



AUG 8, 2005

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Toby L. Coriell, President
V.P. Consultants, Inc.
105 N Creek Lane
Osprey, FL 34229

Ref. No. CL-05-HFS-810-168

Dear Mr. Coriell:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address <http://www.vpnutrition.com> and has determined that the products Enzymedica Virastop™, Enzymedica V-GEST™,™, Enzymedica Repair™, Enzymedica pH-Basic™, Enzymedica Natto-K™, Enzymedica Candidase™, Flu Prevention Trio (Quantum Nucleotide Complex, InfectoStat, Quantum Colostrum), Chronic Fatigue Support Kit (DHLA, Quantum Adaptogen Complex, RenewZyme), Fibromyalgia Support Kit (Super Nano Green Tea, DHLA w/ resveratrol, Quantum Kidney Complex, RenewZyme), Super Nano-Green Tea –Potent Polyphenols, Premier Research Labs Quantum Kidney Complex – Cordyceps / Agaricus Bisporus Extract, and Premier Research Labs Quantum Bone and Joint Complex 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:

Enzymedica Virastop™

Under heading “Indications”:

- “Anti-viral support”
- “Antibacterial support”
- “Inflammatory conditions of the throat, nose, mouth, ear, sinus, and gums.”

Enzymedica V-GEST™

“Amylase [a constituent of the product] Allergy Assistance”

“Amylase [a constituent of the product] has been shown to have antihistamine qualities. V-gest™, with its amylase components ...may help individuals suffering from seasonal allergies.”

Enzymedica Repair™

“Natural Anti-inflammatory Proteolytic Enzymes [constituents of the product]”

“One of the major concerns of inflammation is capillary blood flow....After an injury some of these capillaries may be damaged, making them incapable of carrying fluid to and from the damaged tissue....Proteolytic enzymes [constituents of the product] ...have been shown to reduce the amount of fibrin in the damaged capillary, improve circulation and speed healing.”

Enzymedica pH-Basic™

“This product is specifically designed to raise the pH of people who are too acidic.... When the body is too acidic ... disease and infections proliferate. This is especially true in cases of arthritis and rheumatic situations.”

Enzymedica Natto-K™

“Nattokinase [a constituent of the product] breaks down Fibrin....[E]xcess fibrin has been shown to contribute to...high blood pressure.... Bacteria, viruses, fungi and toxin present in the blood also trigger an inflammatory condition resulting in excess cross-linked Fibrin.... This contributes to the formation of blood clots, slows blood flow and increases blood viscosity contributing to the elevation of blood pressure.

"Nattokinase [a constituent of the product] has been the subject of 17 studies, including two small human trials.... The tests indicated that natto generated a heightened ability to dissolve blood clots.”

Enzymedica Candidase™

“Candidase™ for Yeast Overgrowth (Candida Overgrowth)”

“The combination of Cellulase and Protease enzymes [constituents of the product] was formulated to manage Candida yeast overgrowth.”

“In individuals with Candida yeast overgrowth there is often a large amount of undigested fiber in the large intestine. It is believed that the mucous that the body naturally produces due to the difficulty of digesting this fiber (cellulose) may protect the Candida from our body’s natural overgrowth prevention mechanisms. Cellulase is the enzyme that breaks down fiber.”

Flu Prevention Trio (Quantum Nucleotide Complex, InfectoStat, Quantum Colostrum)

“Unable to get your ‘flu vaccination’? Afraid of the consequences to your health of either the flu or the vaccination? Now you have the healthiest alternative ...!”

“The genetic code of a cold virus enters the body as a strand of RNA that contains about 7,000 nucleotides coiled inside a viral shell. This code acts to trigger the body's cellular machinery to start duplicating the viral code and spreading the infection cycle. If an extra

source of nucleotides is available, billions of these sturdy, fresh nucleotides can be absorbed by the cell to help fight back and put and [sic] end to the infection cycle.”

“This formula is designed to help the body cleanse itself and keep itself free of infection.”

“Recent studies show that colostrum has the power to severely inhibit or destroy the growth of many dangerous bacteria, viruses and funguses, including E. coli, Helicobacter pylori, Listeria, rotaviruses, Streptococcus (many different varieties), Staphylococcus (many different strains), Salmonella, Shigella, Bacteroides, Borrelia, Clostridium, HIV, and Candida albicans.”

Chronic Fatigue Support Kit (DHLA, Quantum Adaptogen Complex, RenewZyme)

“The combination of DHLA, RenewZyme and these spectacular adaptogenic herbs provides a wonderful, powerful remedy, delivering the kind of help a CFS [Chronic Fatigue Syndrome] sufferer can really notice.”

“RenewZyme is formulated to speed recovery, address inflammation and repair tissue.

RenewZyme is a high potency enzyme blend that has exhibited anti-inflammatory qualities.

Proteolytic Enzymes help relieve the types of inflammation that require ice (injury, trauma, sprains, surgery, etc.).”

Fibromyalgia Support Kit (Super Nano Green Tea, DHLA w/ resveratrol, Quantum Kidney Complex, RenewZyme)

"Studies in Japan have shown Agaricus Disporus [a constituent of the product] saved 6 out of 9 patients in kidney failure, delivering extraordinary blood purification. A critical player in all fibromyalgia is waste products building in the blood and in turn, bio-accumulating in lymph and connective tissues throughout the body. Downloading blood toxins has translated to fewer fibromyalgic symptoms in anecdotal case reports."

Super Nano-Green Tea - Potent Polyphenols

" [P]olyphenols [constituents of the product] help promote anti-hyperglycemic, anti-hypertensive, anti-hypercholesterolemic...effects."

“The antioxidant 'oomph' of green tea has also been recommended as a preventative measure for heart disease, kidney disease”

Premier Research Labs Quantum Kidney Complex – Cordyceps / Agaricus Bisporus Extract

“Many factors weaken and damage the kidneys, especially the long-term stress of chronic illness.... Agaricus Extract ... can help turn back all this damage by strengthening the kidneys.”

“Taking agaricus extract can return power to your kidneys. This can mean dramatic help to overcome chronic disease and get well. This extract contains unique phytonutrients known to...help reduce cholesterol, lower blood pressure, help clear allergies....”

[Under heading “Cordyceps - The super Kidney and Lung tonic”] “It was used to rebuild the body after long term illness. Excellent clinical results...have been reported for those with weakened kidneys, even those in chronic kidney failure.”

“Other kidney related problems...which the mushroom extract can help overcome are chronic fatigue, back and joint pain,...anemia, and many types of sexual problems such as impotence.”

“Cordyceps has a sterling reputation in helping to overcome chronic lung problems, such as asthma....”

“Cordyceps is a well-known anti-cancer, anti-tumor and anti-infective agent.”

“It [Cordyceps] has also significantly helped normalize arrhythmia (irregular heart beats).... Cordyceps also has an excellent potential to fight depression....”

Premier Research Labs Quantum Bone and Joint Complex

“[S]upports the body’s natural anti-inflammatory, anti-infective ... processes.”

In addition, the name “Virastop™” is an implied claim that the product is useful in preventing or treating diseases caused by viruses. The names “Flu Prevention Trio,” “Chronic Fatigue Support Kit,” and “Fibromyalgia Support Kit” are implied claims that the products are useful in preventing or treating flu, chronic fatigue, and fibromyalgia, respectively.

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 of disease 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 Shari H. Shambaugh, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 33751. If you have any questions concerning this letter, please contact Ms. Shambaugh at (407) 475-4730.

Sincerely,

/s/

Jimmy E. Walthall
Director
Compliance Branch
Florida District Office