

EnzymaticTherapy®
NATURAL MEDICINES™

January 11, 2003

1671 13 FEB-6 9:11 AM

Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 811
Food and Drug Administration
Attention: Robert Moore
5100 Paint Branch Parkway
College Park, MD 20740

1/13/03

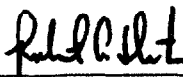
RE: Label Claims/Disclaimers

Dear Sir/Madam:

This letter is to notify you that Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 is a 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.

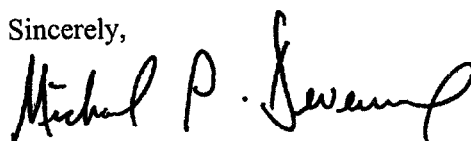
<u>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	Black Cohosh	Black Cohosh (Cimicifuga racemosa) Root and Rhizome Extract	The benefits of Black Cohosh may be first experienced in two to three weeks; however, the full benefits may not be realized until after four to eight weeks of administration.*

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 C. Doster
Title: Senior Vice President of Scientific Affairs

Date: 1/11/03

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

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

975 0162

LET

Black Cohosh 11e

11393

83178

EnzymaticTherapy®
NATURAL MEDICINES™

January 10, 2003

Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 811
Food and Drug Administration
Attention: Robert Moore
5100 Paint Branch Parkway
College Park, MD 20740

JAN 24 2003

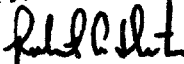
RE: Label Claims/Disclaimers

Dear Sir/Madam:

This letter is to notify you that Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 is a 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.	Black Cohosh	Black Cohosh (Cimicifuga racemosa) Root and Rhizome Extract	In a more recent 6-month randomized, open-label trial involving 53 women, significant decreases in unwanted menopause-related symptoms were reported following the administration of 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 C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/10/03

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

Black Cohosh 10e

EnzymaticTherapy®
 NATURAL MEDICINES™

January 9, 2003

Office of Nutritional Products, Labeling &
 Dietary Supplements, HFS 811
 Food and Drug Administration
 Attention: Robert Moore
 5100 Paint Branch Parkway
 College Park, MD 20740

JAN 9 4 12 03

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 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.	Black Cohosh	Black Cohosh (Cimicifuga racemosa) Root and Rhizome Extract	In a randomized, placebo-controlled, double-blind study, a researcher compared women who took standardized black cohosh extract with women taking a placebo. At the end of the study, the women taking the standardized black cohosh extract showed improvement relative to the placebo as measured by the Kupperman Menopausal Index, the Hamilton Anxiety Scale, and the Maturation Index of vaginal epithelium.* No clear improvement of menopausal complaints was observed in the control (placebo) group. This study demonstrated clinical and statistical improvement of menopausal symptoms by the women taking the standardized black cohosh 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 C. Doster

By: _____

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/9/03

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

Sincerely,

Michael P. Devereux

Michael P. Devereux
Chief Financial Officer

EnzymaticTherapy®
NATURAL MEDICINES™

January 7, 2003

Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 811
Food and Drug Administration
Attention: Robert Moore
5100 Paint Branch Parkway
College Park, MD 20740

JAN 9 4 2003

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 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.	Black Cohosh	Black Cohosh (Cimicifuga racemosa) Root and Rhizome Extract	To date, there is no definitive published data available to clearly describe the process; however, forty years of clinical studies on a standardized black cohosh extract have shown efficacy in their relief of hot flashes, profuse sweating, insomnia and depressive moods associated with menopause with few adverse 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.

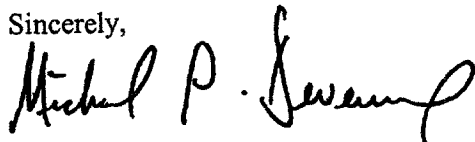
By: Robert C. Doster
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/7/03

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

Sincerely,



Michael P. Devereux
Chief Financial Officer

Black Cohosh 8c

825 Challenger Drive
Green Bay, WI 54311-8328

Ph: 920-469-1313

Fax: 888-570-6460

www.enzy.com

EnzymaticTherapy®
NATURAL MEDICINES™

January 6, 2003

Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 811
Food and Drug Administration
Attention: Robert Moore
5100 Paint Branch Parkway
College Park, MD 20740

JAN 24 2003


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 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.	Black Cohosh	Black Cohosh (Cimicifuga racemosa) Root and Rhizome Extract	Recent animal research shows that black cohosh binds to the estrogen receptor; however, it does not affect the luteinizing hormone level and does not exhibit estrogen-like effects.*

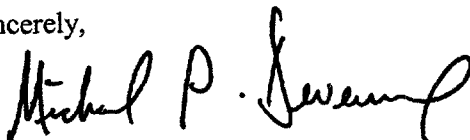
I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

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

Date: 1/6/03

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

Black Cohosh 7e

EnzymaticTherapy®
NATURAL MEDICINES™

January 4, 2003

Office of Nutritional Products, Labeling &
Dietary Supplements, HFS 811
Food and Drug Administration
Attention: Robert Moore
5100 Paint Branch Parkway
College Park, MD 20740

JAN 9 4 2003


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 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.


COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	STATEMENTS
Enzymatic Therapy, Inc.	Black Cohosh	Black Cohosh (Cimicifuga racemosa) Root and Rhizome Extract	Its approved monograph in <i>The Complete German Commission E Monographs</i> discusses the well-documented use of <i>Cimicifuga racemosa</i> for the relief of menopausal complaints.*

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 C. Doster
Title: Senior Vice President of Scientific Affairs

Date: 1/4/03

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
Black Cohosh 6e

Robert C. Doster
By: _____
Robert C. Doster
Title: Senior Vice President of Scientific Affairs

Date: 1/9/03

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

Sincerely,

Michael P. Devereux
Michael P. Devereux
Chief Financial Officer