

# Enzymatic Therapy

NATURAL MEDICINES®

July 25, 2003

5 9 2 1  
**RECEIVED**  
 AUG 06 2003  
 BY: \_\_\_\_\_

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.

<u>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	AM/PM Perimenopause Formula™*	<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	24-Hour relief for women experiencing perimenopausal symptoms!*

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: 7/25/03

97S 0162 LET 12523

85490

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 initial "M".

Michael P. Devereux  
Chief Financial Officer

# Enzymatic Therapy

NATURAL MEDICINES®

July 26, 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

RECEIVED  
 AUG 06 2003  
 BY:

RE: Label Claims/Disclaimers

Dear Mr. Moore

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COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	STATEMENTS
Enzymatic Therapy, Inc.	AM/PM Perimenopause Formula™*	<b>AM Formula:</b> Black Cohosh Root Extract, Rhodiola Rosea 3%, Chaste Berry Extract, Green Tea Extract <b>PM Formula:</b> Hops Flower Extract, Black Cohosh Root and Rhizome Extract, L-Theanine, Valerian Root Extract	Natural support for relief of perimenopausal symptoms including mood swings, restless sleep and low energy.*

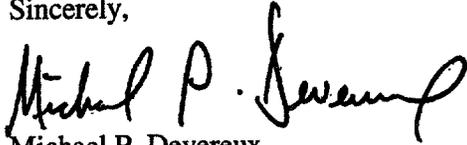
I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: Robert Doster  
 Robert Doster  
 Title: Senior Vice President of Scientific Affairs

Date: 7/26/03

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".

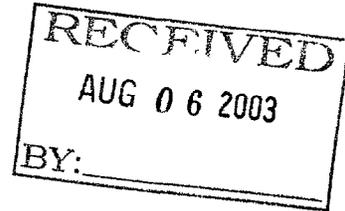
Michael P. Devereux  
Chief Financial Officer

# Enzymatic Therapy

NATURAL MEDICINES®

July 27, 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.

<u>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	AM/PM Perimenopause Formula™*	<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	AM/PM Perimenopause Formula™ gives you day and night relief of perimenopausal symptoms.*

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: 7/27/03

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 initial "M".

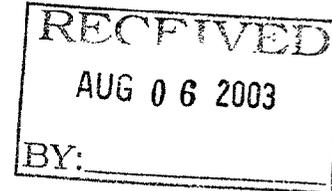
Michael P. Devereux  
Chief Financial Officer

# Enzymatic Therapy

NATURAL MEDICINES®

July 28, 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.

<u>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	AM/PM Perimenopause Formula™*	<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	AM Formula: Black Cohosh for natural hormonal support and relief of occasional hot flashes and mood swings.*

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.

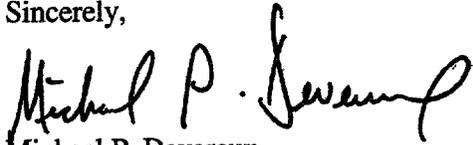
By: Robert Doster  
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 7/28/03

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®

July 29, 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

RECEIVED  
 AUG 06 2003  
 BY: \_\_\_\_\_

RE: Label Claims/Disclaimers

Dear Mr. Moore

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Enzymatic Therapy, Inc.	AM/PM Perimenopause Formula™*	<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	<u>AM Formula:</u> Green Tea for breast health, energy and weight management*

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: 7/29/03

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

Sincerely,

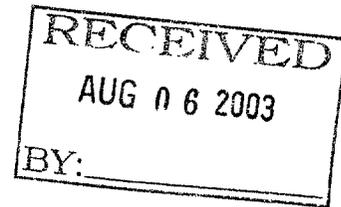
A handwritten signature in black ink, reading "Michael P. Devereux". The signature is written in a cursive style with a large, prominent initial "M".

Michael P. Devereux  
Chief Financial Officer

# Enzymatic Therapy

NATURAL MEDICINES®

July 30, 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

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Enzymatic Therapy, Inc.	AM/PM Perimenopause Formula™*	<p><u>AM Formula:</u> Black Cohosh Root Extract, Rhodiola Rosea 3%, Chaste Berry Extract, Green Tea Extract</p> <p><u>PM Formula:</u> Hops Flower Extract, Black Cohosh Root and Rhizome Extract, L-Theanine, Valerian Root Extract</p>	<p><u>AM Formula:</u> Chaste Berry for natural progesterone balance and relief of menstrual symptoms.*</p>

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: 7/30/03

825 Challenger Drive  
Green Bay, WI 54311-8328

Ph: 920-469-1313

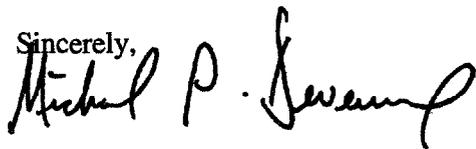
Fax: 888-570-6460

www.enzy.com

AM/PM Perimenopause 6e

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 initial "M".

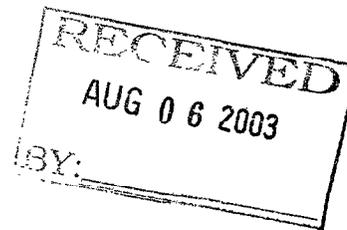
Michael P. Devereux  
Chief Financial Officer

# Enzymatic Therapy

NATURAL MEDICINES®

July 31, 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

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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.

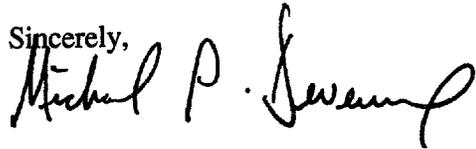
By: Robert Doster  
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 7/31/03

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 initial "M".

Michael P. Devereux  
Chief Financial Officer

# Enzymatic Therapy

NATURAL MEDICINES®

August 1, 2003

RECEIVED  
AUG 06 2003  
BY:

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

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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: 8/1/03

825 Challenger Drive  
Green Bay, WI 54311-8328

Ph: 920-469-1313

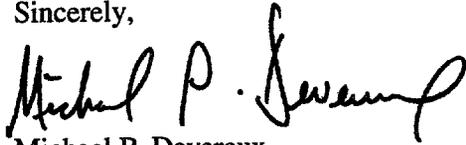
Fax: 888-570-6460

www.enzy.com

AM/PM Perimenopause 8e

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".

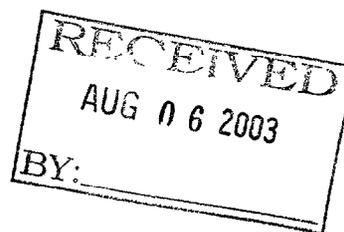
Michael P. Devereux  
Chief Financial Officer

# Enzymatic Therapy

NATURAL MEDICINES®

August 2, 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

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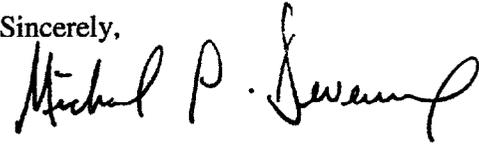
I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: Robert Doster  
Robert Doster  
Title: Senior Vice President of Scientific Affairs

Date: 8/2/03

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".

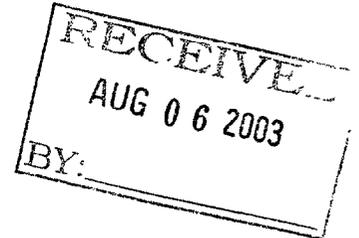
Michael P. Devereux  
Chief Financial Officer

# Enzymatic Therapy

NATURAL MEDICINES®

August 3, 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

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Enzymatic Therapy, Inc.	AM/PM Perimenopause Formula™*	<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	<u>PM Formula:</u> L-Theanine to alleviate nighttime muscle tension and promote restful sleep*

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: 8/3/03

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, appearing to read "Michael P. Devereux". The signature is fluid and cursive, with the first name "Michael" being the most prominent.

Michael P. Devereux  
Chief Financial Officer