

# Enzymatic Therapy

NATURAL MEDICINES®

8955 '03 10 10 12:10  
NOV 19 2003

November 5, 2003

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam::

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. 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.

PRODUCT NAME	STATEMENT	INGREDIENT(S)
AM/PM Menopause Formula™*	With just three simple steps Easy Answers Stage 3 give you a full range of nutritional support, keeps those bones healthy and strong and controls menopausal symptoms.*	<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

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*

By: \_\_\_\_\_  
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 11/5/03

825 Challenger Drive  
Green Bay, WI 54311-8328  
Ph: 920-469-1313  
Fax: 888-570-6460  
www.enzy.com

979 0162

LET 13341

AM/PM Menopause Formula 16e