IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
OCALA DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

JAMES R. HILL, an individual d/b/a VIRUXO LLC,

Defendant.

CIVIL NO. 5:15-cv-577-Oc-30PRL

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), and the civil fraud injunction statute, 18 U.S.C. § 1345, to enjoin and restrain Defendant 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. Defendant sells a product that he promotes as a "natural herpes medicine" that can "Stop Herpes Outbreaks"—and those are just some of the numerous therapeutic claims for his herpes product. Because Defendant intends that his product be used to cure, prevent, mitigate, or treat a disease, the product is a drug under the Act. The drug is also a new drug because it has not been generally recognized as safe and effective for the claimed therapeutic use in the product's labeling. The new drug has not been approved by the Food and Drug Administration ("FDA"), and Defendant therefore violates the Act by introducing the drug into interstate commerce.

3. Defendant knows he is selling an unapproved new drug. FDA warned him that his product was an unapproved new drug and misbranded drug. Defendant's representative responded to the warning by stating that Defendant intended to "fully compl[y] with all applicable guidelines and regulations." But instead of complying, Defendant continues to market the drug—on the internet and in emails to consumers—as a treatment for herpes, even though the drug has not been approved by FDA and without revealing to consumers that there are no well-controlled clinical studies or any other credible scientific substantiation to support Defendant's therapeutic claims. Defendant also uses misleading language on his websites and on the container for the product to suggest that the product is a medicine approved by FDA.

4. Defendant violates 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 violates 18 U.S.C. § 1345 by engaging in a scheme to defraud consumers about the absence of scientific support for the therapeutic claims and the lack of FDA approval for the drug. The United States, in this action, seeks to stop Defendant's 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.

THE DEFENDANT

7. Defendant James R. Hill does business as Viruxo LLC, an unincorporated entity, in Ocala, Florida.

8. Defendant sells his products online through various websites, including viruxo.com and viruxo.net.

DEFENDANT'S PRODUCT IS A DRUG UNDER THE ACT

9. 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]").

10. 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).

11. Defendant markets and sells Viruxo Immune Support ("Viruxo"), previously known as Viruxo Anti-Viral Support, and introduces it into interstate commerce. Viruxo is a

drug within the meaning of the Act because it is "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man." 21 U.S.C. § 321(g)(1)(B). Defendant promotes Viruxo for the cure, mitigation, treatment, and prevention of a disease (herpes) in product labeling, on websites, and in emails to consumers. For example, Defendant's promotional materials include the following disease treatment claims for Viruxo:

a. Viruxo is a "natural herpes medicine," the "Best Option to Stop Herpes Outbreaks!" and an "Over The Counter Herpes Medicine."

b. "Viruxo Is The Most Powerful Product Of It's Type, Available Without A Prescription!" (emphasis and typo in the original).

c. "Order Today and Stop Herpes Outbreaks!"

d. "[T]here is no known cure for the Herpes Virus! However, clinical studies have shown, people suffering from this condition can help keep the Virus in an inactive dormant state with a strong healthy Immune System. Viruxo is an amazing product created to do just that!"

12. Defendant sometimes prints disclaimers, but the disclaimers do not negate the express claims regarding Viruxo's ability to treat, cure, mitigate, and prevent diseases.

BASED ON PREVIOUS WARNINGS, DEFENDANT IS WELL AWARE HE IS NOT COMPLYING WITH THE LAW

13. Defendant is well aware that his conduct violates the law and that continued violations could lead to an enforcement action.

14. FDA and the Federal Trade Commission ("FTC") sent a joint warning letter to Viruxo LLC, to the attention of Defendant, concerning Viruxo Anti-Viral Support on April 28, 2011.

15. Citing statements on viruxo.com, the letter informed Defendant that "[t]he therapeutic claims on your website establish that the product is a drug because it is intended for use in the cure, mitigation, treatment, or prevention of disease," and quoted "[e]xamples of some of the claims" on Defendant's website that "establish that your product is a drug."

16. The letter informed Defendant that: "Your product is not generally recognized as safe and effective for the above referenced uses and therefore, the product is a new drug under section 201(p) of the Act [21 U.S.C. § 321(p)]. New drugs may not be legally marketed in the United States 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."

17. The letter further informed Defendant that "your product's labeling fails to bear adequate directions for its intended use, causing the product to be misbranded," and "the introduction of a misbranded drug into interstate commerce" is also a violation of the Act.

18. Defendant was also informed by the letter that "FTC strongly urges you to review all claims for your products and ensure that those claims are supported by competent and reliable scientific evidence."

19. As an initial response to the warning letter, Defendant sent an email, dated April 29, 2011, to FDA that promised: "All issues will be dealt with in a very prompt manor [sic]."

20. Responding via email to FDA and FTC, a representative of Defendant stated on May 11, 2011, that "Viruxo LLC and Jim Hill referred your dual Warning Letter regarding Viruxo.com ... to me for review and recommendations." The email further stated: "At this time the company staff is in the process of removing challenged claims and other identified 'red flag' wording from the web site. This process has already started and will continue over the next few

days." The email concluded: "Our goal is to ensure that the site fully complies with all applicable guidelines and regulations. The intent is to make only substantiated support of normal structure and function claims, and include only testimonials that meet the post-2009 regulatory changes."

21. Despite the statements to FDA, Defendant's websites continue to market Viruxo by describing how it purports to prevent, treat, mitigate, or cure herpes, and the drug has still not been approved by FDA. Thus, despite recognizing the unlawfulness of his actions, Defendant has continued to market and sell Viruxo as a treatment for herpes.

INTERSTATE COMMERCE UNDER THE ACT AND SECTION 1345

22. Defendant ships his finished products in interstate commerce to locations outside of Florida using the United States mail. For example, on or about May 29, 2015, Defendant caused one bottle of Viruxo to be shipped to Washington, D.C. via the U.S. mail.

23. Defendant markets Viruxo on the internet and in emails to persons outside of Florida, making claims about the product via wire in interstate commerce.

COUNT 1

(FOOD, DRUG, AND COSMETIC ACT –

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

24. The United States realleges and incorporates by reference paragraphs 1 through 23 of this Complaint as though fully set forth herein.

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

26. 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).

27. Viruxo 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. Viruxo lacks substantial evidence of safety and effectiveness. There are no published adequate and well-controlled investigations to show that the drug is 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 product.

28. Viruxo is not the subject of an approved NDA or ANDA, nor an effective IND. Defendant has no such approvals on file from FDA.

29. Defendant violates 21 U.S.C. § 331(d) by introducing or delivering for introduction into interstate commerce an unapproved new drug. Defendant's history of promoting Viruxo to cure, mitigate, treat, and/or prevent herpes demonstrates his unwillingness to comply with the Act.

COUNT 2

(FOOD, DRUG, AND COSMETIC ACT –

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

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

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

32. 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).

33. 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.

34. It is not possible to write adequate directions for use for Viruxo 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 27 above, there are no well-controlled clinical test data for Viruxo.

35. In addition, because of the purposes for which it is intended and/or the potential for serious adverse effects, Viruxo is a prescription drug, 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).

36. Viruxo is misbranded within the meaning of 21 U.S.C. § 352(f)(1) because its labeling fails to bear "adequate directions for use," and Viruxo does not fall within a regulatory exemption from that requirement. See, e.g., 21 C.F.R. Part 201, Subpart D.

37. Defendant violates 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))

38. The United States realleges and incorporates by reference paragraphs 1 through 37 of this Complaint as though fully set forth herein.

39. Defendant is engaged in an ongoing scheme to defraud consumers by promoting Viruxo to cure, mitigate, treat, or prevent a disease despite the absence of well-controlled clinical studies or any other credible scientific substantiation to support those representations and despite having received a warning from FDA and FTC that his therapeutic claims violate the law. Defendant also misleadingly suggests that Viruxo is an FDA-approved drug.

40. Defendant ships Viruxo via the United States mail.

41. Defendant makes his representations about the therapeutic value of Viruxo on the internet and in emails sent via wire in interstate commerce.

42. By reason of the conduct described herein, Defendant violated, is violating, and is 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.

43. By reason of the conduct described herein, Defendant violated, is violating, and is 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.

44. The warning letter advised Defendant that his claims must be supported by "competent and reliable scientific evidence."

45. Defendant promotes Viruxo as an over-the-counter medicine that is effective at treating herpes, and claims it has "No Known Side Effects."

46. Defendant's representations are misleading because they conceal the material fact that there are no well-controlled clinical studies or any other meaningful and credible scientific substantiation to support the use of Viruxo in treating herpes.

47. In addition to referring to Viruxo as an "Over The Counter Herpes Medicine," Defendant's websites state that the product is manufactured with "the highest quality pharmaceutical ingredients" and in a "laboratory" or "facility" that is "FDA approved" or "FDA compliant." The container for the product prominently displays the words "Pharmaceutical Grade" and "USA Made FDA Compliant Facility."

48. Defendant's representations are misleading because they falsely suggest that Viruxo is a drug approved by FDA.

49. Defendant makes therapeutic claims for Viruxo despite clear notice in the warning letter that his actions were unlawful. Yet Defendant continues to sell Viruxo and

continues to make the same or similar therapeutic claims. In light of the warning letter, Defendant's continued marketing of his illegal products shows his intent to defraud consumers.

50. Based on Defendant's conduct, it is evident that, unless restrained by order of this Court, Defendant 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), Defendant, and each and all of his 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), Defendant, and each and all of his 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 Viruxo 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. Defendant has removed all claims that cause his 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 Defendant (including viruxo.com and viruxo.net), Defendant's Facebook page(s), any future website created by Defendant, and Defendant's postings on other websites; and (2) other product labeling and promotional materials, including videos.

III. Permanently restrain and enjoin, under 18 U.S.C. § 1345, Defendant, and each and all of his 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 advertising, promoting, or offering for sale, selling, or distributing Viruxo or 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, Defendant possesses and relies 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, Defendant, and each and all of his 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 Viruxo or any other product that is not an FDA-approved drug, any

representation, expressly or by implication, that the product or its manufacturing facility is approved by FDA or that the product is a medicine or drug.

V. Permanently restrain and enjoin, under 18 U.S.C. § 1345, Defendant, and each and all of his 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 18 U.S.C. § 1341, by using the United States mail or any private or commercial interstate carrier to distribute any product that purports to cure, mitigate, prevent, or treat herpes or any other disease or marketing materials that promote his products for the cure, prevention, or treatment of herpes or any other disease;

B. Violating 18 U.S.C. § 1343, by using the internet or otherwise using wire communications in interstate commerce to sell, distribute, or market any product that purports to cure, mitigate, prevent, or treat herpes or any other disease or to publish marketing materials that promote his products for the cure, mitigation, prevention, or treatment of herpes or any disease.

VI. Order restitution and disgorgement, as appropriate.

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

November 12, 2015

Respectfully submitted,

LEE BENTLEY
United States Attorney

RANDY HARWELL
Civil Chief
United States Attorney's Office
400 North Tampa Street
Suite 3200
Tampa, FL 33602
Tel. (813) 301-3008
Randy.Harwell@usdoj.gov

OF COUNSEL:

WILLIAM B. SCHULTZ
General Counsel
ELIZABETH H. DICKINSON
Chief Counsel
Food and Drug Division
PERHAM GORJI
Deputy Chief Counsel for Litigation
CLAUDIA J. ZUCKERMAN
Senior Counsel
Office of the Chief Counsel
Food and Drug Administration
10903 New Hampshire Avenue
Bldg. 31, Room 4550
Silver Spring, MD 20993-0002
301-796-8609

BENJAMIN C. MIZER
Principal Deputy Assistant Attorney General
United States Department of Justice
Civil Division

JONATHAN F. OLIN
Deputy Assistant Attorney General

MICHAEL S. BLUME
Director
Consumer Protection Branch

JILL FURMAN
Deputy Director
Consumer Protection Branch

DANIEL ZYTNICK
Trial Attorney
Consumer Protection Branch
U.S. Department of Justice
P.O. Box 386
Washington, D.C. 20044
Tel. (202) 598-8337
Fax: (202) 514-8742
Daniel.E.Zytnick@usdoj.gov