



JUN 15 2006

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Whitney Anderson
MyHealthPro.com, Inc.
322 Seventh Avenue
New York, New York 10001

Ref. No. CL-06-HFS-810-225

Dear Ms. Anderson:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address <http://www.myhealthpro.com> and has determined that the products "Olive Leaf Extract D-Lenolate" and "Oxygen Elements Plus" are promoted for conditions that cause the products to be drugs under section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)]. The therapeutic claims on your web site establish that the products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease. The marketing of these products with these claims violates the Act.

Examples of some of the claims observed on your web site include:

Olive Leaf Extract D-Lenolate

"Disease causing pathogens are viruses, bacteria ..."

"One of the most common disease causing pathogens is *Candida* [sic], a single cell fungi that lives within our blood stream, releasing powerful poisons and toxins as it multiplies. The Center for Disease Control (CDC) estimates; by age six months, 90% of all babies born in the U. S. will test positive for *Candida*. By adulthood, virtually *All* [sic] humans play host to *Candida Albicans* and are thus engaged in a life long relationship. Later in life, the *Candida* can manifest itself into various symptoms as follows:

Fatigue, lethargy depression, headaches, muscle aches or weakness, joint pain, abdominal pain, constipation, diarrhea, gas, vaginal burning, itching or vaginal discharge, prostatitis, anxiety, infertility, menstrual problems, PMS, insomnia, eczema, itching eyes, psoriasis, sensitivity to some foods, nervous system problems, recurrent yeast infections in women, allergies, sinus problems, recurrent colds and flu, indigestion, respiratory problems, food cravings, asthma and both over and under weight issues.

A clinical, double-blind, randomized-placebo control study was performed by Dr. Bernard J. Mizock's [sic] laboratory in Chicago, Illinois. The study was conducted in 30 subjects for 60 days. Basal metabolic panels, complete blood counts and Somatomedin-C levels of each subject were recorded at the beginning and completion of the study. Subjects were given 6 capsules per day of either East Park's [sic] D-Lenolate or the placebo. The study was performed from January through June of 1999.

The results are that virtually all of the subjects taking East Park's [sic] D-Lenolate had normal blood counts and basal metabolic panels. The mean score at baseline was 250. Within 60 days of taking D-Lenolate, symptoms were reduced by greater than 50%.

The Conclusion is that East Park's [sic] D-Lenolate will reduce the symptoms of chronic yeast infections by greater than 50% within 60 days of use, with no apparent side effects. This was the finding and conclusion of Dr. Bernard J. Mizock, MD, FACS."

Oxygen Elements Plus

"Inhibits infectious bacteria, viruses, fungi and parasites"

Furthermore, your products are not generally recognized as safe and effective for the above referenced conditions and therefore, the products are also "new drugs" under section 201(p) of the Act [21 U.S.C. § 321(p)]. New drugs may not be legally marketed in the U.S. 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.

FDA is aware that Internet distributors may not know that the products they offer are regulated as drugs or that these drugs are not in compliance with the law. Many of these products may be legally marketed as dietary supplements if claims about diagnosis, cure, mitigation, treatment, or prevention are removed from the promotional materials and the products otherwise comply with all applicable provisions of the Act and FDA regulations.

Under the Act, as amended by the Dietary Supplement Health and Education Act, dietary supplements may be legally marketed with truthful and non-misleading claims to affect the structure or function of the body (structure/function claims), if certain requirements are met. However, claims that dietary supplements are intended to prevent, diagnose, mitigate, treat, or cure disease (disease claims), excepting health claims authorized for use by FDA, cause the products to be drugs. The intended use of a product may be established through product labels and labeling, catalogs, brochures, audio and videotapes, Internet sites, or other circumstances surrounding the distribution of the product. FDA has published a final rule intended to clarify the distinction between structure/function claims and disease claims. This document is available on the Internet at <http://vm.cfsan.fda.gov/~lrd/fr000106.html> (codified at 21 C.F.R. § 101.93(g)).

In addition, only products that are intended for ingestion may be lawfully marketed as dietary supplements. Topical products and products intended to enter the body directly through the skin or mucosal tissues, such as transdermal or sublingual products, are not dietary supplements. For these products, both disease and structure/function claims may cause them to be new drugs.

Certain over-the-counter drugs are not new drugs and may be legally marketed without prior approval from FDA. Additional information is available in Title 21 of the Code of Federal Regulations (21 C.F.R.) Parts 310 and 330-358, which contain FDA's regulations on over-the-counter drugs.

This letter is not intended to be an all-inclusive review of your web site and products your firm markets. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations.

If you need additional information or have questions concerning any products distributed through your web site, please contact FDA. You may respond in writing to Linda J. Webb,

Compliance Officer, Food and Drug Administration, Division of Dietary Supplement Programs, 5100 Paint Branch Parkway, College Park, Maryland 20740-3835. If you have any questions concerning this letter, please contact Ms. Webb at (301) 436-2375.

Sincerely yours,

/s/

Robert J. Moore, Ph.D.
Team Leader, Compliance and Enforcement
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition