DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, Maryland 20740

MAR 27 2006

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Kris Yang
Bio Essence Corporation
5221 Central Avenue, #105
Berkeley, California 94702

Ref. No. CL-06-HFS-810-212

Dear Dr. Yang:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address http://www.bioessence.com and has determined that the products "Cell & Collagen Protect," "Yun Zhi," and "Echinacea & Goldenseal Plus" 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:

Cell & Collagen Protect

"Many researchers believe that the main cause of coronary diseases and atherosclerosis is due to a chronic deficiency in vitamins and other essential nutrients in the vascular walls of millions of cells. Most of the cells in our body produce enzymes that degrade connective tissues. … However, diseases such as cancer occur when the cells start to multiply in this way; viruses and bacteria infect the body through this same process. … This formula is designed to help protect the integrity of the cells and connective tissue so that they will not be weakened by collagen-dissolving enzymes."

Yun Zhi

"Many experimental studies and clinical investigations of PSK and PSP [Yun Zhi's purported active ingredients] in relation to their antitumor effect and especially for their potential use in cancer immunotherapy have been reported."
"These studies include the clinical trial on 485 cases of cancer patients who have used Yun Zhi Extract for the treatment of cancer alone or in combination with chemotherapy and radiotherapy. The results of these studies have consistently shown increased survival rates and improved quality of life without toxic side effects. The total effective rate is 82.96%."
"Animal studies investigating the efficacy of Coriolus versicolor indicate it has … a broad antineoplastic scope. It prolongs the survival time of irradiated (cancer-induced) mice by stimulating phagocytic activity of macrophages and improving the functions of the reticuloendothelial system."
"It also has antiviral and antibacterial effects, which includes anti-hepatitis B and migratory hepatitis virus."
"Modern clinical research has focused on using the water extracts of this mushroom to stimulate and strengthen the immune health of people with cancer."

Echinacea & Goldenseal Plus
"PRIMARY USES: Colds/Flu that are active, Bacterial Infections, Viral Infections ... Pink Eye."
"PROPERTIES: ... Anti-bacterial, Anti-viral, Anti-microbial ..."
"INDICATIONS: Echinacea & Goldenseal Plus is an acute formula, to be used when either one feels like they are about to come down with a cold/flu (take every couple hours), or if cold/flu symptoms are already present (take at least 3 times per day until symptoms subside)."
"Effective for infections ..."

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

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