



NOV 24 1997

Simon Hsia, Ph.D.
Vice President of Technology
Viva America Marketing Corporation
1239 Victoria Street
Costa Mesa, California 92627

0560 '98 MAR 24 P2:43

Dear Mr. Hsia:

This is in response to your letter of November 10, 1997 to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act). Your submission states that Viva America Marketing Corporation is making the following claims for the product "LipoGuard:"

- "Maintains Healthy Cholesterol Levels"
- "Reduces Total Cholesterol"
- "Reduces Triglycerides"
- "Reduces LDL "Bad Cholesterol"

Section 403(r)(6) of the act 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, cure, mitigate, or prevent disease, namely hypercholesterolemia and hypertriglyceridemia. These claims do not meet the requirements of section 403(r)(6) of the act. These claims suggest that this product is intended for use as a drug within the meaning of section 201(g)(1)(B) of the act, 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 we may be of further assistance.

Sincerely,

James T. Tanner, Ph.D.
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

975-0163

LET126

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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, Los Angeles District Office, Compliance Branch, HFR-PA240

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO, JGordon)

HFS-456 (File)

HFS-450 (r/f, File)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-600 (Reynolds)

HFS-605 (Bowers)

GCF-1 (Nickerson, Dorsey)

f/t:rjm:HFS-456:11/201/97:55782.adv:disc24



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NOV 17 1997

Ms. Elizabeth Yetley
Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
200 C Street, SW
Washington, DC 20204

November 10, 1997

Dear Ms. Yetley:

Notice is hereby given pursuant to the requirements of section 403 (r) (6) (21 U.S.C. 343 (r) (6) of the Federal Food, Drug and Cosmetic Act and in accordance with the requirements of 21 CFR 101.93, that Viva America Marketing Corp., 1239 Victoria Street, Costa Mesa, CA, 92627, within the past 30 days commenced marketing a dietary supplement, **LipoGuard**, bearing the following statements on the label and/or in the labeling:

- Maintains Healthy Cholesterol Levels
- Reduces Total Cholesterol
- Reduces Triglycerides
- Reduces LDL "Bad Cholesterol"

The undersigned certifies that the information contained in this notice is complete and accurate and that Viva America Marketing Corp., has substantiation that the statement is truthful and not misleading.

Sincerely,

Dr. Simon Hsia, Ph.D.
Vice President of Technology

P.S. Dr. Simon Hsia is currently on assignment in Asia and will return on November 15. In order to get this notification to your department within the allotted time period, Dr. Hsia signed a faxed document and returned by fax to us to attach to this original letter. Upon his return to the States another original letter will be sent with his original signature to attach to this document.

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