



APR - 8 2002

8 3 7 8 '02 APR 12 P 1:35

Ms. Gladys Valencia
Owner
Shanti Herbs
P.O. Box 74488
Los Angeles, California 90004

Dear Ms. Valencia:

This is in response to your letter of December 15, 2002 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)).

The product **Gluco Health** uses the claim "helps 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 a disease. 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 we may be of further assistance.

Sincerely,



John B. Foret

Director

Division of Compliance and Enforcement
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, Los Angeles District Office, Office of Compliance, HFR-PA240

S H A N T I HERBALS

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December 15, 2001

Dr. Elizabeth Yetley
Office of Special Nutrition (HFS-450)
Center of Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street S.W.
Washington, DC 20204

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RECEIVED
FEB 27 2002

BY:.....

Re: Notification of Product Claims

Dear Dr. Yetley:

This letter serves as notification of the nutrition support labeling statements being made by our company in connection with our line of dietary nutritional supplements. A list of the products and their respective nutritional support statements and ingredients are listed in the attached Exhibit "A".

Shanti Herbals certifies that the information contained in this notice is complete and accurate, and the company maintains documentation to substantiate that its product claims are truthful and not misleading.

If you have any questions, please feel free to contact me and I will do my best to answer your questions.


Gladys Valencia
Owner
Shanti Herbals

EXHIBIT "A"

SHANTI HERBALS

GLUCO HEALTH

Stops Sugar Cravings, Helps Maintain Healthy Blood Sugar Level, Revitalizes Body, Optimizes Many Body Functions.

Ingredients: Gymnema Sylvestre; Momordica Charantia; Azadirachta Indica; Emblica Officinalis; Eugenia Jambolana; Pterocarpus Marsupium; Curcuma Longa; Tinospora Cordifolia; Trigonella Foenumgraecum; Withania Somnifera; Shilajit

VIGOR FORTE

(For Men)

Powerful Rejuvenator; Promotes Sexual Vigor and Vitality; Supports Erection & Satisfactory Libido.

Ingredients: Withania-Somnifera; Shilajit; Asparagus Racemosus; Glycyrrhiza Glabra; Tribulus-Terrestris; Myristica-Fragrans; Crocus-Sativus.