

# Enzymatic Therapy

NATURAL MEDICINES®

February 16, 2004

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.

<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
AM/PM Menopause Formula™*	Designed to provide day and night relief of menopausal symptoms, AM/PM Menopause™* contains ingredients that support energy and stamina (AM tablet) as well as restful sleep (PM tablet).*	AM Formula: Green Tea (Camellia sinensis) Leaf Extract, Panax Ginseng Root Phytosome™, Black Cohosh (Cimicifuga racemosa), PM Formula: Valerian (Valeriana officinalis), Hops (Humulus lupulus), L-Theanine, Black Cohosh (Cimicifuga racemosa)

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: 2/16/04

825 Challenger Drive  
Green Bay, WI 54311 8328

Ph. 920-469-1313

Fax. 888-570-6460

www.enzy.com

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AM/PM Menopause Formula 49c

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

# Enzymatic Therapy

NATURAL MEDICINES®

February 17, 2004

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
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5100 Paint Branch Parkway  
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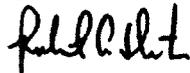
RE: Label Claims/Disclaimers

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
AM/PM Menopause Formula™*	Clinical studies have shown that supplementation of ginseng provides relief of menopausal symptoms, including reduction in fatigue, and improvement of mood, sleep quality, and overall well being.*	Ginseng Root Phytosome™

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

Title: Senior Vice President of Scientific Affairs

Date: 2/17/04

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, prominent "M" and "D".

Michael P. Devereux  
Chief Financial Officer

# Enzymatic Therapy

NATURAL MEDICINES®

February 18, 2004

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

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
AM/PM Menopause Formula™*	Green tea contains a very small amount of caffeine (equivalent to 1/3 to 1/5 cup of coffee) for energy, as well as flavonoids and polyphenols that support healthy breast cell development.*	Green Tea (Camellia sinensis) Leaf 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.

By:   
\_\_\_\_\_

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 2/18/04

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

# Enzymatic Therapy

NATURAL MEDICINES®

February 19, 2004

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

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
AM/PM Menopause Formula™*	Research studies have found that L-theanine is associated with an increase in alpha brain waves, the type of brain wave linked with feelings of relaxation.*	L-Theanine

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.

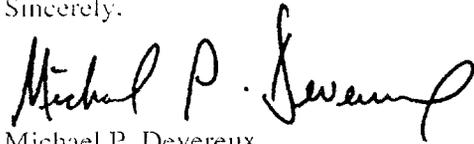
By: Robert Doster  
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 2/19/04

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