethel 30 (Lot #120514) detected sibutramine and phenolphthalein in the product.

57. At the close of the 2013 inspection, Defendant Kariny Ramirez told FDA investigators that she would remove the disease claims from Defendants' website and discontinue sales of their HCG product. Ms. Ramirez also submitted a written promise, dated June 22, 2013, to correct the Dietary Supplement CGMP deviations documented on the 2013 Form FDA-483.

58. During discussions with FDA investigators during the 2014/2015 inspection, Defendant Kariny Ramirez again promised to remove the disease claims from Defendants' website and take actions to correct their Dietary Supplement CGMP deviations. Ms. Ramirez also stated to the investigators that she has not ordered any more HCG products but was continuing to sell Defendants' remaining inventory.

59. Following the 2013 inspection, FDA issued to Defendants a Warning Letter dated October 9, 2014, that detailed many of the violative claims on www.bethel30.com that caused Defendants' products to be unapproved new drugs. The Warning Letter provided 21 examples of products that were drugs within the meaning of the Act because of Defendants' website claims. The Warning Letter noted that, although FDA investigators had made Defendants aware of some of the violative claims during the 2013 inspection, Defendants continued to promote their products for use in the cure, mitigation, treatment, or prevention of diseases - including cancer, Alzheimer's disease, depression, diabetes, rheumatoid arthritis, attention deficit hyperactivity disorder, erectile dysfunction, heart attack, and stroke - as revealed during FDA's follow-up review of www.bethel30.com in September 2014. The Warning Letter emphasized the serious nature of the violations and stated that it was Defendants' responsibility to ensure compliance with the Act and its implementing regulations. The letter also informed Defendants that failure to take prompt action to correct the violations may result in legal action, including injunction.

60. By letter dated October 22, 2014, Defendant Kariny Ramirez responded to the Warning Letter and stated that she had removed the claims from Defendants' website for the products cited in the letter. FDA replied to Ms. Ramirez by letter dated November 19, 2014, and informed her that Defendants' corrective action was inadequate because their website continued

to contain a multitude of disease claims, including some of the same violative claims that FDA had highlighted in the Warning Letter.

61. At the time of the most recent inspection, FDA documented that Defendants' website contained many disease claims for their products, causing them to be unapproved new drugs. Moreover, Defendants had not followed through on promises to correct their Dietary Supplement CGMP violations, as shown by the FDA investigators' observation and documentation of ongoing CGMP deficiencies during the 2014/2015 inspection.

62. 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. 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 Act, in a manner acceptable to FDA;

B. Defendants have methods, processes, and controls adequate to ensure that none of the products that they receive, manufacture, prepare, pack, repack, label, hold, or distribute, and that they market as, or intend to market as, dietary supplements, contain an article "approved as a

new drug" or "authorized for investigation as a new drug" within the meaning of 21 U.S.C. § 321(ff)(3)(B), in a manner acceptable to FDA;

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

D. Defendants' claims do not cause any dietary supplement that they receive, manufacture, prepare, pack, repack, label, hold, or distribute to be a drug within the meaning of the Act, 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);

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

C. 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 misbranded within the meaning of 21 U.S.C. § 343;

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;

E. Violating 21 U.S.C. § 331(k), by causing articles of drug that are held for sale after shipment in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352; and

F. 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).

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 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, including the costs of investigation to date, and such other equitable relief as the Court deems just and proper.

DATED this 13th day of November, 2015.

Respectfully submitted,

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