

October 9, 2002

*02 WEW -4 P1554

Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition U. S. Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740-3835

RE:

Label Claims/Disclaimers

Dear Sir/Madam:



This letter is to notify you that Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 is a manufacturer 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.

COMPANY	PRODUCT NAME	<u>DIETARY</u> <u>INGREDIENTS</u>	STATEMENTS
Enzymatic Therapy, Inc.	L-Theanine	L-Theanine	Scientific studies show L-theanine impacts both the nervous and cardiovascular systems to produce a calming effect on mental state, which is why it's often referred to as the "feel good supplement."*

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,

L-Theanine 6e

Chief Financial Officer

Green Bay, WI 54311-8328

825 Challenger Drive

Ph: 920-469-1313

Fax: 888-570-6460

www.enzy.com

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COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	L-Theanine	L-Theanine	It's been shown to promote deep muscle relaxation and improve good quality sleep.*

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

Date: 10/10/0>

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Michael P. Devereux

Chief Financial Officer

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October 11, 2002

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COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	STATEMENTS
Enzymatic Therapy, Inc.	L-Theanine	L-Theanine	A recent study concluded L-theanine promotes the generation of alpha brain waves, and promotes relaxation.*

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

Date: 10/11/02

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