

**EnzymaticTherapy**<sup>®</sup>  
NATURAL MEDICINES™

August 9, 2002

RECEIVED  
AUG 14 2002  
12:06:17 PM  
BY: \_\_\_\_\_

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.

<u>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	Valerian-400	Valerian (Valeriana officinalis) Root Extract	Valerian-400 is designed to promote restful 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.

By:   
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 8/9/02

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 10906

825 Challenger Drive

Green Bay, WI 54311-8328

Ph: 920-469-1313

Fax: 888-570-6460

www.enzy.com

Valerian-400 2e

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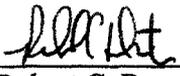
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Enzymatic Therapy, Inc.	Valerian-400	Valerian (Valeriana officinalis) Root Extract	Recent clinical studies have substantiated valerian's ability to improve sleep quality.*

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.

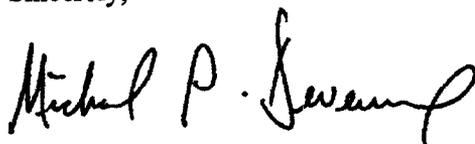
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