DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

JUL 30 2003

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

Dear Mr. Goldberg:

This is in response to your letter of April 19, 2002 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. intends to use the following statement for its product Liquid Glucosamine Chondroitin 1500/12000:

> "...glucosamine and chondroitin sulfate can act synergistically in reducing the pain and stiffness associated with degenerative joint conditions."

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 diseases. 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, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20852.

Please contact us if we may be of further assistance.

Sincerely,

Susan J. Walker, M.D.
Acting Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

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 Office, Office of Compliance, HFR-PA240

Source Naturals, Inc.
Scotts Valley, CA 95066

April 19, 2002

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 Liquid Glucosamine Chondroitin 1500/1200, a dietary supplement. Source Naturals® is the manufacturer Liquid Glucosamine Chondroitin 1500/1200.

Statements being made in the labeling of Liquid Glucosamine Chondroitin 1500/1200:

(1) Glucosamine and chondroitin sulfates are the metabolic precursors of normal cartilage.

(2) Recent studies have demonstrated that glucosamine and chondroitin sulfate can act synergistically in reducing the pain and stiffness associated with degenerative joint conditions.

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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