

**EnzymaticTherapy**<sup>®</sup>  
NATURAL MEDICINES™

7356 03 10-3 0127

October 7, 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

OCT 15 2003  
BY: \_\_\_\_\_

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.

COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	STATEMENTS
Enzymatic Therapy, Inc.	EstroBalance™ with DIM	Indoplex® Complex modified food starch, 25% diindolylmethane (DIM), d-alpha tocopheryl succinate, silicon dioxide, and phosphatidylcholine	The role of DIM in the body is to support healthy estrogen metabolism and hormonal balance, two factors known to prevent estrogen dominance.*

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: 10/17/03

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

975 0162

LET

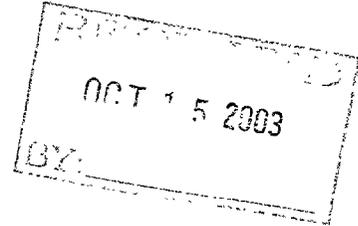
13221

86195

**EnzymaticTherapy®**  
NATURAL MEDICINES™

October 8, 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



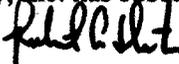
RE: Label Claims/Disclaimers

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.

COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	STATEMENTS
Enzymatic Therapy, Inc.	EstroBalance™ with DIM	Indoplex® Complex modified food starch, 25% diindolylmethane (DIM), d-alpha tocopheryl succinate, silicon dioxide, and phosphatidylcholine	Hormone Free EstroBalance™ with DIM supports, restores, and maintains favorable estrogen metabolism and balance.*

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: 10/8/03

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

**EnzymaticTherapy®**  
NATURAL MEDICINES™

October 9, 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  
OCT 15 2003  
BY:

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.

COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	STATEMENTS
Enzymatic Therapy, Inc.	EstroBalance™ with DIM	Indoplex® Complex modified food starch, 25% diindolylmethane (DIM), d-alpha tocopheryl succinate, silicon dioxide, and phosphatidylcholine	Hormone Free EstroBalance with DIM provides superior support for hormonal balance for women in all stages of reproductive health.*

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.

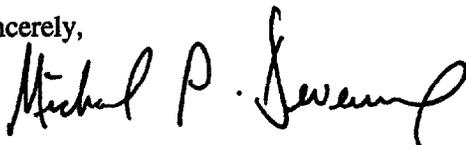
By:   
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 10/9/03

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

Sincerely,



Michael P. Devereux  
Chief Financial Officer

EstroBalance™ with DIM 8c

**EnzymaticTherapy®**  
NATURAL MEDICINES™

October 10, 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  
OCT 15 2003  
BY:

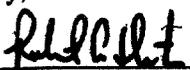
RE: Label Claims/Disclaimers

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.

COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	STATEMENTS
Enzymatic Therapy, Inc.	EstroBalance™ with DIM	Indoplex® Complex modified food starch, 25% diindolylmethane (DIM), d-alpha tocopheryl succinate, silicon dioxide, and phosphatidylcholine	For years, an observational association has been noted between healthy estrogen balance and a high dietary intake of vegetables, such as broccoli, cauliflower, and cabbage. Scientific study determined that such cruciferous vegetables contain several phytochemicals including indole-3-carbinol (I3C), phenethyl isothiocyanate (PEITC), sulforaphane, and diindolylmethane (DIM). Further research has demonstrated that DIM is the most bioactive of these phytonutrients and the most effective in increasing the ration of beneficial to undesirable estrogen metabolites.*

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

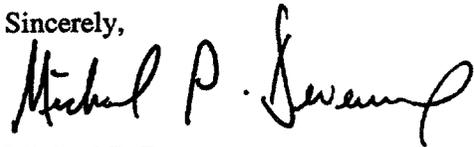
Title: Senior Vice President of Scientific Affairs

Date: 10/10/03

EstroBalance™ with DIM 9e

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

Sincerely,

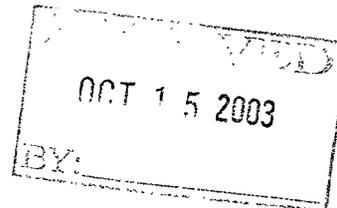
A handwritten signature in black ink that reads "Michael P. Devereux". The signature is written in a cursive style with a large, stylized initial "M".

Michael P. Devereux  
Chief Financial Officer

**EnzymaticTherapy®**  
NATURAL MEDICINES™

October 11, 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



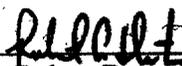
RE: Label Claims/Disclaimers

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.

COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	STATEMENTS
Enzymatic Therapy, Inc.	EstroBalance™ with DIM	Indoplex® Complex modified food starch, 25% diindolylmethane (DIM), d-alpha tocopheryl succinate, silicon dioxide, and phosphatidylcholine	The 2-hydroxy and 2-methoxy estrogen metabolites stimulate increased progesterone production from ovarian cells. By promoting 2-hydroxy production, supplementation with Hormone Free EstroBalance™ with DIM can help support hormonal balance and reduce PMS 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.

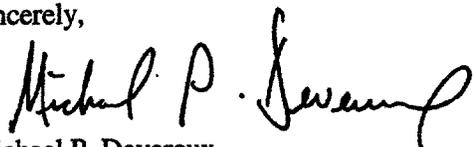
By:   
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 10/11/03

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

Sincerely,

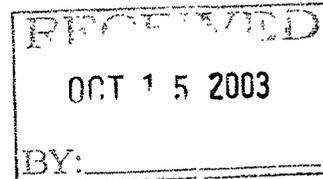


Michael P. Devereux  
Chief Financial Officer  
EstroBalance™ with DIM 10e

**EnzymaticTherapy®**  
NATURAL MEDICINES™

October 12, 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



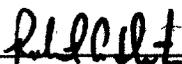
RE: Label Claims/Disclaimers

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.

COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	STATEMENTS
Enzymatic Therapy, Inc.	EstroBalance™ with DIM	Indoplex® Complex modified food starch, 25% diindolylmethane (DIM), d-alpha tocopheryl succinate, silicon dioxide, and phosphatidylcholine	Hormone Free EstroBalance with DIM shifts estrogen metabolism to the C-2 pathway in the liver, which may ease the symptoms of perimenopause, including heavy periods, moodiness, and breast tenderness.*

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: 10/12/03

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  
EstroBalance™ with DIM 11e

**EnzymaticTherapy®**  
NATURAL MEDICINES™

October 13, 2003

OCT 15 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

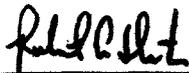
RE: Label Claims/Disclaimers

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.

COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	STATEMENTS
Enzymatic Therapy, Inc.	EstroBalance™ with DIM	Indoplex® Complex modified food starch, 25% diindolylmethane (DIM), d-alpha tocopheryl succinate, silicon dioxide, and phosphatidylcholine	By increasing the amount of the beneficial estrogen metabolites, Hormone Free EstroBalance with DIM supports the healthy, regulated cell growth.*

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: 10/13/03

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

EstroBalance™ with DIM 12e

**EnzymaticTherapy®**  
NATURAL MEDICINES™

October 13, 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

OCT 15 2003

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.

COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	STATEMENTS
Enzymatic Therapy, Inc.	EstroBalance™ with DIM	Indoplex® Complex modified food starch, 25% diindolylmethane (DIM), d-alpha tocopheryl succinate, silicon dioxide, and phosphatidylcholin	Hormone Free EstroBalance with DIM supports a beneficial ratio of 2-hydroxy and 2-methoxy estrogen metabolites over the undesirable 16-hydroxyestron estrogen metabolites.*

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: 10/13/03

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

EstroBalance™ with DIM 13e

# Enzymatic Therapy

NATURAL MEDICINES®

October 14, 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

OCT 15 2003

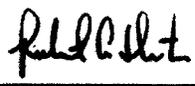
RE: Label Claims/Disclaimers

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.	EstroBalance™ with DIM	Indoplex® Complex modified food starch, 25% diindolylmethane (DIM), d-alpha tocopheryl succinate, silicon dioxide, and phosphatidylcholine	It has been noted that dietary supplements containing other cruciferous phytochemicals, most notable indole-3-carbinole (I3C), claim to provide the same estrogen balancing benefits as DIM in Hormone Free EstroBalance with DIM. However, I3C is highly unstable and has no biologic activity until it is converted to DIM. Conversion of I3C takes place in the stomach and requires an appropriately acidic environment. In contrast to I3C, DIM is highly stable, requires no conversion in the stomach, and is the most active cruciferous phytonutrient in promoting beneficial estrogen metabolism.*

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

825 Challenger Drive

Green Bay, WI 54311-8328

Ph: 920-469-1313

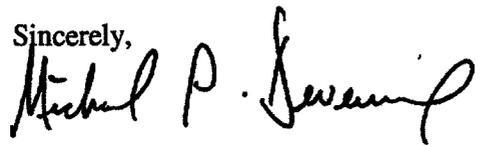
Fax: 888-570-6460

www.enzy.com

EstroBalance™ with DIM 14e

Date: 10/14/03

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

**EnzymaticTherapy**<sup>®</sup>  
NATURAL MEDICINES™

October 15, 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

OCT 15 2003

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.

COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	STATEMENTS
Enzymatic Therapy, Inc.	EstroBalance™ with DIM	Indoplex® Complex modified food starch, 25% diindolylmethane (DIM), d-alpha tocopheryl succinate, silicon dioxide, and phosphatidylcholine	Hormone Free EstroBalance with DIM supports healthy estrogen metabolism and the breakdown of estrogen into its beneficial metabolites.*

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: 10/15/03

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  
EstroBalance™ with DIM 15e

**EnzymaticTherapy®**  
NATURAL MEDICINES™

October 16, 2003

OCT 15 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

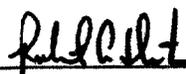
RE: Label Claims/Disclaimers

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.

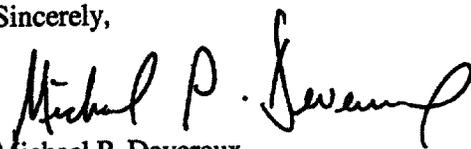
COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	STATEMENTS
Enzymatic Therapy, Inc.	EstroBalance™ with DIM	Indoplex® Complex modified food starch, 25% diindolylmethane (DIM), d-alpha tocopheryl succinate, silicon dioxide, and phosphatidylcholine	Through restoration of hormonal balance, Hormone Free EstroBalance with DIM relieves the distressing symptoms of premenstrual syndrome, perimenopause, and menopause.*

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: 10/16/03

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  
EstroBalance™ with DIM 16c