

December 12, 2002

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Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition U.S. Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740-3835 PRICEIVED
DEC 1 6 2002
BY:

RE:

Label Claims/Disclaimers

Dear Sir/Madam:

This letter is to notify you that Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 is a distributor and has included statements provided for by section 403(r)(6) of the Food, Drug, and Cosmetic Act on the labels of the following product. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	STATEMENTS
Enzymatic Therapy, Inc.	Vitaline® CoQ10	Vitamin E, Coenzyme Q10	Only available CoQ10 shown in published studies to cross cellular membranes and the blood/brain barrier resulting in increased mitochondrial levels of CoQ10.*

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy. Inc. has substantiation that the statements are truthful and not misleading.

By:

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Data

12/12/02

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Sincerely,

825 Challenger Drive Green Bay, WI 54311-8328

en Bay, W1 54311-8328

Ph: 920-469-1313

Fax: 888-570-6460

www.enzy.com

Michael P. Devereux Chief Financial Officer

Vitaline CoQ10 22e

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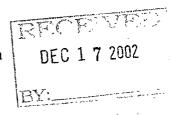
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COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	Vitaline® CoQ10	Vitamin E, Coenzyme Q10	Scientific studies at Harvard Medical School, the National Institutes of Health, and the Veterans Administration Health Care System show Vitaline® Chewable CoQ10 provides exceptional nutritional support for cardiovascular function.*

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

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Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 12/13/02

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