

**CERTIFIED MAIL**
RETURN RECEIPT REQUESTED

Otto Roder
President
VitaPurity
A Division of VitaPurity Corporation
5246 Dobrot Way
Central Point, OR 97502

February 24, 2005

Ref. No. CL-04-HFS-810-131

Dear Mr. Roder:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address <http://www.vitapurity.com> and has determined that the products Ellagic Ultra™, Lycopene 25™ with Tomato Powder, Buffered Vitamin C Powder, Joint Recovery Formula™, Saw Palmetto, Ocean Splendor™ Omega-3 Fish Oil, and Miracle Mushroom Blend 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:

Ellagic Ultra™

“Ellagic Acid has been found to promote cell death in cancer cells.”

“[P]revents the binding of carcinogens to DNA and strengthens connective tissue, which may keep cancer cells from spreading.”

“Ellagic Acid may, [sic] reduce heart disease, birth defects, and liver fibrosis and promote wound healing.”

“Ellagic Acid acts as a scavenger to “ bind” ...cancer-causing chemicals, making them inactive.”

“Ellagic Acid exhibits anticarcinogenic and antimutagenic activity in humans.”

“VitaPurity Ellagic Ultra™ contains Green Tea Catechin Extract.... Greet Tea has been shown to lower LDL cholesterol Green Tea has also been shown to inhibit abnormal clot formation as effectively as aspirin, and, it has been shown to elevate HDL, the good cholesterol that helps remove atherosclerotic plaque from arterial walls. New studies are testing Green Tea as a potential cancer therapy. Green Tea may be especially protective against lung cancer”

Lycopene 25™ with Tomato Powder

“[I]t is a proven antioxidant that may lower the risk of certain diseases including cancer and heart disease.”

“Lycopene with tomato powder is far more effective than Lycopene alone in the prevention of cancer.... Tomato powder consumption clearly extended the life and reduced the cancer in this particular model.... Lycopene with Tomato Powder may offer the best anti-cancer effect.”

“[D]ietary consumption of Lycopene has been associated with a lowered risk of prostate cancer. Men with higher levels of Lycopene in their blood had statistically significantly lower rates of cancer than did men with lower blood levels of Lycopene. Studies also shown that men who eat more Lycopene-rich foods have less heart disease.... Lycopene can reduce the risk of macular degenerative disease, ...and cancers of the lung, bladder, cervix, and skin.”

“[D]iets rich in tomatoes and tomato products significantly reduced the risk of developing prostate cancer.”

“Lycopene was the only carotenoid that appeared to protect against heart attack.”

“Lycopene is believed to ‘turn off’ free radicals in the body that can cause cell damage and lead to cancer. Previous research indicated that lycopene may ward off a whole host of diseases, including prostate, cervical, bladder, breast, digestive-tract, skin and lung cancers.”

Buffered Vitamin C Powder

“Vitamin C is essential in healing wounds [I]t supports the immune system’s ability to fight disease and infection”

“[D]estructive to tumor cells”

“For cancer patients, sodium ascorbate is the preferred form.”

“A significant percent of the ‘terminally ill’ cancer patients for whom death was considered inevitable within a matter of weeks or months went on to long term survival. In short, for some patients, Vitamin C cured their cancer.”

Joint Recovery Formula™

“it’s a[A]bility to slow or even halt the effects of arthritis.”

“Glucosamine is a safe and effective natural supplement that is better for your body than NSAIDS such as ibuprofen and aspirin”

“Osteoarthritis is the primary reason people use Glucosamine and Chondroitin as nutritional supplements. In addition to joint health, Glucosamine and Chondroitin can be used to promote wound healing and to treat the pain, swelling, and joint noises of Temporomandibular Joint Syndrome (TMJ). Currently, researchers are exploring how Glucosamine may help reduce the frequency and intensity of migraines”

“Glucosamine has been shown to be as effective, if not more effective, than common NSAIDS such as Ibuprofen or Aspirin at easing arthritis pain.”

Saw Palmetto

“VitaPurity Saw Palmetto Standardized Extract ... is the same formula used in several European countries to treat Benign Prostatic Hyperplasia, available by prescription only.”

“[D]emonstrated impressive results in easing the effects of BPH and has reduced many of its uncomfortable symptoms.”

“One of Saw Palmetto’s key uses is to help Benign Prostatic Hyperplasia (**BPH**). BPH is enlargement of the prostate gland, and can block the urethra and require surgery.”

“VitaPurity Saw Palmetto Standardized Extract helps improve urinary flow, and reduces the frequency and urgency of urination in men with BPH.”

“Saw Palmetto is also effective in helping bladder inflammation and chronic bronchitis”

“Saw Palmetto plays a key role in preventing prostate enlargement”

“[W]idely used for treating BPH.”

“Helps to treat bladder inflammation”

“Used to clear chest congestion, treat coughs, asthma, and bronchitis.”

“[R]elieves symptoms associated with Benign Prostatic Hyperplasia (BPH), such as difficult and frequent urination...Saw Palmetto is also promoted as a treatment for prostatitis (inflamed prostate gland).”

Ocean Splendor™ Omega-3 Fish Oil

“Several clinical studies indicate that Omega-3 Fatty Acids may be helpful for the prevention and treatment of both acute and chronic inflammatory conditions.”

“Omega-3 fatty acids benefit...those at high risk of, or who currently have, cardiovascular disease.”

“[Omega-3s] make the blood less likely to form clots that cause heart attack and protect against irregular heartbeats that cause sudden cardiac death.”

“[P]eople suffering from depression who received a daily dose of 1,000mg of Omega-3 Fatty Acids ...experienced a decrease in their symptoms, such as anxiety, sadness and sleeping problems.”

“[O]mega-3 fatty acids were associated with less coronary heart disease and mortality in people with diabetes.”

Miracle Mushroom Blend

“Reishi Mushroom was comparable to hydrocortisone and aspirin in its ability to reduce inflammation”

“When more than 2,000 patients with chronic bronchitis were given Reishi Mushroom Extract, 60 to 90 percent of these patients showed a marked improvement in health”

“[E]ffective in treating conditions such as stomach ulcers and high blood pressure.”

“The Shiitake Mushroom is ...an aid in the prevention of cerebral hemorrhagic strokes.”

“Shiitake Mushrooms are promoted to fight the development and progression of cancer and AIDS These mushrooms are also said to help prevent heart disease by lowering cholesterol levels in the blood and treating infections”

“Research in Japan shows that the mushroom itself can lower blood pressure in those with hypertension.”

“[G]iving Shiitake to patients with probable pre AIDS improved the patients [sic] general conditions and improved their immune status.... [T]his agent may prove to be effective in the suppression of the AIDS condition.”

“The compounds contained in Maitake have the capacity to ...inhibit tumor growth.”

“People with Type 2 Diabetes may also benefit from Maitake.”

“Maitake Mushrooms may have the ability to ... induce apoptosis (cell death) in cancer cells.”

“[M]ushroom extracts may improve overall survival and quality of life for cancer patients.”

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

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.

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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