



**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**  
 INCORPORATED

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August 26, 2005

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AUG 31 2005

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.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
Petadolex® Fast Acting	Contains a <i>better</i> butterbur extract to support healthy blood vessel tone in the brain, as well as normal blood flow in the brain.*	Purple Butterbur ( <i>Petasites hybridus</i> ) (Petadolex® brand) Root 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: 8/26/05

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 16680



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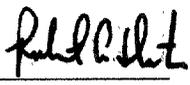
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Petadolex® Fast Acting	Clinical studies have shown that Petadolex Fast Acting is safe, well tolerated and produces no significant adverse effects.*	Purple Butterbur (Petasites hybridus) (Petadolex® brand) Root 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.

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Robert Doster  
Title: Senior Vice President of Scientific Affairs

Date: 8/26/05

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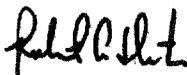
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Petadolex® Fast Acting	Effective for fast-acting, clear-headed comfort in both adults and children.*	Purple Butterbur (Petasites hybridus) (Petadolex® brand) Root Extract

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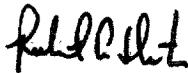
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Petadolex® Fast Acting	On average, participants experienced a 54% decrease in the duration of an occurrence.*	Purple Butterbur (Petasites hybridus) (Petadolex® brand) Root Extract

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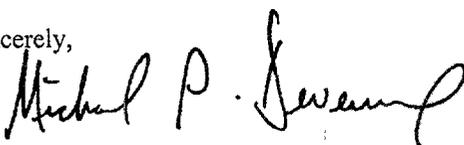
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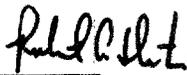
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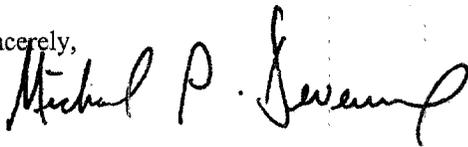
<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Petadolex® Fast Acting	For Fast Acting Relief*	Purple Butterbur (Petasites hybridus) (Petadolex® brand) Root Extract

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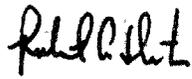
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Petadolex® Fast Acting	Clinically Proven to Deliver Results Fast!*	Purple Butterbur (Petasites hybridus) (Petadolex® brand) Root Extract

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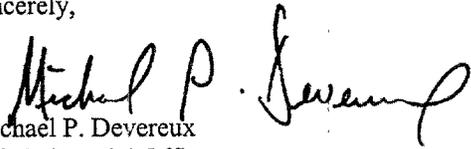
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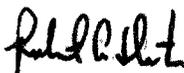
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Petadolex® Fast Acting	The Only Safe, Pure Butterbur!*	Purple Butterbur (Petasites hybridus) (Petadolex® brand) Root Extract

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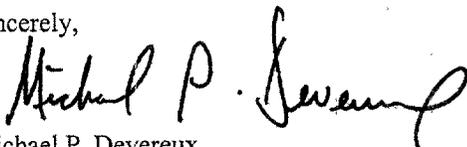
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