



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

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

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

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)

**ENZYMATIC THERAPY**

*What Better feels like™*

April 12, 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 20 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>
Yeast Balance™*	The body's friendly bacteria normally keep yeast levels in balance. Because this balance is so important, we've developed Yeast Balance™*.	Oregano (Origanum vulgare) Aerial Part Oil Extract, Thyme (Thymus vulgaris) Leaf and Stem Oil Extract, Peppermint (Mentha x piperita) Leaf Oil Extract, Goldenseal (Hydrastis canadensis) Root and Rhizome 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*

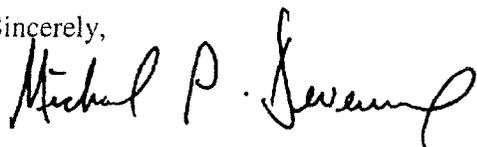
By: \_\_\_\_\_  
 Robert C. Doster  
 Title: Senior Vice President of Scientific Affairs

Date: 4/12/04

975 0162 LET 13917

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 13, 2004

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Yeast Balance™*	Scientists recognize that the volatile oils of oregano and thyme play a role in digestion and other body functions.* Peppermint oil is widely used in Europe to support colon function, and goldenseal contains alkaloid compounds that show great promise for human health.*	Oregano (Origanum vulgare) Aerial Part Oil Extract, Thyme (Thymus vulgaris) Leaf and Stem Oil Extract, Peppermint (Mentha x piperita) Leaf Oil Extract, Goldenseal (Hydrastis canadensis) Root and Rhizome Extract

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*Robert*

By: \_\_\_\_\_

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 4/13/04

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