

# Enzymatic Therapy

NATURAL MEDICINES®

October 14, 2003

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Mr. Robert Moore  
Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 811  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

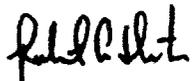
RE: Label Claims/Disclaimers

Dear Mr. Moore:

This letter is to notify you that Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 is a manufacturer and has included statements provided for by section 403(r)(6) of the Food, Drug, and Cosmetic Act on the labels of the following product. 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>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	Petadolex® ASAP*	Purple Butterbur (Petasites hybridus) Root Extract	Petadolex® ASAP* is a dietary supplement to be taken immediately for healthy blood vessel tone in the brain.*

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: 

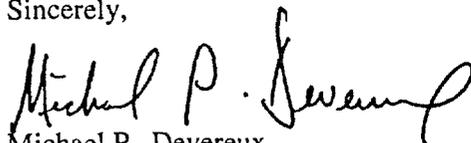
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 10/14/03

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

Petadolex ASAP 5e

825 Challenger Drive  
Green Bay, WI 54311-8328

Ph: 920-469-1313

Fax: 888-570-6460

www.enzy.com

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# Enzymatic Therapy

NATURAL MEDICINES®

October 14, 2003

Mr. Robert Moore  
Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 811  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

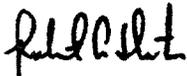
RE: Label Claims/Disclaimers

Dear Mr. Moore:

This letter is to notify you that Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 is a manufacturer and has included statements provided for by section 403(r)(6) of the Food, Drug, and Cosmetic Act on the labels of the following product. 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>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	Petadolex® ASAP*	Purple Butterbur (Petasites hybridus) Root Extract	Petasites hybridus contains several compounds with bioactive properties. Two of these compounds, petasin and isopetasin, have been studied for their ability to support healthy brain blood vessel tone and circulation.*

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: 

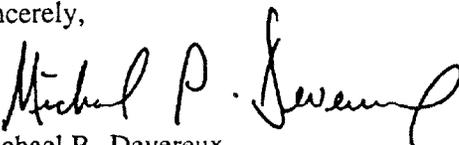
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 10/14/03

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

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Green Bay, WI 54311-8328

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# Enzymatic Therapy

NATURAL MEDICINES®

October 15, 2003

Mr. Robert Moore  
Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 811  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Mr. Moore:

This letter is to notify you that Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 is a manufacturer and has included statements provided for by section 403(r)(6) of the Food, Drug, and Cosmetic Act on the labels of the following product. 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>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	Petadolex® ASAP*	Purple Butterbur (Petasites hybridus) Root Extract	Blood vessel tone is influenced, in part, through neuralgic, vascular, and chemical factors. This includes biosynthesis of neurochemicals, changes in calcium channel regulation, and activation of pro-inflammatory mediators, resulting in both localized and systemic changes.*

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: 

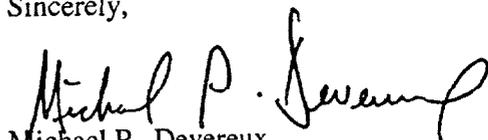
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 10/15/03

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

Petadolex ASAP 7e

825 Challenger Drive  
Green Bay, WI 54311-8328

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# Enzymatic Therapy

NATURAL MEDICINES®

October 16, 2003

Mr. Robert Moore  
Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 811  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Mr. Moore:

This letter is to notify you that Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 is a manufacturer and has included statements provided for by section 403(r)(6) of the Food, Drug, and Cosmetic Act on the labels of the following product. 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>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	Petadolex® ASAP*	Purple Butterbur (Petasites hybridus) Root Extract	Laboratory research has determined the actions of the key <i>P. hybridus</i> compounds. Both petasin and isopetasin support healthy vessel relaxation.* Petasin additionally provides nutritional support for the cellular activity associated with healthy blood vessel wall functioning.*

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: \_\_\_\_\_

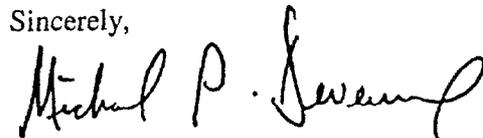
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 10/16/03

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

Petadolex ASAP 8c