

**CERTIFIED MAIL**
RETURN RECEIPT REQUESTED

Tim Lally
President
Optimal Nutrients
1163 Chess Drive, Suite F
Foster City, CA 94404

February 2, 2005

Ref. No. CL-04-HFS-810-117

Dear Mr. Lally:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address <http://www.optimalnutrients.com> and has determined that the products Borage, EPA (Fish Lipid Concentrate), Flax (100% Organic Flax Seed Oil), Evening Primrose Oil, Attention Support, Barley (Barley Juice Powder), Cat's Claw, COQ10 (Co-Enzyme Q10), DHEA (Dehydroepiandrosterone), St. John's Wort, and Valerian Root are promoted for conditions that cause these 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 these products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of diseases. The marketing of these products with these claims violates the Act. Examples of some of the claims observed on your web site include:

Borage

- "GLA is part of the Omega 6 series of essential fatty acids and is the critical precursor to the Series 1 prostaglandins (PGE1) The PGE1 prostaglandins protect the body against ...high blood pressure" "GLA lowers high blood pressure"
- "GLA is frequently deficient in people with eczema, altherosclerosis [sic] and diabetes mellitus"

EPA (Fish Lipid Concentrate)

- "EPA is a precursor of the Series 3 prostaglandins, ...which protect the body from ... high blood pressure DHA is important for ... lowering ... cholesterol levels."
- "Omega 3 EFAs help with high blood pressure ..."
- "Omega 3 EFAs help lower blood ...cholesterol levels"

Flax (100% Organic Flax Seed Oil)

- "Flax Seed Oil is an important source of alpha-linolenic acid (ALA), an Omega 3 series of essential fatty acids. ALA is the precursor to EPA and the Series 3 prostaglandins ... 3PGEs protect the body against the deleterious effects of high blood pressure"

Omega 3 fatty acids help lower cholesterol ... and prevent clots in arteries which may result in strokes, heart attacks, and thromboses.”

- “Omega 3 EFAs help with high blood pressure ...”
- “Omega 3 EFAs help lower blood ... cholesterol levels”

Evening Primrose Oil

- “GLA is a critical nutrient necessary to prevent hardening of the arteries, heart disease, ... multiple sclerosis, and high blood pressure. GLA aids in lowering cholesterol levels, ... and is important in treating cirrhosis of the liver.”
- “GLA may have a positive effect on lowering cholesterol levels”

Attention Support

- “Attention Support contains efficacious doses of ... DMAE ... DMAE has been studied for its ability to increase ...intelligence in children with ADD.”

Barley (Barley Juice Powder)

- “Research and testimonials from Japan suggest that green barley juice can be beneficial in asthma, obesity, ... anemia, and arthritis.”
- “Helps provide nutritional support for people with asthma, anemia, and arthritis”

Cat’s Claw

- “[H]elps create support for people experiencing different stomach and bowel disorders including: colitis, Crohn’s disease, irritable bowel syndrome, and leaky bowel syndrome.”
- “[H]elping with Crohn’s disease, colitis, and leaky bowel syndrome”
- “Aids in relief with arthritis, bursitis, and rheumatism”
- “Helps create support for chemotherapy patients”

COQ10 (Co-Enzyme Q10)

- “CoQ10 may become standard therapy for the prevention and treatment of cardiovascular disease, including angina pectoris and congestive heart failure. CoQ10 deficiency has been reported in 60% to 96% of patients with gingivitis. Deficient levels of CoQ10 have been found in diabetes mellitus, onperiodinatal disease, and muscular dystrophy.”

DHEA (Dehydroepiandrosterone)

- “Studies have shown a direct relationship between plasma DHEA levels and the inhibition of many degenerative diseases.”

- “DHEA works to lower serum cholesterol ...”

St. John’s Wort

- “Xanthrones and hypericin are MAO inhibitors, which can retard the breakdown of serotonin and norepinephrine, leading to improvement in the symptoms of depression.... Hypericin and pseudohypericin are both antivirals. Hypericin in high doses inhibits reproduction of enveloped retroviruses such as HIV”
- “Treats depression through MAO inhibition”
- “Fights retroviruses in high doses”

Valerian Root

- “[U]sed for epileptic seizures”

Furthermore, your products are not generally recognized as safe and effective for the above referenced conditions and therefore, these 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 new drugs on the basis of scientific data submitted by a drug sponsor to demonstrate that the drugs are 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 conditions 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 reach FDA electronically (e-mail) at Kenneth.Taylor@CFSAN.FDA.GOV, or you may respond in writing to Kenneth M. P. Taylor, Ph.D., Chemist, 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 Dr. Taylor at (301) 436-1439.

Sincerely,

/s/

Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition