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

Food and Drug Administration
College Park, Maryland 20740

OCT 25 2005

Josef Margraf
NatureProducts
Mekong Hill Garden
Jinghong, Yunnan 666100
China

Ref. No. CL-05-HFS-810-196

Dear Mr. Margraf:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address http://www.natureproducts.net and has determined that the product "Revivo" is promoted for conditions that cause the product to be a drug 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 product is a drug because it is intended for use in the cure, mitigation, treatment, or prevention of disease. The marketing of this product with these claims violates the Act.

Examples of some of the claims observed on your web site include:

Revivo
"Revivo: a new mix of 12 of the most powerful traditional Chinese herbs to activate the immune system to fight HIV"
"REVIVO is developed in Southern China where HIV/AIDS has become a serious epidemic, starting years ago through migrant workers to Thailand. There, in Northern Thailand, the medicine has been tested first and is since then becoming very popular not only because it is the least expensive of all available drugs but also because it is restoring the immune system function of the body so efficiently that in the majority of patients the CD4 counts are getting back to normal within 1 to 3 months, and a large number of viral secondary infections are cured at the same time.
While this is a new way of looking at the treatment of HIV, the medicine itself is but a sophisticated mixture of traditional Chinese herbs to cure immune system deficiencies."
"Dosage: take 2 bags per day, let at least 4 hours pass before taking the 2nd bag; after 4 days, pause for one day. Continue for at least 1 month at early stages (HIV) and up to 4-6 months at later stages (AIDS).
Note: under medical observation the daily dose can be increased to 4 bags (40 g), and there is no need for pausing after the 4th day. This is particularly recommended if CD4 counts are below 200."
"Treatment for HIV at early stage: one month, which requires 48 bags.
Treatment for ACR-AIDS patients: for patients with additional fever, tiredness, secondary infections, symptoms of chest pain, swelling, nausea, etc.: please get a CD4 and virus check at your hospital. If your CD4 is below 200 and/or your virus count is above 10,000 please opt for a combination of Anti-Viral-Drugs (Western medicine with strong virus reduction effect) and **Revivo** (to build up your immune system). Take **Revivo** for at least 4 - 6 months to ensure curative effect.
important notes:
1: there are about 60 symptoms of secondary infections described. Please note that **Revivo** can only take care of those caused by a virus."

"**Follow up treatment:** once your CD4-count has gone above 560, you may pause and drastically reduce REVIVO to about 1/2 (half) of the monthly dosage described above."
"**Precautions: …**When Revivo has raised the CD4 to 560 cubic mm, the dosage can be reduced by 50% (to 10g per day). Alternatively, you may take the previous dose for 2 weeks per month."
"Patients take Revivo also for other virus infections to benefit from its strong immune system activation. Those infections include herpes zoster, herpes simplex, hepatitis (mainly B), papovavirus, urethritis, rhinitis, peptic ulcer, and common cold. These are all diseases, which often form secondary infections and which the recovering immune system can eliminate while doing its main job on HIV."

Your website also promotes Revivo for the treatment of HIV through graphs purporting to show improved virus counts and CD4 counts in HIV patients at Beijing HIV Hospital.

Furthermore, your product is not generally recognized as safe and effective for the above referenced conditions and therefore, the product is also a "new drug" 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.

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 product to be an unapproved new drug that cannot be legally marketed to consumers in the U.S.

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/

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