IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

UNITED STATES OF AMERICA, Plaintiff, v. FLOR NUTRACEUTICALS, LLC, a corporation, and GUY LYMAN, an individual, Defendants.	CIVIL NO. 2:16-cv-12655

COMPLAINT FOR INJUNCTIVE 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), 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; and

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/or by introducing or delivering for introduction, and/or causing to be introduced or delivered

for introduction, into interstate commerce dietary supplements that are misbranded within the meaning of 21 U.S.C. § 343.

2. Defendants sell liquid and tablet drug and dietary supplement products named Herpaflor, which they intend as herpes treatments. Because Defendants intend that their products be used to cure, prevent, mitigate, or treat a disease, 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 Herpaflor products have not been approved by the Food and Drug Administration ("FDA"). Defendants therefore violate the Act by introducing the drugs into interstate commerce.

3. Defendants also violate the Act by selling the Herpaflor products in interstate commerce because the Herpaflor products lack adequate directions for lay use.

4. The United States, in this action, seeks to stop Defendants' violations.

JURISDICTION AND VENUE

5. 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.

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

DEFENDANTS

7. Defendant Flor Nutraceuticals, LLC ("Flor") is a corporation incorporated in Texas with its principal place of business in New Orleans, Louisiana.

8. Defendant Guy Lyman is an individual residing in New Orleans, Louisiana, who operates Flor. Lyman is the president and secretary of Flor.

9. Flor sells the Herpaflor products online at www.herpaflor.com.

10. Defendants also ship the Herpaflor products to a distributor in British Columbia, Canada, who sells the same Herpaflor products.

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 several products named Herpaflor, including as a liquid, as tablets, and in various combinations, and introduce them into interstate commerce. The Herpaflor products 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).

14. Defendant Lyman developed the Herpaflor products to treat herpes. The title of several pages on the website for Flor contains terms also indicative of Defendants'

intent in selling the Herpaflor products: "Herpaflor Herpes Cold Sore HSV Outbreak Prevention Relief." The words in the title of a web page are generally visible to consumers at the top of the screen in internet web browsers and can also be read by internet search engines.

15. Although most of the herpes treatment claims have been deleted from the Flor website, Defendants' Canadian distributor expressly markets the same Herpaflor products as a herpes treatment making the following claims, among others:

a. "Only Herpaflör contains all of these 16 proven herpes-killing compounds."

b. "Works great for attacking the Herpes Virus on contact and sends it back into remission."

c. "Herpaflor is an all natural, formula used by those who suffer from the herpes virus and is guaranteed to work 100%."

d. Numerous testimonials purportedly from people who say that because of Herpaflor, they have "way fewer outbreaks," "never get a cold sore," and herpes outbreaks disappear "faster than with anything else."

e. "One of the best ways to relieve the pain during the Herpes outbreak is to take a warm bath or apply Herpaflor Topical Liquid to the sores."

f. "You can treat herpes both 'internally' and 'externally.' Herpaflör® Tablets are capsules taken by mouth, and Herpaflör® Topical is for direct application to the skin."

g. "Q. Is Herpaflör® for both cold sores on the mouth and genital herpes? A. Yes, both are caused by two varieties of the herpes virus (HSV-1 and HSV-2)."

16. For several years, the Flor website operated by Defendants expressly promoted the Herpaflor products as a herpes treatment. Currently, the site does not contain any statements describing what the Herpaflor products are or purport to do. The Flor website explains that because of FDA "regulatory requirements that affect the marketing of products such as Herpaflor … we can no longer provide descriptions of our products, or make any health claims for them." But Defendants expect consumers to continue buying the Herpaflor products as a herpes treatment because, in addition to referring to herpes outbreak prevention in the title of internal pages, the website identifies no other use for the Herpaflor products, and it states that the "issue is the marketing of products, not their safety, so please do not be concerned."

17. A U.S. postal inspector posing as a consumer sent an email to Defendants' Canadian distributor, who responded by comparing Herpaflor favorably to Valtrex, a prescription herpes medicine: "From my personal experience, Herpaflor works just as good if not better than Valtrex with no side effects and is certainly more affordable."

BASED ON PREVIOUS WARNINGS, DEFENDANTS ARE WELL AWARE THEY ARE NOT COMPLYING WITH THE LAW

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

19. FDA and the Federal Trade Commission ("FTC") sent a joint warning letter on April 28, 2011 to Defendants concerning the Herpaflor products marketed at herpaflor.com.

20. The letter stated that statements on the website establish that Defendants' products are drugs because they are "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or function of the body of man." The letter further stated that "these products are 'new drugs,' as defined [in the Act], because they are not generally recognized as safe and effective for their labeled uses" and "a new drug may not be introduced into interstate commerce unless an FDA-approved new drug application (NDA) is in effect for it." The letter quoted examples of some of the website claims that establish that Defendants' products are drugs.

21. The letter further advised that "your products' labeling fails to bear adequate directions for these indications, which causes the products to be misbranded," which also violates the Act when the products are introduced in interstate commerce.

22. On May 6, 2011, Defendant Lyman sent a letter on behalf of Flor to FDA acknowledging receipt of the warning letter and stating that he is providing "information regarding the corrective actions undertaken to date, as well as our planned corrections" so that they can be in "full compliance with all federal laws and regulations." The letter stated that "we have stopped the marketing of Herpaflor products and have removed the products and associated labeling statements from the company's website." The letter further stated that they have retained a "professional regulatory compliance advisor" and "do not intend to sell or reintroduce any of the products until such time as, if ever, the

company can verify, with the support from its advisors, that they are in full compliance with all applicable federal laws and regulations."

INTERSTATE COMMERCE

23. Defendants ship the Herpaflor products in interstate commerce. For example, on or about November 6, 2015, Defendants caused a Herpaflor Combo Pack (consisting of one bottle of Herpaflor Outbreak Response Tablets and one bottle of Herpaflor Topical Outbreak Formula) to be shipped from New Orleans, Louisiana to Washington, D.C. via U.S. Mail.

24. Furthermore, Defendants caused the Herpaflor products to be shipped from Louisiana to British Columbia, Canada, to be sold by their Canadian distributor. The Canadian distributor, in turn, states on its website that it ships the Herpaflor products into other countries, including the United States, and it has done so. On or about July 10, 2015, the Canadian distributor caused a Herpaflor Combo Pack to be sent via Canada Post and U.S. Mail to Washington, D.C. from British Columbia, Canada.

COUNT 1

(FOOD, DRUG, AND COSMETIC ACT –

DISTRIBUTING UNAPPROVED NEW DRUGS (21 U.S.C. §§ 331(d) & 355(a)))

25. The United States realleges and incorporates by reference paragraphs 1 through 25 of this Complaint as though fully set forth herein.

26. 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).

27. 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).

28. Each of the Herpaflor products is a "new drug" as defined by 21 U.S.C. § 321(p)(1), because it 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 its labeling. The Herpaflor products lack substantial evidence of safety and effectiveness. There are no published adequate and well-controlled investigations to show that the Herpaflor products 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.

29. The Herpaflor products are not the subject of an approved NDA or ANDA, nor an effective IND. Defendants have no such approvals on file from FDA.

30. Defendants violate 21 U.S.C. § 331(d) by introducing or delivering for introduction into interstate commerce unapproved new drugs. Defendants' history of

promoting the Herpaflor products to cure, mitigate, treat, and/or prevent herpes demonstrates their unwillingness to comply with the Act.

COUNT 2

(FOOD, DRUG, AND COSMETIC ACT –

MISBRANDED DRUGS (21 U.S.C. § 331(a)))

31. The United States realleges and incorporates by reference paragraphs 1 through 30 of this Complaint as though fully set forth herein.

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

33. 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(a).

34. 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.

35. It is not possible to write adequate directions for use for the Herpaflor 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 28 above, there are no well-controlled clinical test data for the Herpaflor products.

36. In addition, because of the purposes for which they are intended and/or the potential for serious adverse effects, the Herpaflor 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).

37. The Herpaflor 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 they do not fall within a regulatory exemption from that requirement. See, e.g., 21 C.F.R. Part 201, Subpart D.

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

39. 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).

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 and/or dietary supplements;

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 the Herpaflor products or any other product, unless and 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 Defendants' 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 herpaflor.com, herpaflor.ca, and herpestherapy.ca), 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. 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: July 12, 2016

Respectfully submitted,

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