



1036 '01 APR 13 P3:21

MAR 26 2001

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

Dear Mr. Goldberg:

This is in response to your letters of December 1, 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 claims, among others, for the products below:

Wellness Garlicell™

“...to help maintain cholesterol levels within a normal range when taken in conjunction with a low-fat, low-cholesterol diet.”

Omega EPA™

“...may help maintain cholesterol levels within a normal range when consumed as part of a low-fat and 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 statements that you are making for these products suggest that they are intended to treat, prevent, cure, or mitigate diseases. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are 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-3 10, 7520 Standish Place, Rockville, Maryland 20855.

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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, 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)

HITS-800 (r/f, file)

HFS-8 10

HFS-811 (file)

HFD-40 (Behrman)

HFD-310

HFD-3 14 (Aronson)

HFS-605

HFV-228 (Benz)

GCF- 1 (Nickerson)

f/t:HFS-811 :afp:02/08/01:docname:74368a:disc1

Source Naturals, Inc.
Scotts Valley, CA 95066

December 1, 2000

1/8/01

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

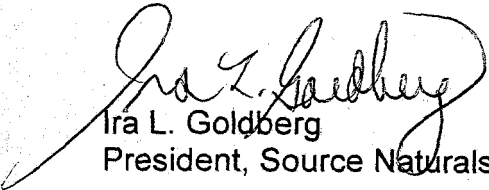
Dear Sir or Madam:

I hereby notify the Food and Drug Administration (FDA) of the use of statements of nutritional support in the labeling of Wellness Garlicell™, a dietary supplement. Source Naturals® is the manufacturer of Wellness Garlicell™.

Statements being made in the labeling of Wellness Garlicell™:

- (1) The Wellness Family™ of products are designed to support the body's immune system when under physical stress.
- (2) Garlic is known (to help maintain cholesterol levels within a normal range when taken in conjunction with a low-fat, low-cholesterol diet.)

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®

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Source Natural?
Scotts Valley. CA 95066



December 1, 2000

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 OmegaEPA™ (marine lipids with EPA and DHA) a dietary supplement. Source Naturals* is the manufacturer of OmegaEPA™.

Statements being made in the labeling of OmegaEPA™:

- (1) OmegaEPA™ is an excellent source of fish oils, rich in omega-3 fatty acids. Omega-3's have been the subject of intensive research, due to repeated observations that people whose diets are high in fatty fish tend to be healthier than other populations. The most important omega-3 fatty acids are EPA and DHA. Preliminary scientific evidence suggests EPA (may help maintain cholesterol levels within a normal range when consumed as part of a low-fat and low-cholesterol dietary program) DHA is an important component of brain tissue.

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@

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