



CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

October 12, 2006

Chang Li
H & L World Wide Inc.
2003 N. Tyler Ave.
South El Monte CA, 91733

Dear Mr. Li:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address <http://www.vitasprings.com> and has determined that the products PureGels GlucoTrim 24, Diamaxol Blood Sugar Support, and Jiang Tang Pian (Diabetes Care) 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 these products with these claims violates the Act.

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

Diamaxol Blood Sugar Support

- “Diabetes is caused by a variety of factors. Diamaxol™ is a natural solution that normalizes blood sugar levels quickly and completely, ONCE AND FOR ALL!!!”
- “Reduces blood sugar levels: Diamaxol™ interferes with glucose absorption from the intestine and prevents adrenal hormones from stimulating the liver to produce glucose, both of which directly reduce blood sugar levels.”
- “Eliminates insulin resistance: Diamaxol™ repairs cell receptors to better recognize insulin which virtually eliminates insulin resistance. Most medical sources agree that insulin resistance is the root cause of Type 2 diabetes.”
- “Normalizes insulin production: Diamaxol™ stimulates the increased production of an organic compound that is naturally produced by the body. If you are Type 2, it is

easily converted to insulin, which helps normalize and relieve stress on the pancreas, allowing it to heal.

PureGels GlucoTrim 24

- “Clinical data shows GlucoTrim assists in maintaining optimal blood glucose levels for those who battle with high blood sugar.”
- “Current health trends also indicate an explosion of adult-onset, and even child-onset diabetes (Type II Diabetes)...GlucoTrim-specific clinical trials show an average of 30% reduction in blood glucose levels after four weeks. It facilitates the lowering of blood sugar....”

Jiang Tang Pian (Diabetes Care)

- “Indication: It is used for polydipsia, polyuria, polyphagia ... diabetes characterized by elevation (sic) of glucose in urine and blood sugar.”

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

These products are also misbranded within the meaning of Section 502(f)(1) of the Act, in that the labeling for these drugs fail to bear adequate directions for use [21 U.S.C. § 352(f)(1)].

The above violations are not meant to be an all-inclusive list of deficiencies in your products and their labeling. While reviewing your web site, we noticed that you promoted other products for disease treatment and/or prevention. It is your responsibility to ensure that products marketed by your firm comply with the Act and its implementing regulations. We urge you to review your website, product labels, and other labeling and promotional materials for your products to ensure that the claims you make for your products do not cause them to violate the Act.

Failure to promptly correct the violations specified above may result in enforcement action without further notice. Enforcement action may include seizure of violative products and/or injunction against the manufacturers and distributors of violative products.

Please advise this office in writing, within 15 working days of receipt of this letter, as to the specific steps you have taken or will be taking to correct these violations, including the steps taken to assure that similar violations do not recur. Include any documentation necessary to show that correction has been achieved. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Your reply should be sent to Quyen Tien, Compliance Officer, Food and Drug Administration, Center for Food Safety and Applied Nutrition, Division of Enforcement (HFS-607), 5100 Paint Branch Parkway, College Park, Maryland 20740-3835.

Sincerely,

Joseph R. Baca
Director
Office of Compliance
Center for Food Safety
and Applied Nutrition

