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

Food and Drug Administration
College Park, Maryland 20740

SEP 6 2005

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Tanya Tang
Brighten Corporation
133-54 41st Avenue, 3rd Floor
Flushing, New York 11355

Ref. No. CL-05-HFS-810-186

Dear Ms. Tang:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address http://www.ginsengcountry.com and has determined that the products "WildSenergy™," "LiverKlin™," and "Wild American Ginseng Capsules" 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:

WildSenergy™

"WildSenergy®, the combination of American wild ginseng and Chinese herbs…. Its therapeutic value has been proven by laboratory experiments and numerous cancer patients over past three years of intensive study."

"Dr. Laura Murphy … reported her astonishing scientific discovery on cancer research involving the use of ginseng and Chinese herb: American ginseng slowed down the growth of human breast and prostate cancer cells in culture. During a three month laboratory experiment, the tumors in the treated mice with 1 percent ginseng extract in drinking water were 50 percent smaller than those in the untreated mice….1 mg WildSenergy® powder has as same potency as 30mg wild ginseng or 25mg Chinese herb powder alone. The combination of the American wild ginseng with the Chinese herb powder dramatically increased the potency of inhibiting cancer cells proliferation by up to 25 times. "

"Numerous scientific studies have shown that wild American ginseng contains more ginsenosides and nutrients at higher concentration such as polysaccharide acid, vitamins and other elements, which have anti- tumor and anti- radiation functions."

"Other major ingredients in WildSenergy® such as Zizphus Jujuba Mill Astragalus, Lycium Fruit, and Poria have been used in traditional Chinese medicine … to combat cancers."

WildSenergy® has been pre-tested clinically by our medical consultants and proven to be effective in … inhibiting cancer cells proliferation; and bringing out the positive forces of the body to fight cancers.

Clinical experiments suggest that WildSenergy® … alleviates chemo and radiotherapy side effects; stimulates the immune system to inhibit cancer cell growth, enhances the ability of immunocytes and accelerates the growth of white blood cells, blood platelets, and red blood cells that are lost during radio and chemotherapy; enhances curative effects and alleviates the toxic side effects of chemo and radiotherapy; ameliorates edema of terminal cancer patients, and increases the opportunity to early and intermediate stage patients of restoring the body's natural resistance. WildSenergy® is the best ginseng product to reduce the pain and enhance the quality of life for cancer patients.

Wildsenergy® may be useful at all stages of cancer, in terms of maximizing the opportunity for recovery for people in early to middle stages of cancer, and also for the possibility of prolonging the survival time of people in their final stage of cancer.

"Recommended Dosages: For people in early to middle stage cancer … For people in final stage cancer … … For people undergoing chemotherapy and radiation ... It is recommended to start taking this product a month before the treatment. WildSenergy may help to strengthen one's immune system rapidly and subsequently and to [sic] improve the comprehensive curative effect of the undergoing chemotherapy and radiotherapy. It may also dispel, alleviate and contain the malicious side effects of surgery, chemotherapy, radiation and medications. … For people in recovering stage.…"
"WildSenergy has been proven to be able to do the latter by killing cancer cells as well as dispelling, alleviating and containing the malicious side effects of surgery and chemotherapy…. This should be seen as the direction of modern cancer treatment."

LiverKlin™
"[C]linical experiment has proved that LiverKlin…prevents Hepatitis B and C from worsening and developing into cancer."
"Who can benefit from LiverKlin? Those who can benefit most from LiverKlin are individuals that are: with Hepatitis B and C, cirrhosis, hepatitis bacterium virus carrying…. LiverKlin is also powerful at protecting and repairing the liver when damaged by chemotherapy."
"Indications: Individuals with Hepatitis B and C, cirrhosis, virus …"
"Recommended Dosages: For people with Hepatitis B, C … For virus carriers … For people with cirrhosis …"

Wild American Ginseng Capsules
"A series [sic] laboratory experiments … showed that American wild ginseng: … Inhibited human breast and prostate cancer cells; the higher the concentration of ginseng, the more it slowed down the rate of cell proliferation. "It doesn't kill the cells, but you can raise the dose to completely inhibit proliferation. It arrests the cell in a certain state of development." They also discovered that the tumors in the treated mice with a water extract of American ginseng were 50 percent smaller than those in the untreated mice."
"Researchers … have found that taking American ginseng before a meal reduces blood sugar in people both with and without diabetes. The study appears in the April 9 issue of the Archives of Internal Medicine, a publication of the Journal of the American Medical Association (JAMA)."
"A study comparing groups of people over time suggests that regular intake of ginseng may reduce one's chances of getting various types of cancer, especially lung, liver, stomach, pancreatic and ovarian."
"INDICATIONS … diabetes … cancer … inhibits the growth of cancer cells … and reduces the side effects of chemotherapy and radiation … hepatitis B& C … cirrhosis … high cholesterolor [sic] … reduces high cholesterol … inhibits the aggregation of platelets… alcoholic … lowers blood alcohol levels … cardiovascular disease … normalizes blood pressure; prevents from arteriosclerosis… "

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

"Mr. Liu of Brooklyn, New York suffered from nasopharyngeal carcinoma ten years ago. He has never fully recovered following chemotherapy. Last year, thyroid adenoma developed on both sides of his throat. He started taking WildSenergy upon recommendation by his friends. After a month of recommended usage, the tumours [sic] became smaller. They almost disappeared three months later. … His tumour [sic] specialist was pleasantly surprised with these improvements. He has now begun his second chemotherapy to clear up the remaining cancer cells. He has not experienced any undesirable side effects of chemotherapy this time."
"Seventy-two-year old Mr. Chen of Flushing, New York was diagnosed as having middle stage liver cancer later stage cirrhosis. After taking Liverklin for three months, his liver function improved incredibly with AFP index dropping to 265 from 1360! There were also significant improvements on other indexes such as AFP, ALT and AST, etc."

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.

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/

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