DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

Food and Drug Administration
College Park, Maryland 20740

APR 25 2005

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Allen Josephs
Vitacost.com
2055 High Ridge Road
Boynton Beach, Florida 33426

Ref. No. CL-04-HFS-810-142R

Dear Mr. Josephs:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address http://www.vitacost.com and has determined that the products "NSI BerryVin (FKA Berryvida) High ORAC Berries," "NSI Glucomannan - 2,000 mg - 180 Caps," "NSI Cinnamon - 500 mg - 240 Caps," and "NSI Sytrinol - 150 mg - 120 Caps" 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 U.S.C. § 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:

NSI BerryVin (FKA Berryvida) High ORAC Berries
"The potential dangers posed by free radicals include … higher risks for cancer, diabetes, arthritis …."

NSI Glucomannan - 2,000 mg - 180 Caps
"Glucomannan … may provide benefits for cholesterol, … diabetes …."
"[R]elief from … diverticulitis."
"Glucomannan may hold properties for colonic/diverticular diseases. In a study published in the journal *Alimentary Pharmacology & Therapeutics*, it was found that after taking glucomannan supplementation, about one-third to one-half of those afflicted with diverticular problems showed reduced symptoms."
"Glucomannan may offer benefits for lower cholesterol, as it attracts bile acids and transports them out of the body. As a result, more cholesterol is used to make new bile acids, which lowers cholesterol levels. Various studies have shown that glucomannan supplementation resulted in reduced levels of triglycerides, and reduced levels of both total blood and LDL ("bad") cholesterol."
"[G]lucomannan may improve overall diabetic control."

NSI Cinnamon - 500 mg - 240 Caps
"Provides benefits for … cholesterol, and diabetes, plus anti-microbial properties."
"Cinnamon has been shown to provide a host of healthful benefits, including those for … cholesterol, and diabetes. And, cinnamon may be an effective anti-microbial agent."

"[W]hen the cinnamon's fiber removes bile, cholesterol must be broken down to make new bile, thus effectively lowering cholesterol levels…. And, studies show that cinnamon can effectively relieve … stomach ulcers."
"It has been shown that impaired levels of fat and sugar metabolism may lead to cardiovascular disease and Type II diabetes. However, in a study published in 2004 in the *Journal of Agricultural and Food Chemistry*, researchers found that specific cinnamon bark compounds increased fat cells' sugar metabolism twenty times. In addition, these compounds' antioxidant properties may provide diabetic benefits. Another study published in 2003 in *Diabetes Care* found that daily cinnamon supplementation of either 1, 3, or 6 grams reduced serum (blood) glucose, triglycerides, LDL ("bad") cholesterol, and total cholesterol in those with Type II diabetes."
"[C]innamaldehyde serves as an effective anti-inflammatory agent."
"[C]innamon may have anti-microbial properties, and may provide defense against vaginal and oral yeast infections, head lice, and possibly Heilcobacter pyiori, the bacteria found to cause stomach ulcers."
"[C]innamon oil compounds may display anti-allergy effects."
"Cinnamon … may provide relief at the onset of a cold."

NSI Sytrinol - 150 mg - 120 Caps
"[M]ay also provide benefits for inflammation, and heart disease and cancer."
"Sytrinol™ … may benefit cholesterol levels …"
"Sytrinol's class of compounds … may also offer benefits for inflammation and degenerative diseases, including heart disease and cancer."
"The patented Sytrinol formula … reducing levels of LDL ("bad") cholesterol."
"[N]atural alternative for lowering LDL cholesterol."
"Sytrinol … may provide benefits for such health concerns as inflammation and degenerative diseases, including cancer and heart disease."

Furthermore, your products are not generally recognized as safe and effective for the above referenced conditions and therefore, the 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 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, 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 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