



**INTEGRATIVE THERAPEUTICS INC.**

NF Formulas • PhytoPharmica  
Tyler Encapsulations • Vitaline Formulas

9755 SW Commerce Circle, Suite B2  
Wilsonville, OR 97070

P: 503.582.8386 • F: 503.582.0467

**ENZYMATIC THERAPY**

**&  
PHYTOPHARMICA**

825 Challenger Drive, Green Bay, WI 54311-8328

P: 920.469.1313 • F: 888.570.6460 (Enzymatic)

P: 920.469.8899 • F: 920.469.4418 (Phyto)

**ENZYMATIC THERAPY**

INCORPORATED

What **Better** feels like.™

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April 6, 2005

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

APR - 7 2005

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. 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.

<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Vitaline® CoQ10	Imagine CoQ10 as a member of an assembly line that extracts energy from raw materials sent into the mitochondria – the “powerhouse” that produces energy in the cells.* CoQ10 is an important link in the chain of chemical reactions that produces this energy.*	Vitamin E (as dl-alpha tocopheryl acetate), Coenzyme Q10 (CoQ10) (ubiquinone 10)

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  
Robert C. Doster  
Title: Senior Vice President of Scientific Affairs  
Date: 4/6/05

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

Sincerely,  
Michael P. Devereux  
Michael P. Devereux  
Chief Financial Officer

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Vitaline® CoQ10	Since CoQ10 is also a potent antioxidant, it helps prevent free radicals from damaging healthy cells.*	Vitamin E (as dl-alpha tocopheryl acetate), Coenzyme Q10 (CoQ10) (ubiquinone 10)

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

Date: 4/6/05

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