



ENZYMATIC THERAPY
INCORPORATED

*What **Better** feels like.™*

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: 920.469.9099 • F: 920.469.4418 (Phyto)

December 1, 2004

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

DEC -7 2004

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	Vitaline CoQ10 is proven to replace the CoQ10 depleted by Cholesterol lowering (statin) drugs.*	Vitamin E (as dl-alpha tocopheryl acetate, d-alpha tocopheryl acetate, and mixed tocopherols), 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.

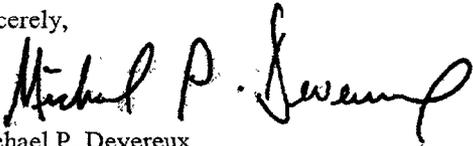
By: 
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 12/1/04

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

Sincerely,


Michael P. Devereux
Chief Financial Officer

975 0162 LET 15246