



FEB 22 2001 3 617 01 MAR 16 A7:16

Mr. Jim Roza  
Director, Quality Assurance  
NOW Foods  
395 S. Glen Ellyn Road  
Bloomington, Illinois 60108

Dear Mr. Roza:

This is in response to your letter of January 25, 2001 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 NOW Foods is making the following claim for the product NOW's®Cholestatin®:

“...help maintain healthy cholesterol levels.”

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, cure, or mitigate disease, namely, hypercholesterolemia. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests 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,

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, Chicago District Office, Office of Compliance, HFR-MW140

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

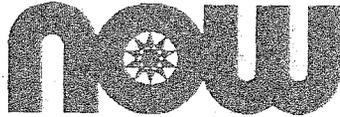
HFD-314 (Aronson)

HFS-605

HFV-228 (Benz)

GCF-1 (Nickerson)

f/t:HFS-811:rjm:2/16/01:docname:74489.adv:disc54



The Future in Natural Foods

FEB 12 2001

74489

January 25, 2001

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

Re: 21 U.S.C. Section 343(r)(6), Notification of Statements on Dietary Supplements

Dear Sir/Madam:

I hereby notify the Food and Drug Administration ("FDA") of the use of statements of nutritional support in the labeling of Cholestatin®, a cholesterol-inhibiting supplement.

Statements being made in the labeling of Cholestatin®

- (1) NOW's® Cholestatin® is a unique dietary supplement rich in beta-sitosterol, campesterol and stigmasterol. These plant sterols can be utilized by the body to help maintain healthy cholesterol levels.

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. Now Foods possesses substantiation that the statements are truthful and not misleading.

Jim Roza  
Director, Quality Assurance  
NOW Foods  
395 S. Glen Ellyn Rd.  
Bloomington, IL 60108

A handwritten signature in black ink, appearing to read "Jim Roza", written over a horizontal line.