## Enzymatic Therapy ()

October 23, 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 <u>PM Formula:</u> Valerian Root Extract, Hops Flower Extract, L-Theanine, Black Cohosh Root and Rhizome Extract	Green Tea has been well known in Asia for many years for its relaxing effects.*

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

10/231 Date:

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

Sincerely, Michael P. Devereux

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

Chief Financial Officer

AM/PM Menopause Formula 7e

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Enzymatic Therapy, Inc.	AM/PM Menopause Formula™*	AM Formula: 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	L-theanine simply promotes a feeling of relaxation, so that when your body is naturally ready to sleep, so are you.* Research has found no adverse effects and no known contraindications with prescription medicines.*

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

10/25/02 Date:

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

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

Michael P. Devereux **Chief Financial Officer** AM/PM Menopause Formula 8e

Sincerely,

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