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

Food and Drug Administration
College Park, Maryland 20740

OCT 6 2005

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Sarfraz Zaidi, M.D., F.A.C.P.
166 North Moorpark Road, #304
Thousand Oaks, California 91360

Ref. No. CL-05-HFS-810-192

Dear Dr. Zaidi:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address http://www.diabetesspecialist.com and has determined that the product "Glupride Multi" is promoted for conditions that cause the product to be a drug 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 product is a drug because it is intended for use in the cure, mitigation, treatment, or prevention of disease. The marketing of this product with these claims violates the Act.

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

"**Glupride Multi is recommended for patients with:**

- Diabetes
- Pre-Diabetes …
- Diabetic Neuropathy
- Polycystic Ovary Syndrome
- Metabolic Syndrome (also known as Insulin Resistance Syndrome)"

"Many vitamins and herbs can lower blood glucose. Some do it by producing more insulin and others do it by reducing insulin resistance…. In patients with Type 2 diabetes, the primary defect is insulin resistance …. [T]he body responds to mounting insulin resistance by producing huge amounts of insulin to keep blood glucose normal. Eventually, … blood glucose starts rising and a person is diagnosed with diabetes…. Now imagine what happens to these over-stressed beta-cells if you take a drug, herbal product or vitamin that further stresses these cells by demanding even more insulin production…. Dr. Zaidi has put together the right combination, in the right doses, of vitamins and herbs that act by reducing insulin resistance; the good vitamins and herbs. This product is called GLUPRIDE Multi."

"A number of scientific studies have clearly shown that alpha-lipoic acid in large doses reduces insulin resistance in diabetic and pre-diabetic individuals.
An excellent study about alpha-lipoic acid was recently published in Endocrine Practice, the official journal of the American College of Endocrinology. In this study, alpha-lipoic acid was found to be effective in lowering blood glucose. It was also found to be extremely safe. I use alpha-lipoic acid in my diabetic as well as pre-diabetic patients and have found it to be extremely useful."

"Alpha-lipoic acid also functions as a strong anti-oxidant. The cells of diabetic patients are under a tremendous amount of daily oxidative stress. Oxidative stress further worsens insulin

resistance.
Alpa-lipoic [sic] acid treats this oxidative stress-mediated insulin resistance. That's why it makes perfect sense to use this product as a supplement in diabetic patients."

"Several studies have also shown alpha-lipoic acid to be effective in the treatment of diabetic peripheral neuropathy.
In Germany, this product has been used to treat diabetic neuropathy for over 30 years. Fifteen clinical trails … have clearly established the effectiveness of alpha-lipoic acid in treating peripheral as well as autonomic neuropathy due to diabetes."

Furthermore, your product is not generally recognized as safe and effective for the above referenced conditions and therefore, the product is also a "new drug" 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