



NOV 12 1998 8 32 9 '98 NOV 18 P2:12

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 October 23, 1998 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 statement, among others, for the products:

Acidophilus and DDS-1 Acidophilus

“...inhibit undesirable flora...”

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 these products suggest that they are intended to treat, prevent, mitigate, or cure disease, namely, diseases caused by pathogenic microorganisms. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests 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.

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

975-0163

LET 234

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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, 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)

HFS-450 (r/f, file)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-600 (Reynolds)

HFS-605 (Bowers)

GCF-1 (Nickerson, Dorsey)

r/d:HFS-456:RMoore:11/10/98

init:GCF-1:DDorsey:11/10/98

f/t:HFS-456:rjm:11/12/98:docname:62182.adv:disc33

October 23, 1998

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

11/9/98

RE: Notification of Nutritional Support Statements

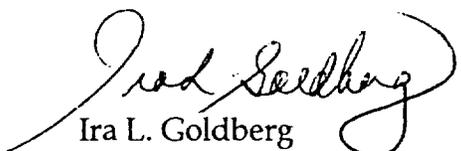
Dear Sir or Madam:

I hereby notify the Food and Drug Administration (FDA) of the use of statements of nutritional support in the labeling of Acidophilus and DDS-1 Acidophilus, a dietary supplement. Source Naturals® is the manufacturer of Acidophilus and DDS-1 Acidophilus.

Statements being made in the labeling of Acidophilus and DDS-1 Acidophilus:

- (1) Lactobacillus acidophilus supports colon health by altering the microflora ecology, to inhibit undesirable flora and favor "friendly" flora.
- (2) Acidophilus also manufactures some B-Vitamins, especially Folic Acid.

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.


Ira L. Goldberg
President, Source Naturals®

see also docket 975-0163

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