



MAR 25 2005

Mr. Ira L. Goldberg  
President  
Source Naturals  
23 Janis Way  
Scotts Valley, California 95066

Dear Mr. Goldberg:

This is in response to your letter of February 25, 2005 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)).

The product **Cholesterol Rescue™** is using the claims “[P]romote cholesterol wellness and may reduce your risk of heart disease” and “[R]educer the risk of coronary heart disease.” These statements are not claims subject to 21 U.S.C. 343(r)(6), but claims subject to 21 U.S.C. 343(r)(1)(B) because they represent that the product will reduce the risk of a disease or health related condition (i.e., coronary heart disease). FDA has authorized a health claim about the relationship between phytosterol and phytostanol esters and coronary heart disease (see 21 CFR 101.83)<sup>1</sup>. A dietary supplement that meets the eligibility and message requirements set forth in the regulation may bear a claim for the relationship between phytosterol/stanol esters and coronary heart disease. A health claim on the label or in the labeling of a food or dietary supplement that is not in accordance with the requirements in 21 CFR 101.83 would misbrand the food or dietary supplement under 21 U.S.C. 343(r)(1)(B). Moreover, failure to make a claim in accordance with the requirements in 21 CFR 101.83 subjects the product to regulation as a drug under 21 U.S.C. 321(g)(1)(B) because the product is intended to treat, cure, prevent, or mitigate a disease, coronary heart disease.

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<sup>1</sup>Also see February 14, 2003 letter regarding enforcement discretion with respect to expanded use of an interim health claim rule about plant sterol/stanol esters and reduced risk of coronary heart disease; <http://www.cfsan.fda.gov/~dms/ds-ltr30.html>.

Page 2 - Mr. Ira L. Goldberg

Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to be 'SJK', written in a cursive style.

Susan J. Walker, M.D.  
Director  
Division of Dietary Supplement Programs  
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-310

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200

FDA, Los Angeles District Office, Office of Compliance, HFR-PA240

Source Naturals®  
23 Janis Way  
Scotts Valley, CA 95066

February 25, 2005

MAR 14 2005

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

To whom it may concern:

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

Statements being made in the labeling of Cholesterol Rescue™

CHOLESTEROL RESCUE™..

- 1) Cholesterol Rescue™ part of the *Cholesterol Rescue™* family of products, is a scientifically formulated, all-natural blend of three key ingredients that work to promote cholesterol wellness and may reduce your risk of heart disease.
- 2) It contains plant sterols, which inhibit excess dietary cholesterol absorption.
- 3) Research suggests that daily consumption of 800mg of plant sterols, taken with food in two divided doses as part of a diet low in saturated fat and cholesterol, may reduce the risk of coronary heart disease.
- 4) Combined with the patented Sytrinol® ingredients - polymethoxylated flavones, which balance your body's cholesterol production, and tocotrienols that protect the cholesterol in your arteries from free radical damage, Cholesterol Rescue may support your healthy heart.

To the best of my knowledge and belief, and based upon information available 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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