

August 19, 2002

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	DIETARY INGREDIENTS	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	AM/PM Menopause Formula™*	AM Formula: Green Tea Leaf Extract, Panax Ginseng Root Phytosome™, Black Cohosh Root and Rhizome Extract PM Formula: Valerian Root Extract, Hops Flower Extract, Theanine, Black Cohosh Root and Rhizome Extract	The PM Formula includes valerian and theanine to help ensure a better quality of sleep at night.*

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 Doster

Title: Senior Vice President of Scientific Affairs

978 0162 LET 10963

8/19/02

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

Chief Financial Officer Ph: 920-469-1313

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www.enzy.com

825 Challenger Drive

81611

AM/PM Menopause Formula 4e