



FEB 18 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 December 28, 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 submission states that Source Naturals is making the following claim, among others, for the product **Migraine Blocker™** :

“[G]ives temporary relief of migraine headache pain, pressure and throbbing.”

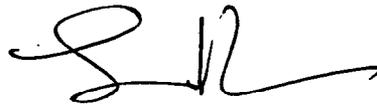
21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product, including the name of the product that uses the disease name migraine headache in the product name, suggests that it is intended to treat, prevent, or mitigate a disease, namely migraines. The claim you are making for this product 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.

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Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'SJW', with a long horizontal flourish extending to the right.

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

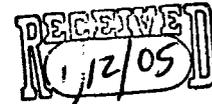
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

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

Source Naturals®
23 Janis Way
Scotts Valley, CA 95066

December 28, 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



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 Migraine Blocker™, a dietary supplement. Source Naturals® is the manufacturer of Migraine Blocker™.

Statements being made in the labeling of Migraine Blocker™

- 1) Homeopathic medicine is a safe treatment alternative for most minor ailments.
- 2) Symptom relief is attained through stimulation of the natural healing process.
- 3) Precise levels of homeopathic ingredients work safely and without side effects.
- 4) Source Naturals Migraine Blocker™ is safe, natural and gives temporary relief of migraine headache pain, pressure and throbbing.

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.

A handwritten signature in black ink that reads "Ira L. Goldberg".

Ira L. Goldberg
President, Source Naturals®

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