

Enzymatic Therapy

NATURAL MEDICINES®

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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

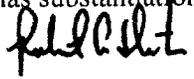
RE: Label Claims/Disclaimers

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.

| <u>PRODUCT NAME</u> | <u>STATEMENTS</u> | <u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u> |
|-------------------------------------|--|--|
| AM/PM PeriMenopause Formula™* | Natural support for relief of: Mood swings Restless sleep Low energy Irregular periods Abdominal weight gain* | AM Formula: Black Cohosh Root Extract, Rhodiola Rosea 3%, Chaste Berry Extract, Green Tea Extract PM Formula: Hops Flower Extract, Black Cohosh Root and Rhizome Extract, L-Theanine, Valerian Root 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: 11/5/03

825 Challenger Drive
Green Bay, WI 54311-8328

Ph: 920-469-1313

Fax: 888-570-6460

www.enzy.com

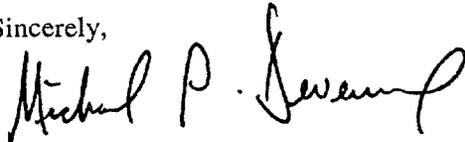
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LET 13331

AM/PM Perimenopause 47c

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, reading "Michael P. Devereux". The signature is written in a cursive style with a large, prominent initial "M".

Michael P. Devereux
Chief Financial Officer

Enzymatic Therapy

NATURAL MEDICINES®

November 6, 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

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| <u>PRODUCT NAME</u> | <u>STATEMENTS</u> | <u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u> |
|-------------------------------------|--|--|
| AM/PM PeriMenopause Formula™* | With Easy Answers Stage 2 you can cover all your nutritional bases, support bone health and find relief from symptoms of perimenopause.* | <u>AM Formula:</u> Black Cohosh Root Extract, Rhodiola Rosea 3%, Chaste Berry Extract, Green Tea Extract <u>PM Formula:</u> Hops Flower Extract, Black Cohosh Root and Rhizome Extract, L-Theanine, Valerian Root 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: 11/6/03

825 Challenger Drive
Green Bay, WI 54311-8328

Ph: 920-469-1313

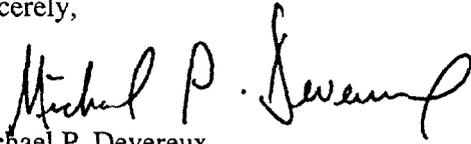
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AM/PM Perimenopause 48c

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Michael P. Devereux
Chief Financial Officer