



SEP 29 2004

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Robert Watson
Vitamin Research Products, Inc.
3579 Highway 50 East
Carson City, Nevada 89701

Ref. No. CL-04-HFS-810-93

Dear Mr. Watson:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address <http://www.vrp.com> and has determined that the products "Garlic Extract 500 mg 180 capsules", "A Vitamin (from fish liver oil) 25,000 IU 100 softgels", "Coenzyme Q10 30 mg 120 capsules", and "Lycopene 10 mg 60 softgels" 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 USC 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:

Garlic Extract 500 mg 180 capsules

"Garlic May Kill Antibiotic-Resistant Bacteria"

"Researchers at the December 2001 Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) in Chicago presented cell-culture evidence to suggest that the active component of garlic called allicin may kill or inhibit antibiotic-resistant bacteria."

"The researchers suggested that individuals at high-risk for antibiotic resistant infections—such as people with impaired immunity or those about to enter a germ-rich hospital environment—could use garlic supplements to prevent infections."

"Garlic Protects Human Cells From Malaria, Cancer"

"... new in vitro study suggests garlic may do double duty in battling both malaria and cancer..."

"Chemicals known as disulfides, found in... garlic, are known to be antifungal, antibacterial and to inhibit cancer. Animal studies have also shown compounds in garlic can fight malaria."

"The researchers found that the compounds not only killed the malaria parasites, but they also inhibited cultured melanoma (cancer) cells."

"Dr. Crandall hypothesized that ajoene and dysoxysulfone, two of the most active disulfide compounds found in garlic... may stop malaria by interfering with an enzyme. This enzyme allows malaria to infect cells and encourages cancer cells to reproduce."

"Garlic Reduces Prostate Cancer Risk"

"Since SARS is caused by a virulent virus that is unresponsive to available treatments it seems reasonable to use a combination of antivirals and immune enhancers to protect those at risk, or even to treat those who may be infected. ...[A]ntiviral nutrients like Olive Leaf Extract and Garlic may also be helpful."

A Vitamin (from fish liver oil) 25,000 IU 100 softgels

“Carotenoids, Vitamins and Other Nutrients Protect Against Prostate Cancer”

“A number of nutrients can protect against the development of prostate cancer.... [S]tudies ... have focused on antioxidants shown to reduce the incidence or prevent the occurrence of prostate cancer. The literature examined focused on the anti-cancer effects of such nutrients as...vitamin[] A.... After examining the studies, the reviewers concluded that many nutrients have significantly inhibited prostate cancer cell proliferation (the multiplying of cancer cells), differentiation, and signaling–events related to the initiation and progression of prostate cancer.”

“Researchers concluded that neonatal vitamin A supplementation reduces infant mortality rates, as well as lessens the severity of respiratory infection.”

Coenzyme Q10 30 mg 120 capsules

“Coenzyme Q10 May Offer Migraine Relief”

”Coenzyme Q10 May Slow Progression of Parkinson's”

”Coenzyme Q10 Reduces Progression of Symptoms in Parkinson's Patients”

“CoQ10 has been used in the treatment of different heart disorders that include arrhythmias related to primary cardiomyopathies or secondary forms of heart failure. ... CoQ10 helps prevent potentially life-threatening dysrhythmias during the immediate period following a myocardial infarction. This is the period of time when arrhythmia has the greatest likelihood of causing death.”

Lycopene 10 mg 60 softgels

”Lycopene Intake Lowers Prostate Cancer Risk”

”Lycopene May Benefit Prostate Cancer Patients”

”Lycopene Stops Risk Factor of Heart Disease”

“[S]tudies ... have focused on antioxidants shown to reduce the incidence or prevent the occurrence of prostate cancer. The literature examined focused on the anti-cancer effects of such nutrients as carotenoids (such as lycopene)”

Furthermore, your products are not generally recognized as safe and effective for the above referenced conditions and therefore, the product is 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 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 (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 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)).

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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 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 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 Linda.Webb@FDA.GOV, or 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/

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