



MAR - 5 2001

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Mr. Ira L. Goldberg  
President  
Horizon Nutraceuticals  
P. O. Box 1806  
Santa Cruz, California 95061

Dear Mr. Goldberg:

This is in response to your letter 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 Horizon Nutraceuticals is making the following claim, among others, for the product **Cholesterin**:

“...help maintain cholesterol levels with a normal range when consumed as part of a low-cholesterol and low-fat dietary program.”

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 suggests that it is intended to treat, prevent, or mitigate disease. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim 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 you require 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

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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-PA240

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cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-800 (r/f, file)

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:docname74381:disc1

Horizon Nutraceuticals  
P.O. Box 1806  
Santa Cruz, CA 95061

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

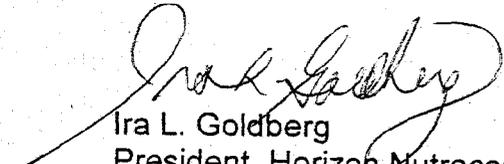
Dear Sir or Madam:

I hereby notify the Food and Drug Administration (FDA) of the use of statements of nutritional support in the labeling of **Cholesterin**, a dietary supplement. Horizon<sup>®</sup> is the manufacturer of **Cholesterin**.

Statements being made in the labeling of Cholesterin:

(1) Cholesterin is a unique blend of select nutrients and fibers which scientific research has shown may help maintain cholesterol levels with a normal range when consumed as part of a low-cholesterol and low-fat dietary program.)

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. Horizon possesses substantiation that the statements are truthful and not misleading.

  
Ira L. Goldberg  
President, Horizon Nutraceuticals

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