DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

October 12, 2006

Health Sites, Inc.
653 West 23rd Street #287
Panama City, FL 32405

Dear Sir or Madam:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address http://www.flourishwellness.com and has determined that the products Glucobetic and Neuro-Betic are promoted for conditions that cause them 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:

Glucobetic

- (Testimonials) "For 3 years I had been fighting a losing battle with high blood sugar levels. The consistently high blood sugar was taking a toll on my body in regards to eyesight and nerve pain in my hands and feet. Now, with the help of Glucobetic, the blood sugar levels read in the 80 to 120 range daily."

- (Ingredient in the product) "Chromium can even improve insulin resistance in diabetics. Nearly 20 controlled studies have demonstrated the positive effect for chromium in the treatment of diabetes. In clinical studies of type II diabetes patients, supplementing the diet with chromium has been shown to decrease fasting glucose levels, improve glucose tolerance, lower insulin levels, and decrease total cholesterol and triglyceride levels..."

- (Ingredient in the product) "[V]anadyl is being used by progressive alternative physicians and natural healers to treat diabetes, a condition that is characterized by excess sugar in the blood and urine."

- (Ingredient in the product) “Gymnema Sylvestre is a plant native to the tropical forests of India, and has been long used as a treatment for diabetes. Recent scientific investigation has upheld its effectiveness in both Type I and Type II diabetes. Gymnema Slyvestre is probably the most practical herbal recommendation for improving blood sugar control in diabetics.”

- (Ingredient in the product) “Bitter Melon is an herb that has traditionally been used by Ayurvedic (Indian) healers to treat Type II, or adult-onset diabetes. Numerous studies have shown that it can normalize elevated blood sugar levels.”

- (Ingredient in the product) “Fenugreek has demonstrated significant anti-diabetic effects in experimental and clinical studies. Two studies in the European Journal of Clinical Nutrition reported that Fenugreeek improves glucose tolerance in both Type I and Type II diabetes.”

- (Ingredient in the product) “Bilberry is widely used as a possible preventative treatment for complications of diabetes.... Research, done mostly in Italy, has also uncovered bilberry’s potential for treating...diabetes-caused glaucoma....”

- (Ingredient in the product) “Jambolan is used for diabetes and diseases of the pancreas.... Jambolan is used to treat diabetes because it quickly reduces blood sugar.... Jambolan may also decrease the risk of a person with diabetes developing atherosclerosis….”

- (Ingredient in the product) “Pterocarpus Marsupium has a long history of use in India as a treatment for diabetes.”

<u>Neuro-Betic</u>

- “Neuro-Betic is an exclusive formula with 11 ‘Neuro-Protective’ nutrients in the most effective form to promote nerve comfort and health nerve function. One of the most common long-term complications of high blood sugar levels is diabetic neuropathy, or nerve damage.”

- “It’s not too late to prevent or delay the onset of diabetic neuropathy.”

- (Ingredient in your product) “Vitamin B6 supplementation appears to offer significant protection against the development of diabetic neuropathy...”

- (Ingredient in your product) “Biotin - People with type 2 diabetes often have low levels of Biotin.... There have been reports of Biotin supplements improving the symptoms of peripheral neuropathy for some people who have developed this condition from either long-standing diabetes...”

- (Ingredient in your product) “Ginko Biloba Extract - Ongoing studies are assessing the possible effectiveness of Ginkgo in speeding recovery from certain strokes and head injuries, as well as in treating other conditions that may be related to circulatory or nervous system impairment, including impotence, multiple sclerosis, and nerve damage tied to diabetes.”

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