

April 7, 2003

2440 '03 MAY -5 P1:57

Mr. Robert Moore
Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 811
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

APR 1 4 2003

RE:

Label Claims/Disclaimers

Dear Mr. Moore:

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	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	CoQ10	Coenzyme Q10 (CoQ10)	While CoQ10 is synthesized in the body, and in fact, is present in every cell, it is particularly important in muscle tissue-especially the heart.*

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: KILLI

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date:  $4/\eta/03$ 

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

Sincerely,

Green Bay, WI 54311-8328

Ph: 920-469-1313

Michael P. Devero

Chief Financial Officer

Fax: 888-570-6460

825 Challenger Drive

www.enzy.com

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April 8, 2003

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Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 811
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

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COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	CoQ10	Coenzyme Q10 (CoQ10)	Supplementing with higher dietary levels of CoQ10 can nutritionally support cardiovascular health.*

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: KILLL Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 4/8/03

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

Sincerely,

Green Bay, WI 54311-8328 Michael P. Devereux

Ph: 920-469-1313 Chief Financial Officer

Fax: 888-570-6460

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CoQ10 5e