



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

DEC - 3 1999 7943 '99 DEC 13 P3:15

Simon Hsia, Ph.D.
Vice President of Technology
and Marketing Support
VIVA Life Science, Inc.
1239 Victoria Street
Costa Mesa, California 92627

Dear Dr. Hsia:

This is in response to your letter to the Food and Drug Administration (FDA) dated November 19, 1999, 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 VIVA Life Science, Inc. is making the following claim, among others, for the product "DailyGuard:"

"Helps maintain healthy cardiac risk ratios."

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 claim that you are making for this product suggests that it is intended to treat, prevent, cure, or mitigate disease, namely cardiovascular 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.

Please contact us if you require further assistance.

Sincerely,

Lynn A. Larsen, Ph.D.
Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

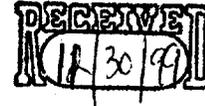
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Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
200 C Street, SW
Washington, DC 20204



November 19, 1999

Dear Acting Director for Office of Special Nutritionals:

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 Life Science, Inc., previously known as VIVA America Marketing Corp., at 1239 Victoria St., Costa Mesa, CA 92627, within the past 30 days commenced marketing dietary supplements for which the following structure/function statements are made.

DailyGuard

DailyGuard is your premium supplemental source of multi-vitamins, minerals, phytonutrients and antioxidants, formulated in a base of more than 30 fruit and vegetable concentrates.

- ◆ Clinically studied to help promote healthy cholesterol levels.
- ◆ Helps maintain healthy cardiac risk ratios.

Following are a few of the references for substantiation on file.

Medical Science Research, February 1999, Vol. 27, No. 2, pages 121-125
Progress in Cardiovascular Nursing 1997, 12(3): 3-23

LipoGuard

- ◆ LipoGuard softgels contain concentrated Omega-3 fatty acids, garlic and other nutrients in a proprietary formulation that helps maintain your healthy cholesterol and triglyceride levels.
- ◆ Clinically studied to help maintain healthy cholesterol and triglyceride levels.

Following are a few of the references for substantiation on file.

National Medical Association, October 1997, Vol 89, No. 10, pages 673-678
International Journal of Clinical Pharmacology, Therapy and Toxicology 1991, Vol. 29, No. 4, pages 151-155

The undersigned certifies that the information contained in this notice is complete and accurate and that VIVA Life Science, Inc., previously known as VIVA America Marketing Corp., has substantiation that the statements are truthful and not misleading.

Sincerely,

Dr. Simon Hsia, Ph.D.
Vice President of Technology and Marketing Support

VIVA Life Science, Inc.