DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

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

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

October 12, 2006

David Goldberg
2005 S 91st ST
Omaha, NE 68124-2019

Dear Mr. Goldberg:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address http://www.informulab.com and has determined that the products Beta Fast GXR Glucose Balance and Beta Fast GXR Glucose Tolerance 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:

- "Clinical trials conducted in the USA involving Beta Fast have shown substantial reductions in blood glucose and HbA1c levels."

- "Typically, individuals with diabetes experience reduced glucose averages of 10 to 15% within 45 to 60 days of initiating GS. After 180 days, users have shown declines in the 30 to 40% range. Studies show that in approximately 20% of Type 2 cases, oral hypoglycemic use can be substantially reduced or replaced with consistent administration of GS."

Examples of Claims made in the form of testimonials:

- "I just wanted to inform you about the positive results that I've experienced by taking the BETA-FAST Gymnema Sylvestre.… The glycemic No. (HbA1c) dropped from 7.3 to 6.4, in those 3 months."

- "Without BetaFast I was in the 145-155 range. My first two tests after BetaFast were 116 and 109."

- "My HbA1c test went up to 8 plus and since I started with Beta Fast the last reading was 6.1."

- "I have been taking BetaFast GXR Glucose Balance for a few years now. Since I've been on this supplement my hemoglobin A1c has dropped from 7.8 to 6.5. I have lost 20 lbs., and my doctor has had to take me off of my Humulin-R insulin. This is the first time since I became a Type 1 diabetic at the age of 8 years old. I am now 45 yrs."

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. Your products are also misbranded within the meaning of section 502(f)(1) of the Act, in that the labeling for these drugs fails 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 ensure 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 addressed to Kristen Moe, Compliance Officer, Food and Drug Administration, Division of Compliance and Enforcement, 5100 Paint Branch Parkway, College Park, Maryland 20740-3835, or you may respond electronically (e-mail) at kristen.moe1@FDA.HHS.GOV.

If you have any questions concerning this letter, please contact Ms. Moe at 301-436-2064.

Sincerely,

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