IN THE UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, Plaintiff, v. LEHAN ENTERPRISES, INC. d/b/a OPTIMUM HEALTH SERVICES, and LESA SVERID, Defendants.	CIVIL NO. 15-13860

COMPLAINT FOR INJUNCTIVE RELIEF

INTRODUCTION

1. The United States brings this statutory injunction action under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), to enjoin and restrain Defendants Lehan Enterprises, Inc., d/b/a Optimum Health Services, and Lesa Sverid 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 new drugs within the meaning of 21 U.S.C. § 321(p) that are 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).

2. Defendants sell topical products that they promote as treatments for cancer, arthritis, glaucoma, bladder diseases, and other diseases. Because Defendants intend that their products be used to cure, prevent, mitigate, or treat diseases, the products are drugs under the

Act. The drugs are also new drugs within the meaning of the Act 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 has warned Defendant Sverid that the products are unapproved new drugs and misbranded drugs. Although Defendants made some modifications to the therapeutic claims, Defendants continue to market the drugs—on the internet and in printed material sent to purchasers—as a treatment for diseases, even though the drugs have not been approved by FDA for the claimed uses. The Act's premarket approval requirement for new drugs helps ensure, among other things, that the public is not misled by unsubstantiated claims of safety and effectiveness. Based on information and belief, Defendants' safety and effectiveness claims have not been scientifically substantiated. Accordingly, the claims are likely to mislead consumers of Defendants' products.

4. Defendants violate the Act by introducing or delivering for introduction, and/or causing to be introduced or delivered for introduction, into interstate commerce unapproved new drugs and misbranded drugs. 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 Lehan Enterprises, Inc., is a corporation incorporated in Massachusetts with its principal place of business in Hyannis, Massachusetts. It does business as Optimum Health Services ("Optimum").

8. Defendant Lesa Sverid operates Optimum as the named president, treasurer, secretary, and director of Lehan Enterprises, Inc.

9. Defendants sell their products online through www.neveranoutbreak.com.

DEFENDANTS' PRODUCTS ARE DRUGS UNDER THE ACT

10. 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).

11. 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).

12. Defendants market and sell products that purport to contain DMSO (dimethyl sulfoxide), including "DMSO Cream," "DMSO Cream with Aloe," and "DMSO Roll On" (collectively, the "DMSO Products"), and introduce them into interstate commerce.

13. Defendants promote the DMSO Products for the cure, mitigation, treatment, and prevention of diseases in product labeling and on their website, www.neveranoutbreak.com. For example, internal pages on Defendants' website, which are accessible through internet searches, make numerous claims about DMSO Products' ability to cure, mitigate, and treat diseases:

a. "Although denounced by the FDA and other government organizations as a medical scam, DMSO has been proposed and discussed by medical professionals for decades as a treatment for many diseases, including arthritis and cancer."

b. "DMSO is used extensively throughout the world as a medical treatment for many inflictions, including arthritis, head and spinal cord injuries, infectious diseases, herpes, bladder infections and diseases and much more."

c. "The use of DMSO can be found to alleviate symptoms of inflammation from arthritis and sports injuries[,] to help treat infections like the herpes virus[,] to giving [sic] relief to interstitial cystitis of the bladder, aid in the healing of minor burns, and helping [sic] with spinal cord and head injuries."

d. "DMSO has been successful with reducing the pain of headaches, osteoarthritis, facial pain and interstitial cystitis. DMSO is often used for eye conditions like cataracts, glaucoma and retina issues. Fungus of the toe nails, bunions and calluses heal quicker with the topical use of DMSO. It can also be used to topically treat skin damage from certain chemotherapies. It speeds the healing of herpes outbreaks when used topically several times a day."

e. "DMSO is what the natural community touts as being great for healing burns, reducing inflammation, muscular pain, herpes, shingles, gall stones, joint disease and more. Some have found headache relief after applying DMSO topically along with some eye conditions like glaucoma and cataracts. It is also used with chemotherapy to treat skin and tissue damage that can happen from chemo agents leaking onto the skin."

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

15. In addition, a flyer sent by Defendants to the purchaser of a DMSO product provided these instructions: "[A]pply a small amount to any affected area that is causing you concern like arthritis, bursitis, … burns, etc."

16. In response to an online inquiry to Optimum by a person purporting to have prostate cancer, an individual responding on behalf of Defendants wrote in an email that he would explain how to cure the disease and advised against traditional treatments:

> I can tell you exactly how to cure your prostate cancer. But I am occupied at this moment. I will email you later today or tomorrow. Do not undergo chemotherapy, radiation or operation.

17. An individual writing on behalf of Defendants subsequently sent two emails advising the recipient to use DMSO Cream as part of his cancer treatment. Although the individual began one of those emails by stating that "I am not a doctor and cannot describe how to heal yourself of cancer," in the next paragraph he stated that the "DMSO/cesium/potassium protocol … is the most effective cancer treatment available today." Responding to a subsequent email seeking clarification, the individual stated: "I recommend the DMSO cream with aloe." That is one of the DMSO Products sold by Defendants.

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. On April 28, 2011, FDA and the Federal Trade Commission sent a joint warning letter to Defendant Sverid concerning the DMSO Products and other products marketed at www.neveranoutbreak.com.

20. The letter informed Defendant Sverid that statements on the website established that Defendants' products are drugs as defined by the Act 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 quoted "[e]xamples of some of the [website] claims" that establish that Defendants' products are drugs.

21. The letter further explained 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."

22. In addition, the letter advised Defendant Sverid that "your products' labeling fails to bear adequate directions for these indications, which causes the products to be misbranded." The letter explained that, because the DMSO Products are intended to treat conditions such as genital herpes, a disease that is not amenable to self-diagnosis and treatment by individuals who are not medical practitioners, "adequate directions for use cannot be written for them so that a layperson can use your products safely for these uses."

23. On May 16, 2011, Defendant Sverid sent an email to FDA stating that it is "our wish to fully comply with all the regulations controlling the sale and marketing of our products" and identifying a number of ways she had removed therapeutic claims from the www.neveranoutbreak.com website, online advertising, and product labeling.

24. Sverid later requested that FDA consider the matter closed. FDA responded by letter dated November 13, 2012, which stated that "you have not made adequate corrections to be in compliance with federal law" and identified numerous claims that caused Defendants' products to be drugs under the Act.

25. Defendants' website and material accompanying their products continue to market the DMSO Products by describing how they are used to prevent, treat, mitigate, or cure diseases, yet the DMSO Products remain unapproved by FDA. Although some of the specific therapeutic claims identified by FDA were modified in various ways, numerous other disease claims remain. Thus, despite recognizing the unlawfulness of their actions, Defendants have continued to market and sell the DMSO Products in violation of the Act.

INTERSTATE COMMERCE

26. Defendants ship their finished DMSO Products in interstate commerce to locations outside of Massachusetts. For example, on or about June 25, 2015, Defendants caused one container of DMSO Cream to be shipped from Hyannis, Massachusetts, to Washington, D.C. via the U.S. mail.

COUNT 1

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

27. The United States realleges and incorporates by reference paragraphs 1 through 26 of this Complaint as though fully set forth herein.

28. 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, it must have substantial evidence of safety and effectiveness. 21 U.S.C. § 355(d).

29. 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).

30. Each of the DMSO 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 DMSO Products lack substantial evidence of safety and effectiveness. There are no published adequate and well-controlled investigations to show 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 DMSO Products.

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

32. 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 DMSO Products to cure, mitigate, treat, and/or prevent diseases demonstrates their unwillingness to comply with the Act.

COUNT 2

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

33. The United States realleges and incorporates by reference paragraphs 1 through 32 of this Complaint as though fully set forth herein.

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

35. 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" are defined as "directions under which the layman can use a drug safely and for the purposes for which it is intended." 21 C.F.R. § 201.5.

36. The DMSO Products are intended for use in the treatment and prevention of conditions such as herpes, arthritis, and cancer, which are not amenable to self-diagnosis and which require the supervision of a practitioner licensed to prescribe drugs. Because of the purposes for which they are intended and/or the potential for serious adverse effects, Defendants' DMSO Products are prescription drugs as defined by 21 U.S.C. § 353(b)(1). By definition, a drug that is a prescription drug cannot have adequate instructions for lay use. See 21 U.S.C. § 352(f)(1); 21 C.F.R. § 201.5(a).

37. In addition, it is not possible to write adequate directions for use for the DMSO 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 alleged in paragraph 30 above, there are no well-controlled clinical test data for the DMSO Products.

38. The DMSO 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.

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

40. 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;

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 DMSO 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' DMSO 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 www.neveranoutbreak.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. Order restitution and disgorgement, as appropriate;

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

Dated: November 16, 2015

Respectfully submitted,

CARMEN ORTIZ
United States Attorney

/s/ Deana K. El-Mallawany
DEANA K. EL-MALLAWANY
BBO #674825
Assistant United States Attorney
One Courthouse Way
Suite 9200
Boston, MA 02210
Tel. (617) 748-3652
deana.el-mallawany@usdoj.gov

OF COUNSEL:
WILLIAM B. SCHULTZ
General Counsel

ELIZABETH H. DICKINSON
Chief Counsel
Food and Drug Division

PERHAM GORJI
Deputy Chief Counsel, Litigation
Office of the Chief Counsel

CHARLOTTE F. HINKLE
Assistant Chief Counsel for Enforcement
Office of the Chief Counsel
Food and Drug Administration
10903 New Hampshire Avenue
Bldg. 31, Room 4525
Silver Spring, MD 20993
301-796-6629

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

/s/ Daniel Zytnick
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