



AUG 28 2001

Mr. Ira Goldberg

President

Source Naturals

Scotts Valley, California 95066

Dear Mr. Goldberg:

This is in response to your letter of August 6, 2001 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 is making the following claim, among others, for its product **Calcium Citrate**: "...help support and maintain a healthy skeletal system, especially during the menopausal years when bone loss increases."

This statement is a statement about the relationship solely between calcium and osteoporosis and is not a claim subject to 21 U.S.C. 343(r)(6), but a claim subject to 21 U.S.C. 343(r)(1)(B). FDA has authorized a health claim on the relationship between calcium and osteoporosis (see 21 CFR 101.72). A dietary supplement that meets the eligibility and message requirements set forth in this regulation may bear a claim for the relationship between calcium and osteoporosis. 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 101.72 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 101.72 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, osteoporosis.

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

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975-0163

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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

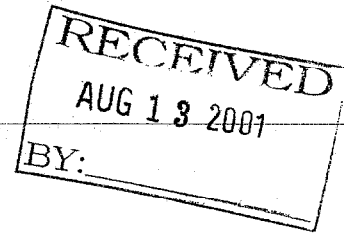
FDA, Los Angeles District Compliance, HFR-PA240

Source Naturals, Inc.
Scotts Valley, CA 95066

August 6, 2001

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

77255



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 Calcium Citrate, a dietary supplement. Source Naturals® is the manufacturer of Calcium Citrate.

Statements being made in the labeling of Calcium Citrate:

- (1) Calcium citrate is a form of calcium that is soluble and better absorbed by the body than other forms of calcium.
- (2) Research suggests that people who experience low levels of HCl in the stomach may benefit more from calcium citrate than calcium carbonate with regards to better absorption of calcium into the body.
- (3) Calcium citrate can help support and maintain a healthy skeletal system, especially during the menopausal years when bone loss increases.

A handwritten signature in cursive script, appearing to read "Ira L. Goldberg".

Ira L. Goldberg
President, Source Naturals, Inc.