



CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Richard A Merriam
President
GCI Nutrients Worldwide, Inc.
1501 Adrian Rd.
Burlingame, CA 94010

February 16, 2005

Ref. No. CL-04-HFS-810-121

Dear Mr. Merriam:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address <http://www.gcinutrients.com> and has determined that the products Tribulus (Bulgarian), Ashwaganda, Boswellia, Ginger, Gotu Kola, Gymnema, Noni, Turmeric, Artichoke, Bacopa, Cat's Claw, DHEA, Evening Primrose Oil, Valerian, St. John's Wort, Squalene, and Milk Thistle 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:

Tribulus (Bulgarian)

"Tribulus is widely recommended ... in the treatment of sexual dysfunction."

"Tribulus has been a frequent component of therapy for a variety of disorders affecting the liver, kidneys, and urinary tract."

"**Pharmacological Properties**... lowers high blood pressure · acts as an anti-urolithiatic (urinary/kidney stone preventing) and litholytic (dissolving)..."

Ashwaganda

"**Pharmacological Properties** · anti-tumor activity · may prove useful as an adjunct to chemotherapy ..."

Boswellia

"The gum resin of Boswellia has been traditionally used to treat coughs, ...and inflammatory conditions[sic] such as arthritis and ulcerative colitis."

"Boswellia has attracted alot[sic] of attention in the world medical community because it possesses anti-inflammatory action that is effective against most types of induced arthritis as most prescription medication, yet does not have any side effects."

"Pharmacological Properties . possesses potent anti-inflammatory properties useful in the treatment of inflammatory bowel disorders . useful in the treatment of arthritic conditions"

Ginger

"Traditional uses of Ginger include ... alleviating the symptoms of the common cold, ...mild asthma symptoms...."

"Pharmacological Properties ... may prove useful in the prevention of migraine headaches · it could be useful in childhood and juvenile migraine headache... · possesses anti-ulcerative properties"

Gotu Kola

"Traditional uses for Gotu Kola include; skin disorders, ... expelling parasites, ... asthma...."

"Pharmacological Properties. effective in treating bladder ulcers in human subjects ...
. increased wound healing ... "

Gymnema

"Gymnema silvestre ... has traditionally been used in the treatment of arthritis, gout, and most notably diabetes."

"Pharmacological Properties · hypoglycemic activity · shows promise in the treatment of Type 2 diabetes · reduces blood glucose levels ... · reduces and normalizes plasma lipids (cholesterol, triglycerides, and free fatty acids) · may prevent reduction of lean body mass associated with diabetes ... · normalizes blood sugar levels ..."

Noni

“The ripe noni fruit juice has been taken orally...to alleviate...arthritis, diabetes, gastric ulcers, sprains, ...cancer, and problems associated with high blood pressure.”

“**Pharmacological Properties** -anti-tumor activity in laboratory animals....has promise as a supplement agent in cancer chemotherapy.

anticancer activity
anti-bacterial action”

Turmeric

"[Turmeric] has been used ... for the treatment of jaundice and other liver ailments, ulcers, parasitic infections, various skin diseases, sprains, strains, ... inflammation of the joints, cold and flu symptoms...."

"Pharmacological Properties... · possesses anti-inflammatory actions · lowered blood cholesterol levels in laboratory animals ... · lowers cholesterol levels in kidney and liver tissue · helps protect against or lessen the degree of kidney lesions seen in diabetic pathologies ... · possesses anti-thrombotic activity · potent anti-carcinogenic action ... · possesses antiviral, anti-microbial, and anti-parasitic activity · inhibited the incidence of stomach, intestinal, and colon cancer ... in laboratory animals ...

Artichoke (Globe)

“Traditional uses have included ...atherosclerosis.”

“Artichokes contain cynarin ... Cynarin has been reported to lower cholesterol ...levels. Artichokes ... has been used for kidney diseases and proteinuria.”

Bacopa

“Traditional uses of Bacopa include ...insanity, head aches...anemia, leprosy, liver ailments”

“**Pharmacological Properties**...Prevented epileptic seizures in 40% of patients tested...”

Cat’s Claw

“The root and bark of Cat’s Claw is used... for...arthritic conditions, asthma, cancer, fevers, ulcers, wounds”

“**Pharmacological Properties** · anti-viral effect present against vesicular stomatitis virus in vitro · anti-inflammatory effect observed in laboratory animals ... · Austrian studies show anti-viral effects in humans . German studies showed a promise for leukemia...inhibits the proliferation of leukemic cells”

DHEA

“Possible therapeutic applications of DHEA supplementation include the prevention and/or treatment of heart disease, diabetes, obesity, and arthritis.”

“[S]upplementation with DHEA can indirectly help to decrease the risk of atherosclerosis.”

Evening Primrose Oil

“In Germany, [Evening Primrose Oil] is approved for use as a treatment for atopic eczema, to lower high cholesterol levels, ...and treat hyperactivity in children.”

“**Pharmacological Properties**.... may prove helpful in the treatment of rheumatoid arthritis . shown therapeutic effects in diabetic neuropathy in laboratory animals ... [Evening Primrose Oil] administration reduced cholesterol values by 25% ...in hyperlipidemic animal subjects... relieved inflammation, dryness, and itching in patients with Atopic Eczema...”

Valerian

“Valerian was traditionally used for epilepsy, and as a diuretic [sic]”

St John’s Wort

St John’s wort has...been used...for a wide variety of ailments, including... depression, neuralgia, wounds and burns, ...and for its anti-bacterial and anti-inflammatory actions.”

“St. John’s wort has been used for centuries to ...treat depression.... Taken internally, the oil has been used for ulcers and gastritis.”

“An infusion of the herb has also been used as an expectorant for bronchitis...”

Squalene

“Squalene has also been shown to help wound healing, ...and to strengthen the resistance to cancer.”

Milk Thistle

“Milk Thistle was commonly used to treat liver diseases,”

“Milk thistle has been used for hepatitis, viral hepatitis, cirrhosis, jaundice, and fatty degeneration of the liver.”

FDA has no information that your products are generally recognized as safe and effective for the above referenced conditions and therefore, these products may also be “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.

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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