



WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

October 12, 2006

Geromatrix
Robert Magedeoff
Pulsecast Interactive Corp
19219 N. Creekshore Ct
Boca Raton, FL 33498

Dear Mr. Magedeoff:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address <http://www.geromatrix.com> and has determined that the products "Glucose Balance" and "Glucose Support" 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:

Glucose Balance and Glucose Support

- "Diabetes supplements can assist you in keeping your blood sugar stabilized if you suffer from Type I or Type II Diabetes.
...
Complications from this disease can be kept to a minimum if ... you take diabetes supplements that will enable you to better control your blood glucose levels. Our Geromatrix diabetes supplements will provide you with sugar normalizing benefits without any of the unwanted side effects - naturally." [followed by a link to your products Glucose Balance and Glucose Support]
- "Manage your Disease With Diabetes Supplements" [followed by a link to your products Glucose Balance and Glucose Support].
- "GeromatrixTM Glucose Balance works to assist the body to normalize glucose levels in a natural way.
...
About 90% of individuals who have diabetes suffer from type 2 diabetes.

People with this condition either don't produce enough insulin to control glucose levels or their cells simply do not respond to the insulin. If the pancreas produces some insulin, the production level is often not sufficient to lower the blood glucose level to normal."

- [on a web page for your product Glucose Support] "Here at Geromatrix, we believe that supplementing ... with glucose supplements, will help assist diabetics in maintaining normal glucose levels."
- "Geromatrix™ Glucose Support contains:
 - Lagerstroemia Speciosa Leaf, a phytochemical complex that contains Colosolic Acid, clinically shown to have insulin-like effects. ... Lagerstroemia Speciosa Leaf exhibits glucose-lowering properties. The decoction of leaves has been clinically tested and found to lower blood sugar. ...
 - 400 mg of Gymnema Sylvestre, the clinically proven amount of the 'sugar destroyer' found useful in reducing blood sugar levels"

Examples of some of the claims on your web site in the form of testimonials include:

- "I've been a diabetic for more than 20 years ... I found my traditional medicine not working as well and then I discovered Glucose Support and Glucose Balance I can eat more; my sugars have dropped to reasonable levels, and they remain more consistent. I was frustrated before I introduced [Glucose Balance] and [Glucose Support] to my arsenal to fight this terrible disease. ... I've cut back (not completely) on traditional medicine that is covered by my health care plan."
- "I have now been using Glucose Balance and Glucose Support for my Type II diabetes instead of the prescription meds my doctor prescribed and for the first time in two years my blood sugar is back to normal levels."
- "Your Glucose Support helped get me off my prescription medication while maintaining my blood sugar level within the normal range...Thank you!"
- "I'm doing fantastic on your Glucose Balance and Glucose Support. In fact, my blood sugar has never been better. Recently, I had my A1C checked and it came back at 6.5 (7 is what the Doctor was shooting for). Before these two products, I was at 10.6 and my blood sugar averaged 240-250. Glucophage did not work well nor did it agree with me. Now taking your all natural products for just 6 weeks my readings are in the 90/100 range."

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 "Glucose Balance" and "Glucose Support" 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 promote 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 web site, 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. 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