DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
College Park, MD

AUG 2, 2005

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ryuji Hirooka
President
World Nutrition, Inc.
7001 N. Scottsdale Rd. Ste. 2000
Scottsdale, AZ 85253

Ref. No. CL-05-HFS-810-189

Dear Mr. Hirooka:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address http://www.vitalzym.com and has determined that the products Vitalzym™, VitalzymSEB™, and NattoQ10™ 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:

Vitalzym™

"The ingredients found in Vitalzym™ are used widely in Europe and Asia as a natural remedy for fibromyalgia and natural medicine for joint pain."
"[T]he original Vitalzym has become the leading systemic enzyme formulation recommended for pain, inflammation, and scar tissue. Countless sufferers of chronic conditions, such as arthritis, fibromyalgia, systemic inflammation, fibroids,…have found relief with the regular use of Vitalzym."
"Vitalzym was formulated specifically for pain, inflammation, and systemic fibrosis. Vitalzym's chief fibrinolytic enzyme is serrapeptase. Serrapeptase has the ability to reduce chronic pain, systemic inflammation and systemic fibrosis."
"Vitalzym is better for pain, inflammation and systemic fibrosis. It will also help with…reducing vascular inflammation."

VitalzymSEB™
"Recent studies have shown the correlation between elevated vascular inflammation and heart disease. The enzymes in VitalzymSEB have been shown to reduce the levels of C-Reactive Proteins (inflammation marker)."

"VitalzymSEB is better for cleansing ….arterial plaque."

NattoQ10™

"Reishi mushroom [in the product] has been shown to reduce…cholesterol in the blood, and highly thrombolytic enzymes such as NattoVega [in the product] promote heart health by helping the body prevent and dissolve unhealthy coagulation of the blood."

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