DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
College Park, MD

MAY 24, 2005

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Charles Hill
Austin Nutritional Research
11103 Beach Road
Leander, TX 78641

Ref. No. CL-05-HFS-810-152

Dear Mr. Hill:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address http://www.anrvitamins.comand has determined that the products Vitamin A, Niacinamide, Pantothenic Acid, Phosphatidyl Choline, Inositol, Vitamin C, Vitamin E, Bioflavonoids-Hesperidin-Rutin-Quercetin, Calcium, Ginger, Gotu Kola, and Histidine 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 disease. The marketing of the products with these claims violates the Act.

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

Vitamin A (Beta Carotene)

"[H]elps maintain … disease-free skin; helps protect the mucous membranes of the mouth, nose, throat & lungs, thereby reducing susceptibility to infections …."
"Current medical research shows that food rich in Beta Carotene will help reduce the risk of lung cancer & certain oral cancers."

Niacinamide (Niacin- vitamin B-3)

"[R]educes the cholesterol level in the blood … reduces high blood pressure …."

Pantothenic Acid

"[F]ights infections by building antibodies."

Phosphatidyl Choline

"[H]elpful in the prevention of arteriosclerosis, heart disease, gallstones …. Medical studies have also shown that PHOSPHATIDYL Choline is beneficial in neurological disorders … and depression."

Inositol

"[H]elps reduce blood cholesterol …."

Vitamin C (Ascorbic Acid)

"[H]elps heal wounds, scar tissue, & Fractures [sic]; … builds resistance to infection; aids in the prevention & treatment of the common cold …."
"It prevents the conversion of nitrates (from tobacco smoke, smog, bacon, lunch meats, & some vegetables) into cancer-causing substances…. Vitamin C will decrease the risk of getting certain cancers by 75%."

Vitamin E

"[P]revents the red blood cells from destructive poisons; prevents & dissolves blood clots; has been used by doctors in helping prevent sterility, muscular dystrophy, calcium deposits in blood walls and heart conditions."

Bioflavonoids, Hesperidin, Rutin, Quercetin

"[B]eneficial in hypertension; helps hemorrhages and ruptures in the capillaries and connective tissues and builds a protective barrier against infections."

Calcium

"[E]ases insomnia; … lowers blood pressure; … reduces the incidence of colon cancer, and reduces blood cholesterol levels."

Ginger (zangiber officinale)

"The rhizome of ginger…has also been used as an herbal remedy for asthma and coughs related to … allergies."
"Ginger has been used to treat nausea … migraine headaches and to lower blood cholesterol."

Gotu Kola (hydrocotyle asiatica or centella asiatica)

"The whole gotu kola plant has been widely used … to treat skin inflammations,…to aid in the treatment of … congestion and depression."

Histidine

"[H]as been used in the treatment of rheumatoid arthritis, allergic diseases, ulcers & anemia."

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 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 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