IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MISSOURI
SOUTHERN DIVISION

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	**Civil No. 05-3494-CV-FJG**
v.	)	
	)	
VITA-ERB, LTD., a business, and MARY BARNES, MOSES R. BARNES, and FRED R. PAULICKA, PH.D., individuals,	)	
	)	
Defendants.	)	

SUPPLEMENTAL COMPLAINT FOR PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, 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), to enjoin Vita-Erb, Ltd. ("Vita-Erb" or "the firm"), a business, and Mary Barnes, Moses R. Barnes, and Fred R. Paulicka, individuals (hereafter, collectively "Defendants") from:

A. Violating 21 U.S.C. § 331(d) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce new drugs within the meaning of 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);

B. Violating 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B);

C. Violating 21 U.S.C. § 331(k) by causing drugs that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B);

D. Violating 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are misbranded within the meaning of 21 U.S.C. §§ 352(a) and (e)(1)(A)(ii); and

E. Violating 21 U.S.C. § 331(k) by causing drugs that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become misbranded within the meaning of 21 U.S.C. §§ 352(a) and (e)(1)(A)(ii).

2. This Court has jurisdiction over the subject matter and over all parties to this action pursuant to 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 ©).

The Defendants

4. Defendant Vita-Erb is a business incorporated in the State of Illinois on June 27, 1978. Upon information and belief, this corporation was administratively dissolved on November 2, 1992. Upon information and belief, the Missouri registered foreign corporation, Vita-Erb Inc., Ltd., was administratively dissolved on March 5, 2003. Vita-Erb is located at 1358 North Stewart Avenue, Springfield, Missouri, within the jurisdiction of this Court. Vita-Erb manufactures a liquid herbal extract drug product that is intended to prevent and treat cancer.

The firm also has been and is currently manufacturing, processing, packing, labeling, holding, and/or distributing over-the-counter ("OTC") drugs for human use in interstate commerce that include, but are not limited to medicated shampoos that treat scalp conditions, pain relieving gels, and antimicrobial hand cleansers.

5. Defendant Mary Barnes, an individual, is the President and co-owner of Vita-Erb. She is present at the firm on a daily basis and has authority over the administrative duties, financial operations, and acquisition of new customers for the firm. Ms. Barnes performs her duties at 1358 North Stewart Avenue, Springfield, Missouri, within the jurisdiction of this Court.

6. Defendant Moses R. Barnes, an individual, is the husband of Mary Barnes and is the Vice-President and co-owner of Vita-Erb. He is present at the firm on a daily basis and is the firm's Quality Assurance Director. Mr. Barnes is responsible for overseeing the receipt of raw materials and the manufacture, packaging, and distribution of products. He performs his duties at 1358 North Stewart Avenue, Springfield, Missouri, within the jurisdiction of this Court.

7. Defendant Fred Paulicka, Ph.D., an individual, is the firm's consultant and is also a co-owner of Vita-Erb. Dr. Paulicka resides outside the State of Missouri, but he makes periodic visits to 1358 North Stewart Avenue, Springfield, Missouri several times a year. He also speaks regularly with Defendant Moses R. Barnes and assists the firm in developing new product lines, creating product formulas, and establishing test specifications. Dr. Paulicka also advises Vita-Erb regarding compliance with FDA laws and regulations.

8. Defendants manufacture, process, pack, label, hold, and/or distribute various OTC products that are drugs within the meaning of 21 U.S.C. § 321(g). These products are drugs because the products' container labels, promotional labeling, and formula information, as well as

other information, establish that the products are intended to be used in the cure, mitigation, treatment, and prevention of diseases in man and/or to affect the structure or function of the human body.

9. Defendants manufacture drugs using components they receive in interstate commerce, and they introduce or deliver for introduction into interstate commerce finished drug products.

10. The United States Food and Drug Administration ("FDA") conducted eight inspections of Vita-Erb on October 18 to 20, 2005, March 3 to 10, 2005, August 23 to 30, 2004, October 27 to November 12, 2003, February 19 to March 14, 2003, April 29 to May 2, 2002, September 29 to October 1, 1999, and December 11 and 12, 1997. During the five most recent inspections, FDA discovered that Defendants manufacture, hold, and/or distribute unapproved new drugs in violation of 21 U.S.C. § 331(d) and misbranded drugs in violation of 21 U.S.C. §§ 331(a) and 331(k). Moreover, in every inspection dating back to December 1997, FDA has documented numerous violations by Defendants of FDA current good manufacturing practice ("CGMP") regulations, 21 C.F.R. Parts 210 and 211, that cause the adulteration of Vita-Erb's drug products within the meaning of 21 U.S.C. § 351(a)(2)(B). Defendants distribution of these adulterated drug products in interstate commerce violates 21 U.S.C. §§ 331(a) and 331(k).

Unapproved New Drugs

11. FDA's inspections in October 18 to 20, 2005, March 3 to 10, 2005, August 23 to 30, 2004, October 27 to November 11, 2003, and February 19 to March 14, 2003, revealed that Defendants manufacture, process, pack, hold, and/or distribute unapproved new drugs. They introduce the unapproved new drugs or cause them to be introduced into interstate commerce, in violation of 21 U.S.C. § 331(d). These unapproved new drugs include:

- THE ORIGINAL HERBAL TEA CONCENTRATE (also known as THE ORIGINAL CELL REVITALIZER)
- OBEDIENCE MEDICATED SHAMPOO S-S
- HANDCLEANER, WATERLESS CREAM FORM - ANTIMICROBIAL
- VITA-ERB ARTHRITIS PAIN FORMULA (also known as VALLEY-OF-YOUTH R-THRITIS RELIEF ROLL-ON)
- FLOWS HERBAL FOOT & BODY SOAK
- PES 828 PAIN RELIEVING GEL WITH ILEX
- PES CLEAN - INSTANT ANTISEPTIC HAND CLEANER
- SEWSOFT PAIN RELIEVING GEL

12. The drugs listed in Paragraph 11 (hereafter, "the Paragraph 11 Drugs") are "new drugs" within the meaning of 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.

13. The Paragraph 11 Drugs lack an approved new drug application (i.e. THE ORIGINAL HERBAL TEA CONCENTRATE; OBEDIENCE MEDICATED SHAMPOO S-S; HANDCLEANSER, WATERLESS CREAM FORM - ANTIMICROBIAL; VITA ERB ARTHRITIS PAIN FORMULA; FLOWS HERBAL FOOT & BODY SOAK; PES 828 PAIN RELIEVING GEL WITH ILEX; PES CLEAN - INSTANT ANTISEPTIC HAND CLEANER; and SEWSOFT PAIN RELIEVING GEL) and/or fail to comply with an established OTC monograph (i.e. OBEDIENCE MEDICATED SHAMPOO S-S).

14. FDA has established and published monographs that identify certain categories of drugs that can be marketed as OTC drugs, provided they comply with specific regulatory criteria. See 21 C.F.R. Part 330. Drugs marketed in conformance with these OTC monographs are generally recognized as safe and effective, 21 C.F.R. § 330.1, and can be marketed without the submission and approval of new drug applications ("NDAs").

15. Defendants manufacture, process, pack, label, hold, and distribute at least one OTC drug product that is subject to an FDA monograph: OBEDIENCE MEDICATED SHAMPOO S-S. OBEDIENCE MEDICATED SHAMPOO S-S is subject to the monograph governing "Drug Products for the Control of Dandruff, Seborrheic Dermatitis, and Psoriasis," 21 C.F.R. Part 358 (hereafter, "the Dandruff Monograph"). However, this drug product fails to comply with the requirements of the Dandruff Monograph because its labeling fails to include the directions for use required by 21 C.F.R. § 358.750(d)(1). Therefore, OBEDIENCE MEDICATED SHAMPOO S-S is not generally recognized as safe and effective for the use recommended, prescribed, or suggested in its labeling.

16. There is not now, nor has there ever been, an approved NDA filed with the FDA pursuant to 21 U.S.C. §§ 355(b) or (j) for any of the Paragraph 11 Drugs. Moreover, the Paragraph 11 Drugs are not exempt under 21 U.S.C. § 355(I) from the pre-market approval requirement.

17. As a result of the allegations described in ¶¶ 11-16, all of the Paragraph 11 Drugs are unapproved new drugs within the meaning of 21 U.S.C. § 355(a).

Adulteration

18. Defendants' drugs are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B) in that the methods used in, and the facilities and controls used for, their manufacture, processing, packing, or holding do not conform to FDA's CGMP regulations. *See* 21 C.F.R. Parts 210 and 211.

19. FDA's CGMP regulations include procedures and practices that are intended to ensure that drugs have the quality, purity, and other attributes necessary for their safe and

effective use. FDA has promulgated regulations establishing minimum CGMP requirements applicable to human drugs. *See* 21 C.F.R. Parts 210 and 211. These regulations require manufacturers to control all aspects of the processes and procedures by which drugs are manufactured, processed, packed, or held to prevent production of unsafe and ineffective products. Drugs not manufactured, processed, packed, or held in conformance with CGMP regulations are deemed adulterated as a matter of law, without any showing of an actual defect. *See* 21 U.S.C. § 351(a)(2)(B).

20. In FDA's October 18-20, 2005, inspection of Vita-Erb, FDA observed and documented numerous violations of CGMP regulations, including, but not limited to:

A. The failure to establish changes in finished product testing procedures (*see* 21 C.F.R. § 211.165);

B. The failure to implement a written testing program designed to assess the stability characteristics of drug products (*see* 21 C.F.R. § 211.166(a));

C. The failure to establish scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality, and purity (*see* 21 C.F.R. § 211.160(b));

D. The failure to thoroughly review discrepancies in drug production records (*see* 21 C.F.R. § 211.192);

E. The failure to establish written procedures for evaluating, at least annually, the quality standards for each drug product, which include provisions requiring a review of investigations conducted under 21 C.F.R. § 211.192 (related to review of production records) for each product (*see* 21 C.F.R. § 211.180(e)(2)); and

F. The failure to establish written procedures for cleaning and maintenance of equipment that includes a description in sufficient detail of the methods, equipment, and materials used in cleaning and maintenance operations (*see* 21 C.F.R. § 211.67(b)(3)); and

G. The failure to have a quality control unit that reviews production records to assure that no errors have occurred, or if errors have occurred, that they have been fully investigated, and the failure to have written responsibilities and procedures applicable to the quality control unit (*see* 21 C.F.R. §§ 211.22(a) and (d)).

21. FDA's prior inspections of Defendants' facility during March 3 to 10, 2005; August 23 to 30, 2004; October 27 to November 12, 2003; February 19 to March 14, 2003; April 29 to May 2, 2002; September 29 to October 1, 1999; and December 11 and 12, 1997; also revealed numerous significant violations of the CGMP regulations. Many of the violations in these inspections are similar to the CGMP violations observed during the most recent inspection.

Misbranding

22. FDA's three most recent inspections also revealed that at least two drugs manufactured by Defendants, PES 828 PAIN RELIEVING GEL WITH ILEX and MEDI-DERM ANALGESIC LOTION, are misbranded as follows:

A. PES 828 PAIN RELIEVING GEL WITH ILEX is misbranded under 21 U.S.C. § 352(a) because its label is misleading. Specifically, its label includes the proprietary name "Germaben II," a preservative that is made from four inactive ingredients. By only including the proprietary name of the preservative, the label: fails to reveal the proportion of the ingredients in the preservative; implies that Germaben II plays a therapeutic role in the formulation, even though its ingredients are inactive; and creates an impression that the inactive

ingredients have a value greater than a mere preservative. See 21 C.F.R. §§ 201.10(c)(2), (3), and (4); and

B. MEDI-DERM ANALGESIC LOTION (hereafter, "MEDI-DERM") is misbranded under 21 U.S.C. § 352(e)(1)(A)(ii). A drug is misbranded within the meaning of 21 U.S.C. § 352(e)(1)(A)(ii) unless "its label bears . . . the established name and quantity . . . of each active ingredient . . . ." MEDI-DERM is misbranded because its label is missing the established name of its active ingredient.

Prior Warnings To Defendants

23. At the end of each of inspection, FDA issued a List of Inspectional Observations ("Form FDA-483") to Defendants and discussed with them the violative conditions observed by the investigators. In addition, FDA held a meeting with Mr. Barnes and Dr. Paulicka on August 21, 2002, and issued Warning Letters to Mary Barnes on April 29, 2004, June 7, 2002, and January 23, 1998.

24. The April 29, 2004, Warning Letter notified Mary Barnes that Vita-Erb manufactures numerous products that violate the new drug and misbranding provisions of the Act. The Warning Letter stressed that Defendants were responsible for promptly ensuring that all products manufactured by Vita-Erb comply with the Act and that a failure to do so may result in regulatory action without further notice.

25. The June 7, 2002 Warning Letter put Mary Barnes on notice that Vita-Erb was violating the CGMP statute and regulations and requested that the firm take prompt action to correct these violations. Shortly after this letter was sent to Ms. Barnes, FDA met with Mr. Barnes and Dr. Paulicka to discuss Vita-Erb's continuing CGMP violations. The January 23,

1998 Warning Letter outlined the CGMP deficiencies documented during FDA's inspection of Vita-Erb during December 11 and 12, 1997.

26. Defendants have made many promises to correct all of their violations of the Act. In fact, for approximately seven years Defendants have promised FDA that Vita-Erb would come into compliance with the Act. Despite FDA's repeated warnings and Defendants' promises, FDA has documented little or no improvement. Each inspection reveals Defendants' continued inability and/or unwillingness to operate in compliance with the Act.

27. Based on the foregoing, FDA believes that Defendants will continue to violate 21 U.S.C. §§ 331(a), 331(d), and § 331(k) in the manner set forth above, unless restrained by this Court.

WHEREFORE, Plaintiff respectfully requests:

I. That Defendants Vita-Erb, Ltd., a business; Mary Barnes, Moses R. Barnes, and Fred R. Paulicka, individuals; and each and all of their directors, officers, agents, representatives, employees, successors, assigns, attorneys, 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 and indirectly doing or causing to be done the following acts:

A. Violating 21 U.S.C. § 331(d) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce new drugs within the meaning of 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);

B. Violating 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B);

C. Violating 21 U.S.C. § 331(k) by causing drugs that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B);

D. Violating 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are misbranded within the meaning of 21 U.S.C. §§ 352(a) and (e)(1)(A)(ii); and

E. Violating 21 U.S.C. § 331(k) by causing drugs that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become misbranded within the meaning of 21 U.S.C. §§ 352(a) and (e)(1)(A)(ii).

II. That FDA be authorized pursuant to this injunction to inspect Defendants' places of business and all records relating to the receipt, manufacture, processing, packing, labeling, holding, and distribution of any drug to ensure continuing compliance with the terms of the injunction, with the costs of such inspections to be borne by Defendants at the published rates prevailing at the time the inspections are accomplished; and

III. Award plaintiff costs and other such relief as the Court deems just and proper.

DATED this 9th day of June, 2006.

Respectfully submitted,

Bradley J. Schlozman
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By

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