



2004 AUG 31 17:00

AUG 31 2004

Ms. Candis L. Scott  
CEO  
Highland Laboratories  
110 S. Garfield  
P.O. Box 199  
Mt. Angel, Oregon 97362

Dear Ms. Scott:

This is in response to your letter of March 29, 2004 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your letter states that the following statements, among others, will be made for the product **Glucose Response™** :

- “Supports normal range blood sugar level.”
- “[D]emonstrates hypoglycemic activity.” (i.e., bitter melon juice)
- “[T]hought to mimic insulin action.” (i.e., vanadyl sulfate)
- “A normal blood glucose level depends on sufficient supply of insulin; this property of garlic is associated with promoting such a balance.”
- “[A]ssist glucose tolerance.” (i.e., B vitamins)
- “[I]n many people, poor diet and inadequate exercise can lead to an overabundance of glucose in the bloodstream. Glucose Response™ is designed to support...normal glucose balance.”

In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because “many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease,” in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. The same principle applies to claims about the control of blood glucose levels; that is, a claim that does not establish that the claim is about blood glucose levels that are already within normal limits implies that the product is intended to treat elevated blood glucose

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(diabetes), which is a disease. Therefore, because the claims you are making for this product represent that the product is intended to affect blood glucose but do not also include a statement about it being intended to affect blood glucose levels that are already in the normal range, they are implied disease claims. Moreover, your claims about the product's intended effect on blood glucose are made expressly in the context of their being hyperglycemia (i.e., [P]oor diet and inadequate exercise can lead to an overabundance of glucose in the bloodstream. Glucose Response™ is designed to support...normal glucose.”).

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggest that it is intended to treat, prevent, or mitigate disease. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely yours,



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

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300  
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200  
FDA, Seattle District Office, Office of Compliance, HFR-PA340

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March 29, 2004

APR 26 2004

Office of Nutritional Products  
Labeling and Dietary Supplements (HFS-810)  
FDA  
200 C Street, SW  
Washington, DC 20204

P.O. Box 199

RE: Notification for Statement on Dietary Supplement

Dear Sir/Madam:

110 South Garfield

In compliance with the Dietary Supplement Health and Education Act of 1994, **Highland Laboratories, 110 S Garfield, PO Box 199, Mt. Angel, Oregon 97362**, hereby makes its official notification under Section 101.93 that it has included a statement listed in Section 403(r)(6) of the Federal Food, Drug, Cosmetic Act on its label. Accordingly, enclosed please find two (2) copies of this Notification.

Mt. Angel, OR 97362

Company	Product Name	Dietary Ingredients	Statements
Highland Laboratories	Glucose Response™	Vit. B-6 70 mg. Folic Acid 400 mcg. Vit. B-12 50 mcg. Magnesium 100 mg. Chromium 400 mcg. Fenugreek Seed 200 mg. Bitter Melon 175 mg. DMG 100 mg. Green Tea Ext 100 mg. L-Cystine 50 mg. Banaba Ext 20 mg. Vanadyl Sulfate 12 mg. Gamma Glutamylcysteine 2 mg.	Supports normal range blood sugar level, Supports liver and pancreas. Supports cellular health.  <i>Please see attachment 1</i>

503-845-9223

1-800-547-0273

FAX 503-845-6364

email: highlnd@pdx.oneworld.com

8843 4  
(707)

I hereby certify that the information presented and contained in this notice is complete and accurate, and my files contain substantiation that the statements made are truthful and misleading.

Sincerely,

A handwritten signature in cursive script that reads "Candis L. Scott". The signature is written in black ink and is positioned above the printed name and title.

Candis L. Scott  
CEO Highland Laboratories

**Attachment 1**  
**Highland Laboratories**

**Glucose Response™**

Glucose is one of the “nectars” of life. But like a lot of good things, balance is important

Glucose comes from the digestion of sugar, whether in raw form or derived from starchy foods. The function of the pancreas is to produce insulin, which then regulates the amount of glucose in the blood and the rate at which glucose is taken in by cells. Optimum health depends on the ability of cells to properly receive and convert glucose into energy.

In many people, poor diet and inadequate exercise can lead to an overabundance of glucose in the bloodstream. Glucose Response™ is designed to support cellular health and normal glucose balance.

**B Vitamins (B6, Folic Acid, B12)**

B vitamins are involved in many important body functions and work synergistically, creating red blood cells, for instance, which assist glucose tolerance<sup>1</sup> these vitamins also aid in the synthesis of DNA and overall cellular health.

**Minerals ( Magnesium, Chromium)**

Important in the manufacture of new cells and aiding the secretion and balance of insulin.

**Antioxidants (Green Tea Extract, Bilberry Fruit Extract)**

**L-Cystine** - an amino acid and precursor to glutathione, it is one of the best free radical fighters known.

**Fenugreek Seed** – traditional source of rich fiber, thought to be important in the amount of cholesterol absorbed<sup>2</sup> and in maintaining healthy blood sugar levels.

**Bitter Melon Juice** – this tropical fruit is a traditional medicine used for centuries in Asia, Africa and South America, with properties that demonstrate hypoglycemic activity.<sup>3</sup>

**Banaba Extract (Lagerstroemia speciosa)** is another traditional plant used in Southeast Asia and is thought to be beneficial in the normal glucose uptake process – where cells turn glucose into energy.

**DMG (Dimethylglycine)** – a derivative of glycine, the simplest of amino acids. Beneficial in maintaining energy levels, as well as being involved in normal blood glucose, cholesterol and triglyceride levels.

**Vanadyl Sulfate** – an essential nutrient found naturally in black pepper, buckwheat, parsley and shellfish – vanadyl sulfate is thought to mimic insulin action.

**Gamma Glutamylcysteine** (from *Allium sativum* bulb) is a derivative of garlic. A normal blood glucose level depends on sufficient supply of insulin; this property of garlic is associated with promoting such a balance.

**Sources**

1. Spellacy, WN; Buhi, WC; Birk, SA. *Amer. Jnl. Obstet Gynecol.* 1977; 127:599-602
2. Sauvaire, Y; Ribes, G; Baccou, JC; Loubatieres-Mariani, MM. Implication of saponins and sapogenins in...fenugreek. *Lipids*, 1991; 26:191-7
3. Werbach, MR; Murray, MT. A sourcebook of clinical research, Third Line Press, 1994, pgs. 138-139.

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Labeling and Dietary Supplements (HFS-810)  
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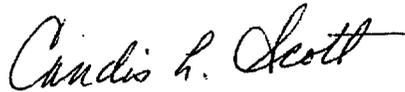
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