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IN THE UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA, Plaintiff, v. CLIFFORD WOODS LLC, a limited liability company d/b/a VIBRANT LIFE, and CLIFFORD WOODS, an individual, Defendants.	Case No.: 2:15-cv-8889 **COMPLAINT FOR INJUNCTION AND OTHER EQUITABLE RELIEF**

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

INTRODUCTION

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 civil fraud

injunction statute, 18 U.S.C. § 1345, to enjoin and restrain Defendants from violating:

a. 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 any new drug within the meaning of 21 U.S.C. § 321(p) that is neither approved under 21 U.S.C. § 355, nor exempt from approval;

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

c. 18 U.S.C. §§ 1341 and 1343, by using the United States mail, private interstate carriers, and interstate wire communication to engage in a scheme to defraud.

2. Defendants sell products that they promote as treatments for cancer, type 2 diabetes, Alzheimer's disease, HIV infection, and AIDS—and those are just some of the numerous therapeutic claims for their products. Because Defendants intend that their products be used to cure, prevent, or treat diseases, the products are drugs under the Act. The drugs are also new drugs because they have not been generally recognized as safe and effective for the claimed therapeutic uses in the products' labeling. The drugs have not been approved by the Food and Drug Administration ("FDA") and are not exempt from approval under the Act. Defendants therefore violate the Act by introducing the drugs into interstate commerce.

3. Defendants know they are selling unapproved new drugs. FDA warned them that their products were unapproved new drugs and misbranded drugs. Defendants responded to the warning by stating that they were correcting their "violations" and promising that their websites would be "FDA compliant."

4. But instead of complying, Defendants continue to market drugs—on the internet and in emails to consumers—as treatments for cancer, HIV, and many other diseases, even though the drugs have not been approved by FDA and without revealing to consumers that no well-controlled clinical studies or any other credible scientific substantiation exist to support Defendants' therapeutic claims.

5. Defendants violate the Act by introducing or delivering for introduction, and/or causing to be introduced or delivered for introduction unapproved new drugs and misbranded drugs into interstate commerce, and violate 18 U.S.C. § 1345 by engaging in a scheme to defraud consumers about the absence of scientific support for their therapeutic claims. The United States, in this action, seeks to stop Defendants' violations.

JURISDICTION AND VENUE

6. This Court has jurisdiction under 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331, 1337, and 1345, and personal jurisdiction over all parties.

7. Venue in this district is proper under 28 U.S.C. § 1391.

DEFENDANTS

8. Defendant Clifford Woods LLC is a California company that does business as Vibrant Life, and sells and distributes dietary supplements under the brand name Vibrant Life.

9. Defendant Clifford Woods owns and operates Clifford Woods LLC and serves as executive director of Vibrant Life. He resides in Los Angeles, California.

10. Defendants sell their products online through various websites, including arthritisinformation.net, bulkmsm.com, chelationtherapyonline.com, heart-disease-bypass-surgery.com, oralchelation.com, vibrantlifemsm.com, and vibrantlifenews.com, as well as on a branded page on Facebook.

DEFENDANTS' PRODUCTS ARE DRUGS UNDER THE ACT

11. Under the Act, a product is a drug if it is "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals." 21 U.S.C. § 321(g)(1)(B). Because a product's intended use determines whether it is a drug, a dietary supplement 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) (providing that a dietary supplement shall be deemed to be a food within the meaning of Act, "[e]xcept for purposes of . . . [21 U.S.C. § 321(g), the Act's drug definition]").

12. The intended use of a product may be determined from any relevant source, including labeling and other promotional materials. See 21 C.F.R. § 201.128. The Act defines 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).

13. Defendants market and sell Taheebo Life Tea, Life Glow Plus, Germanium, and Organic Sulfur (identified as "MSM" (methyl sulfonyl methane)) (collectively "the Products"). The Products that Defendants introduce into interstate commerce are drugs within the meaning of the Act because they are "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man." 21 U.S.C. § 321(g)(1)(B). Defendants promote the Products for the cure, mitigation, treatment, and prevention of various diseases (e.g., cancer, Alzheimer's disease, and HIV) in product labeling, on their websites, and in email marketing to consumers. For example, Defendants' promotional materials include the following disease treatment claims for the Products:

a. Taheebo Life Tea (capsules):

i. "The Alternative Cancer Treatment."

ii. "Read about Taheebo as a treatment for cancer."

iii. "Vibrant Life Taheebo Tea seems to bring improvement in cases of cancer, viral problems and yeast infections because it boosts the immune system naturally."

b. Life Glow Plus (capsules and powder):

i. "Although Life Glow Plus was not designed to deal with Erectile Dysfunction - the results that has [sic] occurred with men taking it has [sic] wonderful!"

c. Germanium (capsules and powder):

i. "Germanium has shown results in tumor reduction . . . and relieving rheumatoid arthritis."

d. Organic Sulfur (MSM) (capsules and powder):

i. "MSM can change a cancer cell into a non-malignant cell. Studies have shown that MSM slows the growth rate of cancerous tumors. MSM does not prevent cancer but it will delay the disease. There is still much to learn about msm and cancer but at least you can increase your life span by at least 10 years if you take msm to aid in the prevention of cancer."

ii. "MSM has been shown to be effective in the treatment of diabetes, which occur[s] when the body produces or uses insulin inefficiently."

iii. "MSM is also used for relief of . . . ulcers, . . . obesity, . . . high blood pressure, and high cholesterol. It is also used for type 2 diabetes, liver problems, Alzheimer's disease, lung disorders including emphysema and pneumonia, chronic fatigue syndrome, autoimmune disorders (systemic lupus erythematous [sic]), HIV infection and AIDS, and cancer (breast cancer and colon cancer)."

iv. "[I]f you had more MSM in your body, you would endure far less pain and suffering from . . . Fibromyalgia . . . ."

v. "MSM is used for . . . rheumatoid arthritis, osteoporosis . . . ."

vi. "Other uses of MSM include . . . parasitic infections of the intestinal and urogenital tracts including Trichomonas vaginalis and Giardia, . . . [and] radiation poisoning . . . ."

14. Defendants sometimes print disclaimers, but the disclaimers do not negate Defendants' express claims regarding the Products' ability to treat, cure, mitigate, and prevent diseases.

WOODS PROMISED TO CORRECT VIOLATIONS AFTER PREVIOUSLY BEING WARNED BY FDA

15. Defendants are well aware that their conduct violates the law and that continued violations could lead to an enforcement action.

16. FDA sent a Warning Letter, dated August 7, 2013, to Defendant Woods (operating at that time as Vibrant Life or Vibrant Life Vitamins) concerning the Products and claims found on his websites.

17. The letter informed Defendant Woods that "[t]he therapeutic claims on your websites establish that the products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease," and that "introducing or delivering these products for introduction into interstate commerce for such uses violates the Act."

18. The letter quoted "[e]xamples of some of the website claims that provide evidence that your products are intended for use as drugs," and also quoted "evidence of intended use in the form of personal testimonials recommending or describing the use of products for the cure, mitigation, treatment, or prevention of disease." The letter also noted that "metatags used to bring consumers to your

websites through Internet searches" provided additional evidence that his products were intended for use as drugs.

19. The letter informed Defendant Woods that: "Your above-referenced products are not generally recognized as safe and effective for the above referenced uses and, therefore, are 'new drugs' under section 201(p) of the Act [21 U.S.C. § 321(p)]. New drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from FDA, as described in section 505(a) of the Act [21 U.S.C. § 355(a)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective."

20. The letter further warned Defendant Woods that the labeling for his products lacked adequate directions for use, causing the products to be misbranded, and that introducing a misbranded drug into interstate commerce violates the Act.

21. Identifying himself as Executive Director of Vibrant Life, Defendant Woods responded to FDA's letter on August 19, 2013, by stating that he would "review, investigate and correct where needed" and "probably simply remove any violations I encounter."

22. Defendant Woods sent a subsequent response to FDA, dated September 7, 2013, stating that he had deleted specified material from his websites.

23. FDA replied to Defendant Woods on October 18, 2013, noting that his response was "inadequate" and identified numerous claims remaining on Vibrant Life's websites that cause his products to be drugs.

24. In a letter dated December 16, 2013, Defendant Woods stated that he believed his www.oralchelation.com website was "now FDA compliant" and that "[a]ny additions to this website in the future will be reviewed thoroughly to ensure they are fully FDA compliant."

25. Despite Defendant Woods' promise to ensure that his website is "FDA compliant," Defendants market Taheebo Life Tea to treat cancer, Life Glow Plus to treat erectile dysfunction, Germanium to treat rheumatoid arthritis, and Organic Sulfur (MSM) to treat numerous diseases including diabetes, breast cancer, colon cancer, Alzheimer's disease, lupus, rheumatoid arthritis, HIV infection, and AIDS. None of these products have been approved by FDA for any of these claimed uses.

INTERSTATE COMMERCE UNDER THE ACT AND SECTION 1345

26. Defendants, operating in California, cause their products to be distributed to customers through a fulfillment center located in Idaho. Defendants' products can be ordered online directly from their websites, using a credit card for delivery by an interstate carrier such as FedEx. Defendants' products can also be ordered from the company by telephone.

27. Defendants ship their finished products in interstate commerce using the United States mail or a private interstate carrier. For example, on or about May 4, 2015, Defendants caused Taheebo Life Tea to be shipped from Idaho to Washington, D.C. via FedEx.

28. Defendants market their products on the internet and in emails to persons outside of California, making claims about the drugs' therapeutic benefits via wire in interstate commerce.

COUNT 1

(FOOD, DRUG, AND COSMETIC ACT – DISTRIBUTING UNAPPROVED NEW DRUGS (21 U.S.C. §§ 331(d) & 355(a)))

29. The United States realleges and incorporates by reference paragraphs 1 through 28 of this Complaint as though fully set forth herein.

30. A "new drug" is defined as any drug "the composition of which is such that the 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/GRAE"), it must have substantial evidence of safety and effectiveness. 21 U.S.C. § 355(d).

31. Under the Act, a "new drug" may not be introduced or delivered for introduction into interstate commerce unless FDA has approved a new drug application ("NDA") or abbreviated new drug application ("ANDA") with respect to such drug, or such drug is exempt from approval. 21 U.S.C. §§ 355(a) & 331(d). A drug may be exempt from the Act's new drug approval requirements, 21 U.S.C. § 355(a), if it is the subject of an investigational new drug application ("IND"). 21 U.S.C. § 355(i).

32. The Products are "new drugs" as defined by 21 U.S.C. § 321(p)(1), because they are not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in their labeling. The Products lack substantial evidence of safety and effectiveness. There are no published adequate and well-controlled investigations demonstrating that the drugs are generally recognized as safe and effective for any use and, therefore, qualified experts cannot come to a consensus of opinion concerning the effectiveness of the Products.

33. None of the Products are the subject of an approved NDA or ANDA, or an effective IND. Defendants have no such approvals on file from FDA.

34. Defendants violate 21 U.S.C. § 331(d) by introducing or delivering for introduction into interstate commerce unapproved new drugs. Defendants' history of promoting products to cure, mitigate, treat, and/or prevent diseases,

including, but not limited to, such serious health problems as cancer, HIV, and diabetes, demonstrates their unwillingness to comply with the Act.

COUNT 2

(FOOD, DRUG, AND COSMETIC ACT – MISBRANDED DRUGS (21 U.S.C. § 331(a))

35. The United States realleges and incorporates by reference paragraphs 1 through 34 of this Complaint as though fully set forth herein.

36. The introduction or delivery for introduction into interstate commerce of any drug that is misbranded violates the Act. 21 U.S.C. § 331(a).

37. 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. "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.

38. 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"). 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' Products 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 and reviewed by FDA during the approval process. As noted in paragraph 32 above, there are no well-controlled clinical test data for the Products.

40. In addition, because of the purposes for which they are intended and/or the potential for serious adverse effects, the Products 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. The Products are misbranded within the meaning of 21 U.S.C. § 352(f)(1) because their labeling fails to bear "adequate directions for use," and the Products do not fall within a regulatory exemption from that requirement. See, e.g., 21 C.F.R. Part 201, Subpart D.

42. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce misbranded drugs.

COUNT 3

(CIVIL FRAUD INJUNCTION (18 U.S.C. § 1345))

43. The United States realleges and incorporates by reference paragraphs 1 through 42 of this Complaint as though fully set forth herein.

44. Defendants are engaged in an ongoing scheme to defraud consumers by promoting the Products to cure, mitigate, treat, or prevent diseases despite the absence of well-controlled clinical studies or any other credible scientific substantiation to support those representations and despite having received warnings from FDA that their therapeutic claims violate the law.

45. Defendants ship the Products via the United States mail and/or a private or commercial interstate carrier.

46. Defendants make their representations about the therapeutic value of the Products on the internet and in emails sent via wire in interstate commerce.

47. By reason of the conduct described herein, Defendants violated, are violating, and are about to violate 18 U.S.C. § 1341 by executing a scheme or

artifice to defraud or for obtaining money or property by means of false or fraudulent representations with the intent to defraud, and, in so doing, using the United States mail and/or a private or commercial interstate carrier.

48. By reason of the conduct described herein, Defendants violated, are violating, and are about to violate 18 U.S.C. § 1343 by executing a scheme or artifice to defraud or for obtaining money or property by means of false or fraudulent representations with the intent to defraud, and, in so doing, transmitting writings by wire in interstate commerce for the purpose of executing such scheme or artifice.

49. For instance, Defendants promote Taheebo Life Tea as a treatment for "cancer, viral problems and yeast infections," but the claims are misleading because they conceal the material fact that there are no well-controlled clinical studies or any other credible scientific substantiation to support the use of Taheebo Life Tea in treating those diseases.

50. FDA's August 7, 2013 Warning Letter expressly cited the claim that Taheebo Life Tea could treat "cancer, viral problems and yeast infections" as one of the "[e]xamples of some of the website claims that provide evidence that your products are intended for use as drugs," and Woods agreed that he would "remove any violations" and ensure his website is "fully FDA compliant." But Defendants continue to promote Taheebo Life Tea with the same representations despite knowing that Taheebo Life Tea is an unapproved new drug and despite the absence of credible and meaningful scientific support for their disease claims.

51. As shown above, Defendants promote their Germanium products as a treatment for tumors and rheumatoid arthritis, Life Glow Plus as a treatment for erectile dysfunction, and their Organic Sulfur (MSM) products as a treatment for numerous diseases, including cancer, HIV, and Alzheimer's.

52. These claims are misleading because Defendants conceal the material fact that there are no well-controlled clinical studies or any other credible scientific substantiation to support their disease claims.

53. Although Defendants print disclaimers with much of their promotional materials, the disclaimers do not reveal to consumers that there are no well-controlled clinical studies or any other credible scientific substantiation to support Defendants' representations.

54. Defendants make therapeutic claims for their Products despite clear notice that Defendants' actions were unlawful. Yet Defendants continue to sell the Products and continue to make the same or similar therapeutic claims. In light of the warnings, Defendants' continued marketing of their illegal products shows their intent to defraud consumers.

55. Based on Defendants' conduct, it is evident that, unless restrained by order of this Court, Defendants will continue to violate the Act, 21 U.S.C. § 331(a) and (d), and 18 U.S.C. § 1345.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that the Court:

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

A. Violating 21 U.S.C. § 331(d), by introducing or delivering for introduction into interstate commerce unapproved new drugs; and

B. Violating 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce misbranded drugs.

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 introducing or delivering for introduction into interstate commerce Taheebo Life Tea, Life Glow Plus, Germanium, Organic Sulfur (MSM), or any other product, unless or until:

A. A new drug application or abbreviated new drug application is approved and in effect for the product pursuant to 21 U.S.C. § 355; or

B. An investigational new drug exemption filed pursuant to 21 U.S.C. § 355(i) is in effect for the product; or

C. Defendants have removed all claims that cause their products to be drugs, as defined by the Act, from labeling and other materials, including, but not limited to: (1) websites owned, controlled by, or related to Defendants (including arthritisinformation.net, bulkmsm.com, chelationtherapyonline.com, heart-disease-bypass-surgery.com, oralchelation.com, vibrantlifemsm.com, and vibrantlifenews.com), Defendants' Facebook page(s), any future website created by Defendants, and Defendants' postings on other websites (collectively, "Defendants' websites"); and (2) other product labeling and promotional materials, including videos.

III. Permanently restrain and enjoin, under 18 U.S.C. § 1345, 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 making, directly or indirectly, in connection with the advertising, promoting, or offering for sale, selling, or distributing of

A. Taheebo Life Tea;

B. Life Glow Plus;

C. Germanium;

D. Organic Sulfur (MSM); or

E. any other product,

any representation, expressly or by implication, about the therapeutic benefits of the product, unless the representation is true, non-misleading, and, at the time of making such representation, Defendants possess and rely upon competent and reliable scientific evidence, that is sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable evidence, to substantiate that the representation is true.

IV. Permanently restrain and enjoin, under 18 U.S.C. § 1345, 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 engaging in any mail fraud or wire fraud in connection with the sale of any product promoted as a cure, prevention, mitigation, or treatment of any disease.

V. Order restitution and disgorgement, as appropriate.

VI. Grant judgment to Plaintiff for its costs herein, and that this Court grant such other and further relief as it deems just and proper.

Dated: November 16, 2015

Respectfully submitted,

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