DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
College Park, MD

JUL 19, 2005

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Lian Jin Chong
Chong's Health Care Enterprise, Inc.
401 N. Garfield Ave, Suite 1
Alhambra, CA 68124

Ref. No. CL-05-HFS-810-179

Dear Dr. Chong:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address http://www.cljhealth.com and has determined that the products "Nature's Purest 5 HTP 100 mg 120 caps" and "NVE Stacker 3 (Ephedra Free) 100 caps" 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:

Nature's Purest 5 HTP 100 mg 120 caps

"5-HTP has ben used in connection with the following conditions and health concerns: Depression, Fibromyalgia, Insomnia, Migraine Headaches, …obesity, Bipolar disorder/manic depression and Seasonal affective disorder."
"Insomnia has been associated with L-tryptophan deficiency in the tissues of the brain; therefore, 5-HTP may provide a remedy for this condition."
"300 mg per day was shown to be effective in reducing many symptoms of fybromyalgia, including pain. [sic] morning stiffness, sleep disturbances, and anxiety. For depression, 300 mg per day is often effective ….For insomnia, a single 100 mg nighttime dose of 5-HTP was sufficient to improve the duration and depth of sleep in one placebo-controlled study. For migraine headaches, amounts ranging from 400-600 mg per day have been shown to be effective at reducing the frequence [sic] and severity of attacks."

NVE Stacker 3 (Ephedra Free) 100 caps

"Chitosan may reduce the absorption of bile acids or cholesterol, either of which may cause a lowering of blood cholesterol."

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 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