



MAR - 5 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 4, 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:

OptiZinc®

“...healing of wounds...”

K-Mag C™

“...regulation of heart action and blood pressure...”

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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Page 2 - Mr. Ira L. Goldberg

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)

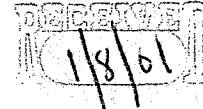
GCF-1 (Nickerson)

f/t:HFS-811:afp:2/8/01:docname:74381:disc1

Source Naturals, Inc.
Scotts Valley, CA 95066

December 4, 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:

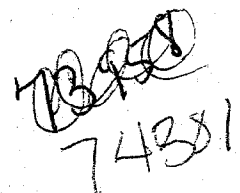
I hereby notify the Food and Drug Administration (FDA) of the use of statements of nutritional support in the labeling of K-Mag C™ a dietary supplement. Source Naturals® is the manufacturer of K-Mag C™.

Statements being made in the labeling of K-Mag C™:

- (1) Potassium and magnesium are the main minerals inside every cell in the body. Potassium is essential for nerve function, muscle strength, glycogen formation, and the (regulation of heart action and blood pressure.) Magnesium is essential for energy production and storage, muscle relaxation, and replenishment of potassium when it is depleted. Dietary surveys indicate that many people get only 2/3 of the U.S. RDA for magnesium, and the typical American high-sodium diet tends to deplete potassium. K-Mag C™ provides a simple solution to these common dietary imbalances, while providing an excellent source of high quality vitamin C.

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.


74381

December 4, 2000

1/8/01

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:

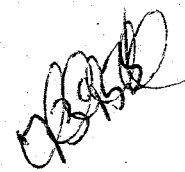
I hereby notify the Food and Drug Administration (FDA) of the use of statements of nutritional support in the labeling of OptiZinc[®] a dietary supplement. Source Naturals[®] is the manufacturer of OptiZinc[®].

Statements being made in the labeling of OptiZinc[®]:

- (1) Zinc is a trace element which is essential for normal growth, development of the reproductive organs, normal functioning of the prostate gland, (healing of wounds) and the manufacture of proteins and nucleic acids (the building blocks for RNA and DNA). It is also necessary for over 100 different enzyme systems in the body.

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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