DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
College Park, Maryland 20740

JUN 29 2004

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Chris Bonnell
Bonnell Techonologies
28826 Woodside Drive
Saugus, California 91390

Ref. No. CL-04-HFS-810-68

Dear Mr. Bonnell:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address http://www.vitamentality.net and has determined that the products "Vitamin B-6," "Lecithin," "Squalene," "Omega -3 Premium Fish Oil," "Deep Sea Fish Oil," and "Vitamin E" offered 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 USC 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 disease. The marketing of these products with these claims violates the Act.

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

Vitamin B-6 (K-Max)
"Helpful for…Depression…"

Lecithin
"Prevent arteriosclerosis, protect against cardiovascular disease…repair damage from alcoholism,...AIDS, herpes and chronic fatigue."

Squalene (K-Max)
"Heart disease, diabetes, arthritis, hepatitis and gastritis."
"…is very useful for patient with Heart disease, diabetes, arthritis and hepatitis."
"…help normalize blood cholesterol levels…"
"…highly recommended for people who suffer from gastritis."

Omega – Premium Fish Oil (K-Max)
"…reduce the risk of cancer…"
"…may help to ameliorate or reverse atherosclerosis, angina, heart attack, heart failure, arrhythmias, stroke, and peripheral vascular disease."

Deep Sea Fish Oil (Golden Alaska)
"…reduce the risk of cancer…"

Vitamin E
"Helpful for…Alzheimer's, Prostate & Stomach Cancer…"

Furthermore, FDA has no information that your product is generally recognized as safe and effective for the above referenced conditions and therefore, the product may also be a "new drug" under section 201(p) of the Act [21 USC 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 USC 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 or as cosmetics if therapeutic claims 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 (DSHEA), 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 into 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 CFR) 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 may market. It is your responsibility to ensure that all products marketed by your firm are in compliance 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 APope@CFSAN.FDA.GOV, or you may respond in writing to Angela F. Pope, Compliance Officer, Food and Drug Administration, Division of Compliance and Enforcement,
5100 Paint Branch Parkway, College Park, Maryland 20740-3835. If you have any questions concerning any issue in this letter, please contact Ms. Pope at (301) 436-2375.

Sincerely yours,

/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