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

Food and Drug Administration
College Park, Maryland 20740

October 4 2006

Manuel Kiok
Green & Gold International
Room 307 Solmac Building
84 Dapitan cor Banawe Street
Quezon City, 1115
Philippines

Ref. No. CL-06-HFS-810-233

Dear Mr. Kiok:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address http://www.tianxian.com and has determined that your "Tian Xian" products in liquid and capsule form 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 the products with these claims violates the Act.

Examples of some of the claims made for your "Tian Xian" products on the home page of your web site include:

"The Tian Xian (pronounced "Dianne Sean") products are herbal dietary supplements. The active herbal ingredients aims [sic] to control, inhibit and destroy cancer cells. … Testimonials of cancer survivors are from USA, Japan, Hong Kong, India, China, Philippines, Taiwan, Thailand, and Malaysia."
"NEW TESTIMONIAL: (May 2005 from Poland) Bladder cancer with a liver & lungs metastatis [sic] testimony."
"Read more cancer survivor stories from patients all over the world, and see how Tian Xian has helped them fought [sic] cancer."
"Cancer Testimonial Lists
Breast Cancer
Colon Cancer
Esophagus Cancer
Intestine Cancer
Liver Cancer
Lung Cancer
Lymph Cancer
Myeloma Cancer
Nasal Cancer
Pleurisy
Pancreatic Cancer
Rectal Cancer
Stomach Cancer
Tongue Cancer

Ulcer Cancer
Uterus Cancer"

Examples of some of the claims that appear on the FAQ page of your web site, or can be accessed through links on that page, include:

"• **Tian Xian and Western Therapies**
Contains valuable information on how Tian Xian complements Western therapies such as chemotherapy, radiotherapy, etc."

"Is it helpful to take Tian Xian Liquid for benign tumor?
Yes. Taking it at the standard dosage for 3 to 6 months will reduce the tumor size significantly. It may be taken to prevent it from developing into malignant tumor."

"Is it effective for viral hepatitis A, B and C sufferers to take the Tian Xian Liquid?
Yes. By taking Tian Xian Liquid in conjunction with Tian Xian Capsule No. 6 , the liver functions may be strengthened to prevent cirrhosis."

"Is it effective to take Tian Xian Liquid for cirrhosis?
By taking Tian Xian Liquid in conjunction with Tian Xian Capsule No. 6, the liver functions may be strengthened to prevent against liver cancer."

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.

The agency is taking steps to warn our citizens that drugs from foreign sources that are promoted and sold via the Internet may not be approved for marketing in this country, and that unapproved new drugs cannot be legally imported. Unapproved new drugs offered for importation into the United States are subject to detention and refusal of admission. With copies of this letter, we are advising the drug regulatory officials in the countries from which you operate that FDA considers your "Tian Xian" products in liquid and capsule form to be unapproved new drugs that cannot be legally marketed to consumers in the U.S.

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/

Vasilios H. Frankos, Ph.D.
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