



# ENZYMATIC THERAPY

INCORPORATED

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December 21, 2005

**INTEGRATIVE THERAPEUTICS INC.™**  
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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)

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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

DEC 23 2005

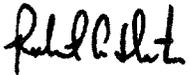
RE: Label Claims/Disclaimers

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>
HyperiMax™ with St. John's Wort	Improve your mood*	St. John's Wort ( <i>Hypericum perforatum</i> ) Flower Head Extract

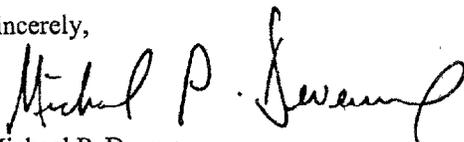
I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

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

Date: 12/21/05

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

Sincerely,

  
Michael P. Devereux  
Chief Operations Officer

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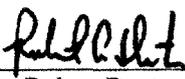
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
HyperIMax™ with St. John's Wort	Supports positive mood and sense of well being.*	St. John's Wort ( <i>Hypericum perforatum</i> ) Flower Head Extract

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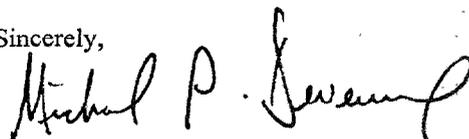
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
HyperiMax™ with St. John's Wort	St. John's wort offers safe and natural nutritional support for a healthy nervous system.*	St. John's Wort (Hypericum perforatum) Flower Head 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.

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

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: \_\_\_\_\_

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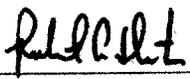
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
HyperiMax™ with St. John's Wort	The standardized dose provides support for stress and mood.*	St. John's Wort ( <i>Hypericum perforatum</i> ) Flower Head Extract

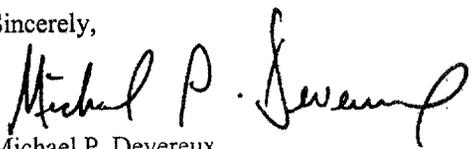
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Michael P. Devereux  
Chief Operations Officer



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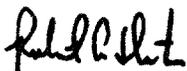
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
HyperiMax™ with St. John's Wort	More than 25 double-blind, controlled clinical studies have shown St. John's wort helps relieve occasional anxiety, apathy, sleeplessness, and feelings of worthlessness.*	St. John's Wort (Hypericum perforatum) Flower Head Extract

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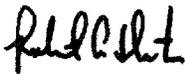
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
HyperiMax™ with St. John's Wort	The herb exerts its neurological effects by influencing the extra-cellular concentration of neurotransmitters, including serotonin, dopamine, and noradrenaline.*	St. John's Wort (Hypericum perforatum) Flower Head Extract

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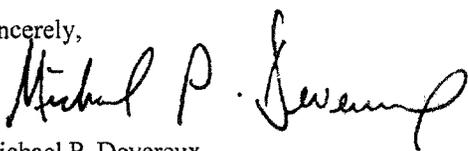
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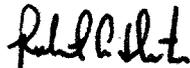
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HyperiMax™ with St. John's Wort	St. John's wort enhances glutamate levels.*	St. John's Wort (Hypericum perforatum) Flower Head Extract

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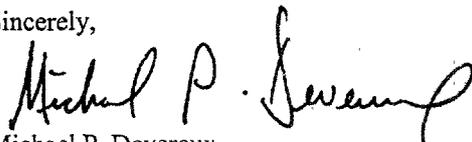
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