



JUN 18 1999

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

Dear Mr. Goldberg:

This is in response to your letter of June 3, 1999, 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 **Chem-Defense**:

“...for persons with chemical sensitivities”
“...for chemically sensitive individuals”

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 this product suggests that it is intended to treat, cure, prevent, or mitigate disease. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest 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, 7520 Standish Place, Rockville, Maryland 20855

Please contact us if we may be of further assistance.

Sincerely,

Lynn A. Larsen, Ph.D.
Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

975-0143

LET 283

Page 2 - Mr. Ira L. Goldberg

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-PA140

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-456 (file, r/f)

HFS-450 (r/f, file)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-605 (Bowers)

HFV-228 (Benz)

GCF-1 (Barnett, Dorsey)

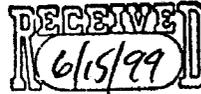
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SOURCE

NATURALS

June 3, 1999

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street SW,
Washington, DC 20204



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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 Chem-Defense tablets, a dietary supplement. Source Naturals® is the manufacturer of Chem-Defense.

Statements being made in the labeling of Chem-Defense:

- (1) Chem-Defense is a nutrient blend formulated for persons with chemical sensitivities. Recent scientific research indicates that molybdenum, a trace mineral which activates the enzymes aldehyde oxidase and sulfite oxidase, may provide necessary nutritional support for chemically sensitive individuals.
- (2) Glutathione (GSH) is a key element of the liver's detoxifying process (and is also the precursor for glutathione peroxidase, a major free radical-scavenging enzyme).

To the best of my knowledge, and based upon information and belief present at the time of the executing 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 cursive script that reads "Ira L. Goldberg".

Ira L. Goldberg
President, Source Naturals®

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