

Enzymatic Therapy

NATURAL MEDICINES®

February 26, 2004

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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

MAR 11 2004

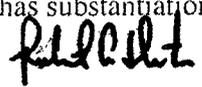
RE: Label Claims/Disclaimers

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 a clinically proven, high purity, natural CoQ10 product.*	Vitamin E, Coenzyme Q10 (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

Date: 2/26/04

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

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Vitaline CoQ10 45e

Enzymatic Therapy

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February 26, 2004

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Vitaline® CoQ10	Vitaline® CoQ10 has been the subject of clinical trials showing benefits for heart and immune health, and has been the focus of cutting edge research showing demonstrated benefits for neurological health.*	Vitamin E, Coenzyme Q10 (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

Date: 2/26/04

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Sincerely,



Michael P. Devereux
Chief Financial Officer

Vitaline CoQ10 46c

Enzymatic Therapy

NATURAL MEDICINES®

February 27, 2004

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College Park, MD 20740

RE: Label Claims/Disclaimers

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Vitaline® CoQ10	Research unique to Vitaline® CoQ10 has demonstrated that it both increases serum and mitochondrial levels of CoQ10, and is safe and effective for use at the high doses currently being investigated in clinical trials.*	Vitamin E, Coenzyme Q10 (CoQ10)

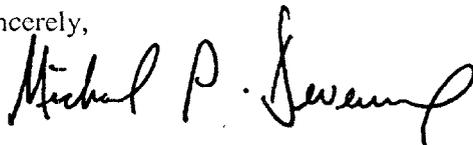
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Robert C. Doster
Title: Senior Vice President of Scientific Affairs

Date: 2/27/04

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Sincerely,



Michael P. Devereux
Chief Financial Officer
Vitaline CoQ10 47e

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Green Bay, WI 54311-8328

Ph: 920-469-1313

Fax: 888-570-6460

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