

# Enzymatic Therapy

NATURAL MEDICINES®

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October 8, 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

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 Therapy, Inc.	AM/PM Menopause Formula™*	<u>AM Formula:</u> Green Tea Leaf Extract, Panax Ginseng Root Phytosome™, Black Cohosh Root and Rhizome Extract <u>PM Formula:</u> Valerian Root Extract, Hops Flower Extract, L-Theanine, Black Cohosh Root and Rhizome Extract	Find balance with AM/PM Menopause Formula™*

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 Doster  
 Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 10/8/03

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 www.enzy.com

975 0162 LET 13225  
 86195

AM/PM Menopause Formula 14e

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

Sincerely,

A handwritten signature in black ink that reads "Michael P. Devereux". The signature is written in a cursive style with a large, stylized initial "M".

Michael P. Devereux  
Chief Financial Officer