



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Washington, DC 20204

DEC - 7 1999

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Mr. Sid Tracy  
President  
Traco Labs, Inc.  
3102 Clark Road  
P.O. Box 6419  
Champaign, Illinois 61826-6419

Dear Mr. Tracy:

This is in response to your letter of November 30, 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 submissions state that Traco Labs, Inc. is making the following claim, among others, for the product:

**Cholestatin<sup>®</sup>**

"Helps reduce bad 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, or mitigate a 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,

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 322

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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-456 (r/f, file)

HFS-450 (r/f, file)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-605

HFV-228 (Benz)

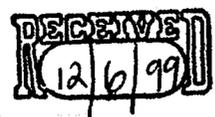
GCF-1 (Dorsey, Barnett)

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November 30, 1999



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

Dear Sirs:

Notice is hereby given pursuant to the requirements of section 403(r)(6) (21 U.S.C. 342(r)(6)) of the Federal Food, Drug and Cosmetic Act and in accordance with the requirements of 21 C.F.R. 101.93, that Traco Labs, Inc., within the past 30 days commenced marketing a dietary supplement bearing the following statements on the label and/or labeling of the product:

**TEXT OF CLAIMS:**

- 1. Helps maintain healthy cholesterol levels;
- 2. Helps block cholesterol uptake;
- 3. Helps reduce bad cholesterol levels.

**NAME OF INGREDIENT THAT IS THE SUBJECT OF THESE CLAIMS**

Traco Labs Cholestatin®, plant phytosterols

The undersigned certifies that the information contained in this notice is complete and truthful and that Traco Labs, Inc., has substantiation that the statement is truthful and not misleading.

Sincerely,

Sid Tracy, President  
Traco Labs, Inc.

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fax	217 352 6433	Champaign, IL 61826-6419
email	traco@tracolabs.com	3102 Clark Road
	www.tracolabs.com	Champaign, IL 61822