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Mr. Ira Goldberg
President
Source Naturals, Inc.
Scotts Valley, California 95066

Dear Mr. Goldberg:

This is in response to your letter of December 8, 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 Source Naturals, Inc., is making the following claim, among others, for the product **Phytosterol Complex™ with 108 mg beta-sitosterol**:

“...may help to maintain normal cholesterol levels when consumed as part of a low cholesterol dietary program.”

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. 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.

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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

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, San Francisco District Office, Office of Compliance, HFR-PA150

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cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-800 (r/f, file)

HFS-811 (file)

HFD-40 (Behrman)

HFD-310

HFD-314 (Aronson)

HFS-605

HFV-228 (Benz)

GCF-1 (Nickerson)

f/t:HFS-811:afp:02/12/01:docname:74386:disc1

Source Naturals, Inc.
Scotts Valley, CA 95066

December 8, 2000

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1/9/01

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

RE: Notification of Nutritional Support Statements

Dear Sir or Madam:

I hereby notify the Food and Drug Administration (FDA) of the use of statements of nutritional support in the labeling of Phytosterol Complex™ with 108 mg beta-sitosterol, a dietary supplement. Source Naturals® is the manufacturer of Phytosterol Complex™ with 108 mg beta-sitosterol.

Statements being made in the labeling of Phytosterol Complex™ with 108 mg beta-sitosterol:

- (1) Preliminary scientific evidence suggests that plant phytosterols (may help to maintain normal cholesterol levels when consumed as part of a low cholesterol dietary program.)

To the best of my knowledge, and based upon information and belief present at the time of the execution of this notice, I certify that the above information is accurate and complete. Source Naturals possesses substantiation that the statements are truthful and not misleading.


Ira L. Goldberg
President, Source Naturals, Inc.

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