



**INTEGRATIVE THERAPEUTICS INC.™**  
 NF Formulas PhytoPharmica  
 Tyler Encapsulations Vitaline Formulas

**ENZYMATIC THERAPY®**  
 &  
**PHYTOPHARMICA®**

**ENZYMATIC THERAPY**

9755 SW Commerce Circle, Suite B2  
 Wilsonville, OR 97070  
 P: 503.582.8386 F: 503.582.0467

825 Challenger Drive, Green Bay, WI 54311-8328  
 P: 920.469.1313 F: 888.570.6460 (Enzymatic)  
 P: 920.469.9099 F: 920.469.4418 (Phyto)

*What **Better** feels like™*

April 19, 2004

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

APR 23 2004

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>
Breast Health*	For women interested in optimal breast health.*	Flax Seed Extract (Brevail® brand)

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: 4/19/04

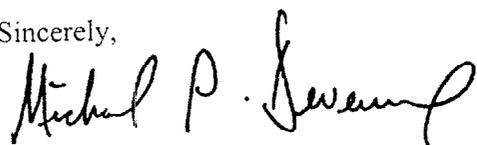
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If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

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

What *Better* feels like.™

April 19, 2004

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Breast Health*	Greatly researched for breast and hormonal health, this product provides a clinically affirmed dosage of natural plant lignans.*	Flax Seed Extract (Brevail® brand)

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: 4/19/04

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**ENZYMATIC THERAPY**  
 INCORPORATED

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April 20, 2004

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<b>PRODUCT NAME</b>	<b>STATEMENTS</b>	<b>INGREDIENT(S) TO WHICH THE CLAIM REFERS</b>
Breast Health*	Natural plant lignans help safeguard against negative hormonal effects, especially estrogen.*	Flax Seed Extract (Brevail® brand)

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.

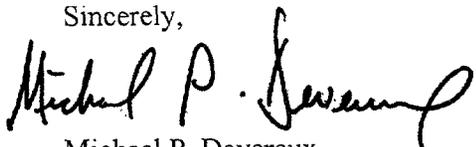
By: Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 4-22-04

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 written in a cursive style with a large, stylized initial "M".

Michael P. Devereux  
Chief Financial Officer



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## ENZYMATIC THERAPY

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April 20, 2004

Office of Nutritional Products, Labeling &  
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RE: Label Claims/Disclaimers

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Breast Health*	Lignans buffer and balance the effects of estrogen.*	Flax Seed Extract (Brevail® brand)

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: 4/20/04



# ENZYMATIC THERAPY

What Better feels like™

April 21, 2004

Office of Nutritional Products, Labeling &  
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Center for Food Safety and Applied Nutrition  
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Breast Health*	Provides support for the development of healthy breast cells.*	Flax Seed Extract (Brevail® brand)

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: R. Doster  
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

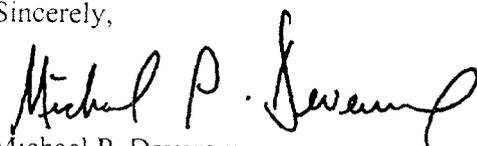
Date: 4/21/04

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**ENZYMATIC THERAPY**

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April 22, 2004

Office of Nutritional Products, Labeling &  
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RE: Label Claims/Disclaimers

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Breast Health*	Researched and developed to increase lignan concentrations in the body that correspond to levels found in women who collectively exemplify an extraordinary history of breast health.*	Flax Seed Extract (Brevail® brand)

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:   
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Title: Senior Vice President of Scientific Affairs

Date: 4/22/04

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