

May 19, 2003

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

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	Vitaline®	Vitamin E, Coenzyme	CoQ10 is vital to the production of adenosine triphosphate (ATP), an organic chemical compound that acts as a "living battery," storing energy that can be used in the body.*
Therapy, Inc.	CoQ10	Q10	

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.

Title: Senior Vice President of Scientific Affairs

Date:

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

Sincerely,

825 Challenger Drive Michael P. Devereux Chief Financial Officer

Green Bay, WI 54311-8328

Ph: 920-469-1313

Fax: 888-570-6460

www.enzy.com

Vitaline CoQ10 30e

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May 20, 2003

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

RE: Label Claims/Disclaimers

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COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	STATEMENTS
Enzymatic	Vitaline®	Vitamin E, Coenzyme	Every cell in the body that produces energy must have CoQ10 in order to function.*
Therapy, Inc.	CoQ10	Q10	

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.

Ву: \_\_\_\_\_

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 5/20/03

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

GICCII Day, 111 34311-0320

Ph: 920-469-1313 Fax: 888-570-6460

www.enzy.com

Chief Financial Officer

Vitaline CoQ10 31e



May 21, 2003

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

Label Claims/Disclaimers RE:

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	STATEMENTS
Enzymatic	Vitaline®	Vitamin E, Coenzyme	Safety and tolerability studies have found no significant adverse effects, including studies in which participants were taking up to 1200 mg of Vitaline CoQ10 per day.*
Therapy, Inc.	CoQ10	Q10	

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.

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

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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