



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Ser.

Food and Drug Administration
College Park, MD 20740

DEC - 3 2004

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

Dear Mr. Goldberg:

This is in response to your letter of October 21, 2004 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 letter states that Source Naturals is marketing a product, Source Naturals Red Yeast Rice, which "is standardized to 1.5% mixed mevinolinic acid monacolins."

FDA, on May 20, 1998, issued an Administrative Decision declaring Cholestin, a red yeast rice product containing lovastatin, to be an unapproved, and therefore illegal, new drug. Lovastatin, also known as Mevinolin or Monacolin K, is the active ingredient in Mevacor, an approved prescription drug intended to lower blood serum cholesterol levels.

Pharmanex, Inc., the manufacturer of Cholestin, challenged FDA's Administrative Decision in federal court. Although the United States District Court for the District of Utah initially ruled in Pharmanex's favor, the 10th Circuit Court of Appeals reversed that decision. Pharmanex v. Shalala, 221 F.3d 1151 (10th Cir. 2000). On March 30, 2001, the District Court, on remand from the 10th Circuit Court of Appeals, dismissed Pharmanex's complaint, and affirmed FDA's 1998 Administrative Decision.

Accordingly, red yeast rice products containing lovastatin are unapproved new drugs. Moreover, red yeast rice products that contain other substances that are approved drugs may also be unapproved new drugs under the Act. The introduction or delivery for introduction of an unapproved new drug into interstate commerce is prohibited under the Act, sections 301(d) and 505(a). The manufacturer, importation, or distribution of red yeast rice products containing lovastatin may also violate other provisions of the Act. Therefore, if the mevinolinic acid monacolins that are contained in your product include lovastatin or other substances excluded from dietary supplements under section 201(ff)(3)(B) of the Act, your product can not be marketed as a dietary supplement.

975-0163

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Please contact us if we may be of further assistance.

Sincerely yours,

for Robert J. Moore

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

October 21, 2004

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

NOV 05 2004

RE: Notification of Nutritional Support Statements

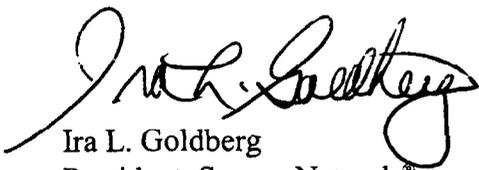
To whom it may concern:

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

Statements being made in the labeling of Red Yeast Rice

- 1) Red yeast rice is a natural compound that supports cholesterol wellness.
- 2) Source Naturals Red Yeast Rice is standardized to 1.5% mixed mevinolinic acid monacolins.
- 3) These monacolins inhibit the normal synthesis of cholesterol in the body by binding to the cholesterol production enzyme HMG-CoA Reductase.

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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