



AUG 16, 2005

Food and Drug Administration
College Park, MD**CERTIFIED MAIL**
RETURN RECEIPT REQUESTEDDavid Goldberg
Informulab
2005 So. 91 St
Omaha, NE 68124

Ref. No. CL-05-HFS-810-180

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.betafast.com> and has determined that the products Beta Fast GXR Glucose Balance and Nutramin Body System™ 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:

Beta Fast GXR Glucose Balance

“Diabetes? Depend on us for selection, savings and fast shipping on clinically tested supplements promoting healthy glucose levels, including Beta Fast® GXR Glucose Balance ...”

Nutramin Body System™

Your website contains a chart of this product’s ingredients with disease prevention or treatment claims for many of the ingredients, including: “White Willow Bark...Precursor to aspirin. Anti-inflammatory”

“Bee Pollen...Anti-allergen.”

“Licorice Root...Anti-inflammatory and antiviral.”

“Garlic...Also boasts anti-bacterial, antifungal properties.”

“Citrus Bioflavonoids...Anti-inflammatory and anti-viral.”

“Rutin...Rutin works as an anti-inflammatory, [and] anti-viral....”

“Alfalfa Herb...Also helpful as an ... anti-inflammatory.”

“L-Lysine...Helps control viral related ailments such as cold sores.”

“L-Glutamine...Anti-inflammatory....”

Your web site also contains disease claims in the form of personal testimonials, including:

“Diagnosed with Types 2 in Jan. 2004. Glucose level was ranging from 275 to 305 and HbA1c was 10.1. Starting taking (Beta Fast) Glucose Balance....” At 6 weeks I tested 147 and my HbA1c was 7.3.”

“It was with pleasure that I reordered my Glucose Balance pills....My numbers were in the high 180’s and low 190’s...After 90 days I’m down 30 to 40 points for my morning readings before breakfast....”

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

“I have been a diabetic for close to 21 years. Starting about 6 months ago my blood sugar levels were in the 170-180 range. I started taking “Beta Fast about 2 months ago. Since then, my fasting blood sugar levels have dropped to the 130 level.”

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