



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

MAR 14 2000

19 17 '00 MAR 17 P2:32

Laurie J. Smidt, Ph.D., R.D.
Owner
TheraNutria
636 S. 1450 East
Springville, Utah 84663

Dear Dr. Smidt:

This is in response to your letter of February 19, 2000 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 submission states that TheraNutria is making the following claim, among others, for the product **Glucovite**:

“...comprehensively addresses the special and general micronutrient requirements of individuals with glucose intolerance and diabetes.”

“...promote normal blood sugar and insulin levels...”

“...promote normal glucose tolerance.”

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 disease, namely diabetes and disorders of glucose tolerance. 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.

Please contact us if you require 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

975-0163

LET 345

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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, Denver District Office, Office of Compliance, HFR-SW240

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-800 (r/f, file)

HFS-811 (r/f, file)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-605

HFV-228 (Benz)

GCF-1 (Dorsey, Barnett, Nickerson)

f/t:HFS-456:rjm:3/10/00:docname:69477.adv:disc45

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TheraNutria

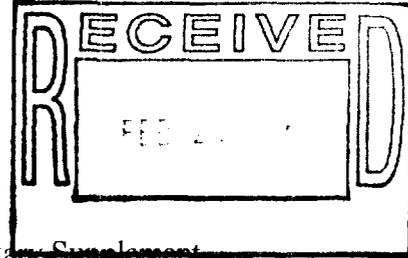
636 S. 1450 East
Springville, UT 84663

Tel.: 801-491-0565
Fax: 801-491-0566

GlucoVite

February 19, 2000

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
200 C St. SW
Washington, DC 20204



RE: Notification for Structure/Function Statements on Dietary Supplement

Dear Sir or Madam:

As required by Section 403(r)(6)(c) of the Food, Drug and Cosmetic Act, TheraNutria, 636 S. 1450 East, Springville, Utah 84663, intends to market a dietary supplement product with the following label statements of nutritional support:

Product identified as "GlucoVite" with the following label statements:

- GlucoVite comprehensively addresses the special and general micronutrient requirements of individuals with glucose intolerance and diabetes.
- GlucoVite helps promote normal blood sugar and insulin levels, nerve function and optimum antioxidant protection.
- GlucoVite helps promote normal glucose tolerance.

I certify that the information contained in this notice is complete and accurate and that TheraNutria has substantiation that these statements are truthful and not misleading.

Sincerely,


Laurie J. Smidt, Ph.D., R.D.
Owner, TheraNutria