DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

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Mr. Ravindra Khare
Financial Controller
Herbo, Inc.
4W, 37th St
3rd Floor
New York, New York 10018

Dear Mr. Khare:

This is in response to your letter of February 6, 2003 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)). In your letter, you notified us about a claim you intend to use for your dietary supplement **Glucogard**.

The product **Glucogard** uses the claim "...help maintain healthy blood sugar level." 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 your claim about control of blood sugar level; that is, a claim that does not establish that the claim is about blood sugar that is already within normal limits implies that the product is intended to treat elevated blood sugar or diabetes, which is a disease.

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 statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate diseases, namely diabetes or other disorders of blood sugar regulation. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests 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, 7520 Standish Place, Rockville, Maryland 20855.

975-0163

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Please contact us if you require further assistance.

Sincerely yours,

Susan J. Walker, M.D.
Acting 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, New York District Compliance, HFR-NE140

MAR - 5 2003

NOTIFICATION PURSUANT TO SECTION 6 OF DSHEA and 21 C.F.R. § 101.93

This notification is being filed on behalf of Herbo, Inc. which is the producer of the product which bear the statements identified in this notification. Its business address is: 4W, 37th Street, 3rd floor, New York, NY 10018. This notification is being made pursuant to Section 6 of DSHEA and 21 C.F.R. § 101.93. The dietary supplement product on whose label or labeling the statements appear is **Glucoguard**

A. The text of each structure-function statement for which notification is now being given is:

Statement 1: Neutralizes the craving for sugar and help maintain healthy blood sugar level.

B. The following summary identifies the dietary ingredients(s) or supplement(s) for which a statement has been made:

Statement Number	**Identity of Dietary Ingredients that are the Subject of the Statement**
1.	Garcina, Gymnema, Momordica and Fenugreek.

I, Ravindra Khare, am authorized to certify this Notification on behalf of Herbo, Inc. I certify that the information presented and contained in this Notification is complete and accurate, and that Herbo, Inc. has substantiation that each structure-function statement is truthful and not misleading.

Date : 02/06/03

By: _____
Ravindra Khare
Financial Controller

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