



FEB 23 2001

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

Dear Mr. Goldberg:

This is in response to your letters of December 22, 2000 and December 29, 2000 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., is making the following claims, among others, for the products below:

HeartResponse

"...increase the strength of contraction of the heart and to increase coronary blood flow."

Dura-Carb™

"...to support blood sugar regulation."

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 statements that you are making for these products suggest that they are intended to treat, prevent, cure, or mitigate diseases. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are 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, 7520 Standish Place, Rockville, Maryland 20855.

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Please contact us if we may be of 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

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, San Francisco District Office, Office of Compliance, HFR-PA150

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cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-800 (r/f, file)

HFS-810

HFS-811 (file)

HFD-40 (Behrman)

HFD-310

HFD-314 (Aronson)

HFS-605

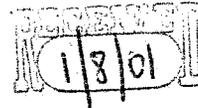
HFV-228 (Benz)

GCF-1 (Nickerson)

f/t:HFS-811:afp:2/9/01:docname:74396, 74400:disc1

December 22, 2000

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

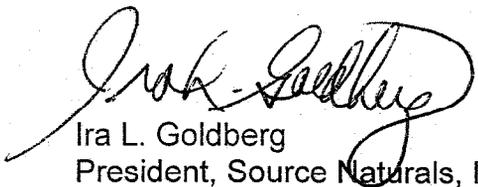
Dear Sir or Madam:

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

Statements being made in the labeling of Heart Response:

- (1) Heart Response combines hawthorn, L-carnitine, and CoQ10 with other herbs, vitamins, amino acids, antioxidants, and minerals to support cardiovascular function.
- (2) Research suggests that hawthorn has the ability to (increase the strength of contraction of the heart and to increase coronary blood flow.)

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, Inc.

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Source Naturals, Inc.
Scotts Valley, CA 95066

December 29, 2000

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

JAN - 3 2001

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 Dura-Carb™, a dietary supplement. Its ingredients contain, Branched, Long Chain, Slow Releasing Complex Carbohydrate from a special corn hybrid, and ChromeMate® brand of Yeast-Free GTF Chromium Polynicotinate. Source Naturals® is the manufacturer of Dura-Carb™.

Statements being made in the labeling of Dura-Carb™:

- (1) DuraCarb™ is the only branched, long chain complex carbohydrate drink, and the only "carbo-loading" drink with ChromeMate™ GTF Chromium (to support blood sugar regulation.)

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, Inc.

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