



**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

October 12, 2006

Annie Rose, Inc.  
704 26 ½ Road  
Grand Junction, Colorado 81506

Dear Ms. Rose:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web sites at the Internet addresses <http://www.westopdiabetes.com> and [www.thefightdiabetes.com](http://www.thefightdiabetes.com) and has determined that the product Food Matrix™ Diabetes Pack™ 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:

- “Lowers Cholesterol and blood pressure”
- “Lowering blood sugar levels 30% in type 2 diabetics in an average of 30 days.”
- “Lower Blood Cholesterol Levels”

In the form of Testimonials:

- “I have been a Type 1 Diabetic for 25 years. This terrible disease has caused me to be partially blind. Through dietary changes and the Diabetes Pack™, the following changes have taken place:
  - I no longer need a night time insulin shot. First time in 25 years.
  - My glucose dropped from 300 to 70 and stabilized.
  - The terrible neuropathy that I was enduring (acute at night) is 99% gone.

After reporting these results to my doctor, he asked me to go off the products for 3 days as a test. These were the results:

Day 1: my blood glucose increased to 140

Day 2: my blood glucose increased to 200

Day 3: my blood glucose increased to 337

"I started back on the Diabetic Pack and my glucose went back down to 70. My doctor told me to stay on the FoodMatrix™ Diabetic Pack." - Richard Tovar, California

- "I was traveling all over the country 5 days a week. I had weeks where I took 5 flights to 4 different States to meet with clients. My eating habits were terrible, eating out at restaurants for every meal. At times I'd grab junk food and run onto the plane. I was under a lot of stress. I had a large monthly payroll that added additional stress. I became very ill. I lost 20 pounds in a few weeks. I went to a doctor and he told me I had a virus. Three days later my wife took me into the emergency room. I was delirious. The whole thing was a blur. I spent 5 days in intensive care. I found out that I was a diabetic. My blood sugar was 650. I was a very sick man. My family prayed that I would survive. I began taking 2 insulin shots a day. I attended 12 hours of diabetic training over 4 weeks. I began walking every morning for an hour. I met with a nutritionist that provided me with a diet to follow. I then began taking "The Diabetic Pack" my blood sugar was 320. Within a 3-week period my blood sugar dropped 100 points to 220. Four weeks later my sugar dropped 80 more points to 140. I was ecstatic. Today I no longer need to take insulin shots or any medication. My energy level is fantastic. I no longer follow the diet from the nutritionist because it supported my insulin needs. If I continued to follow the doctor's instructions I would be taking insulin shots today. To quote he doctor "you are a very sick man and will need to take insulin the rest of your life". I thank God that I was able to take control of my own life and found "The Diabetic Pack". If you want to change your life Diet, Exercise, and the Diabetic Pack'."
- "I was diagnosed last year with type 2 diabetes. My a1c was 11.5 – meaning my blood sugar levels had been averaging over 300. I ended up in the hospital, placed on dialysis and had 5 massive leg ulcers and was put on insulin twice a day. In July, 2004 I started on The Diabetic Pack. **Within 8 weeks** my blood sugars started going down! By the end of the **3rd month** they had dropped over 30%. By the **end of the fourth month**, I went to see my endocrinologist. My a1c was down to 5.1. He couldn't believe it! He took me off all insulin and diabetic medication. He told me I didn't have to come back for 3 months. In January, 2005 I went back. My a1c was down even more – to 4.1. This means my blood sugar levels were averaging in the 90s! He kept asking if I was taking any insulin and I told him "No, just The Diabetic Pack that I told you about before." In addition to the blood sugar correction, in November I was taken off my high blood pressure medicine! My blood pressure runs in the 90s/70s! **And lastly, my leg ulcers have healed much faster than the doctors ever expected!** Thank you for changing my life!"
- "My blood sugar would run between 220 and 300. Now, 60 days after taking Sportron products, it has dropped to 107. The pain and tingling in my feet and legs have also gone. Thank you Sportron."

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. Your product “Food Matrix™ Diabetes Pack™” is also misbranded within the meaning of section 502(f)(1) of the Act, in that the labeling for this drug 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 sites, 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 addressed to Kristen Moe, Compliance Officer, Food and Drug Administration, Division of Compliance and Enforcement, 5100 Paint Branch Parkway, College Park, Maryland 20740-3835. If you prefer to respond electronically, send your e-mail to [kristen.moe1@FDA.HHS.GOV](mailto: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