



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

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

**ENZYMATIC THERAPY**  
 INCORPORATED

*What **Better** feels like.™*

September 14, 2005

9755 SW Commerce Circle, Suite B2  
 Wilsonville, OR 97070  
 P: 503.682.8385 • F: 503.582.4467

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)

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

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>
Holy Basil Trinity Blend™	Holy Basil Trinity Blend is the FIRST of its kind to combine three unique, standardized extracts of Holy Basil to help your customers see the sunny side of life again and handle stress in a natural, healthy manner.*	Unique Trinity Blend: Holy Basil (ocimum sanctum) (leaf) Extract, Holy Basil (ocimum sanctum) (leaf), Supercritical Extract, Holy Basil (ocimum sanctum) (leaf), Steam Distilled 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  
 Robert Doster  
 Title: Senior Vice President of Scientific Affairs  
 Date: 9/14/05

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

Sincerely,  
  
 Michael P. Devereux  
 Chief Financial Officer

975 0162 LET 16757



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9755 SW Commerce Circle, Suite B2  
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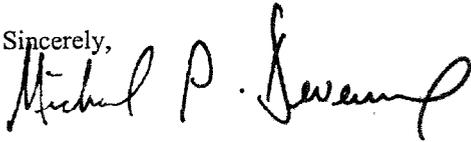
<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Holy Basil Trinity Blend™	For stress and nervous irritability*	Unique Trinity Blend: Holy Basil (ocimum sanctum) (leaf) Extract, Holy Basil (ocimum sanctum) (leaf), Supercritical Extract, Holy Basil (ocimum sanctum) (leaf), Steam Distilled Extract

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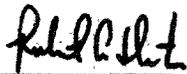
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Holy Basil Trinity Blend™	Holy Basil Trinity Blend supports a better mood and improved mental clarity.*	Unique Trinity Blend: Holy Basil (ocimum sanctum) (leaf) Extract, Holy Basil (ocimum sanctum) (leaf), Supercritical Extract, Holy Basil (ocimum sanctum) (leaf), Steam Distilled Extract

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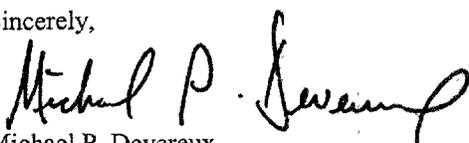
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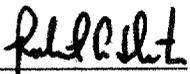
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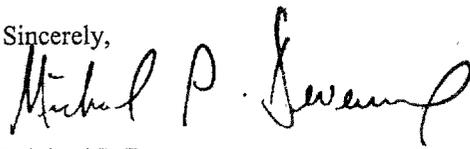
<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Holy Basil Trinity Blend™	The herb has been celebrated for centuries and is still highly prized today because of its association with positive mood and increased awareness.*	Unique Trinity Blend: Holy Basil (ocimum sanctum) (leaf) Extract, Holy Basil (ocimum sanctum) (leaf), Supercritical Extract, Holy Basil (ocimum sanctum) (leaf), Steam Distilled Extract

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Holy Basil Trinity Blend™	Holy Basil, which possesses adaptogenic properties, has long been associated with improved mental clarity and mood.*	Unique Trinity Blend: Holy Basil (ocimum sanctum) (leaf) Extract, Holy Basil (ocimum sanctum) (leaf), Supercritical Extract, Holy Basil (ocimum sanctum) (leaf), Steam Distilled Extract

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Holy Basil Trinity Blend™	In a scientific study, an herbal preparation, which combines holy basil along with three other Ayurvedic herbs, was shown to improve the body's ability to adapt to stress.* The combination exhibited both preventative and restorative effects to stressful stimuli.*	Unique Trinity Blend: Holy Basil (ocimum sanctum) (leaf) Extract, Holy Basil (ocimum sanctum) (leaf), Supercritical Extract, Holy Basil (ocimum sanctum) (leaf), Steam Distilled Extract

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Holy Basil Trinity Blend™	Administration of the alcohol extract significantly reduced the corticosterone level, indicating the supportive potential of the plant.*	Unique Trinity Blend: Holy Basil (ocimum sanctum) (leaf) Extract, Holy Basil (ocimum sanctum) (leaf), Supercritical Extract, Holy Basil (ocimum sanctum) (leaf), Steam Distilled Extract

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