



6388 02 MAR 26 P2:30

MAR 21 2002

Dr. Robert C. Doster  
Senior Vice President of Scientific Affairs  
Enzymatic Therapy, Inc.  
825 Challenger Drive  
Green Bay, Wisconsin 54311

Dear Dr. Doster:

This is in response to your letters of December 12 and 13, 2001 and January 24, 2002 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Enzymatic Therapy, Inc. is making the claims identified below for the products **Enzymatic Therapy FlexAgility** and **PhytoPharmica FlexAgility**.

The products **Enzymatic Therapy FlexAgility** and **PhytoPharmica FlexAgility** use the claims "Reduces joint pain and stiffness due to occasional overuse" and "Reduces joint pain and stiffness due to everyday activity." These claims are disease claims because they suggest that the products are intended to treat, prevent, or mitigate diseases, namely joint disorders such as arthritis. In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1016-17), FDA stated that "joint pain" is characteristic of arthritis and that it is the most sensitive physical sign of rheumatoid arthritis. For that reason, the agency concluded that claims about relieving joint pain are implied disease claims because they represent that the product will have an affect on a characteristic sign or symptom of a disease (see 21 CFR 101.93(g)(2)(ii)). Moreover, elsewhere in the preamble to the final rule (see 65 FR 1000 at 1030) FDA discussed the circumstances under which claims about pain would imply disease treatment. We stated that since pain is not a normal state, nor are there "normal pain levels," a claim about pain treatment or prevention is ordinarily a disease claim. We addressed the issue of joint pain claims in particular, noting that such claims are disease claims because joint pain is a characteristic symptom of arthritis. We added, however, that a acceptable structure/function claim could be made for pain associated with non-disease states, such as muscle pain following exercise.

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Neither of the claims contained in your notification refer to pain associated with a non-disease state. Although "occasional overuse" and "everyday activity" are not themselves diseases, they would not be expected to result in joint pain unless a person already suffered from an underlying disease that predisposed him or her to such pain.

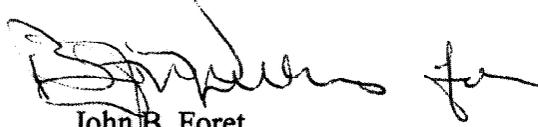
You also submitted notifications dated February 1, 2002, March 8, 2002, March 9, 2002, March 10, 2002, March 11, 2002, March 12, 2002, and March 13, 2002 for the products **Enzymatic Therapy MygraClear™**, **PhytoPharmica MygraHealth**, and **PhytoPharmica MygraPreve**. These products use the claims "...for proper blood vessel structure and blood flow in the brain," "healthy blood vessel tone in the brain, as well as healthy blood flow in the brain," and "healthy blood vessel tone." These claims, used in conjunction with the names of the products, **MygraClear™**, **MygraHealth**, and **MygraPreve** are implied claims that your products are intended to treat a disease, namely, migraine headaches. The use of the name of a disease or other words or terms related to a disease is an implicit claim that a product is intended to treat, prevent, or mitigate that disease. See 21 CFR 101.93(g)(2)(iv)(A). The terms **MygraClear™**, **MygraHealth**, and **MygraPreve** are obvious derivations from "migraine" that serve to identify a population of consumers with a disease for which the products are intended. FDA considers a brand name that includes a disease name or a clearly recognizable derivation of a disease name to be a disease claim unless the context of the labeling as a whole makes clear that the name does not imply disease treatment or prevention because the product is intended for some other use. The names of these products, however, provide no indication of what other uses the products could be intended for and, moreover, include claims that are clearly related to one of the underlying predisposing clinical causes of migraine headaches. As such, the names of these products and the accompanying claims are disease claims.

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products suggest that they are intended to treat, prevent, or mitigate diseases. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Page 3 - Dr. Robert C. Doster

Please contact us if we may be of further assistance.

Sincerely,

A handwritten signature in black ink, appearing to read "John B. Foret". The signature is fluid and cursive, with a large initial "J" and a distinct "F" at the end.

John B. Foret  
Director  
Division of Compliance and Enforcement  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

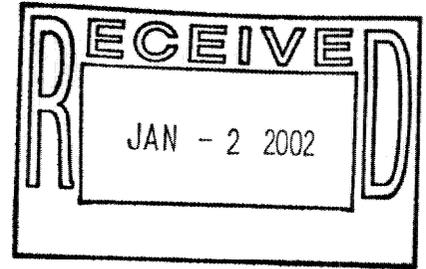
**Copies:**

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200

FDA, Minneapolis District Office, Office of Compliance, HFR-MW240

December 13, 2001



Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C St. SW  
Washington, DC 20204

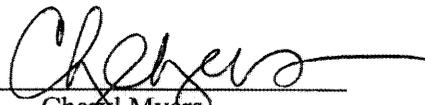
RE: Label Claims/Disclaimers

Dear Sir/Madam:

This letter is to notify you that PhytoPharmica (A Division of Integrative Therapeutics, 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.

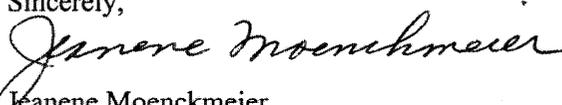
<u>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
PhytoPharmica (A Division of Integrative Therapeutics Inc.)	FlexAgility	Ginger (Zingiber officinale), Greater Galangal (Alpinia galanga)	Reduces joint pain and stiffness due to everyday activity*

I certify that the information contained in this notice is complete and accurate and that PhytoPharmica (A Division of Integrative Therapeutics, Inc.) has substantiation that the statements are truthful and not misleading.

By:   
Cheryl Myers  
Title: Director of Product Development

Date: 12-13-01

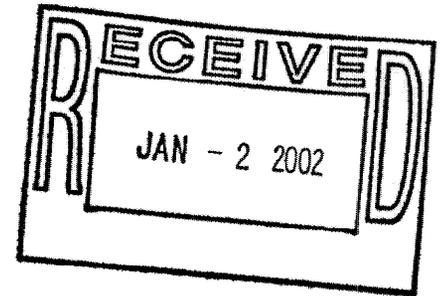
If you have any questions, please contact Jeanene Moenckmeier, Director of Legal Affairs at (920) 469-4440.

Sincerely,  
  
Jeanene Moenckmeier  
Director of Legal Affairs  
FlexAgility 2p

825 CHALLENGER DRIVE  
GREEN BAY, WI 54311-8328  
920-469-9099  
TOLL FREE 800-553-2370  
FAX 920-469-4418  
FAX TOLL FREE 888-311-5657  
WWW.PHYTOPHARMICA.COM

78755

December 12, 2001



Office of Special Nutritionals (HFS-450)  
 Center for Food Safety and Applied Nutrition  
 Food and Drug Administration  
 200 C St. SW  
 Washington, DC 20204

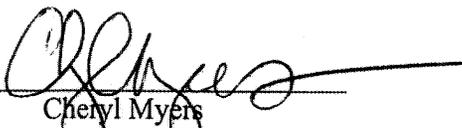
RE: Label Claims/Disclaimers

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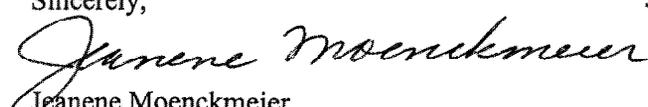
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PhytoPharmica (A Division of Integrative Therapeutics Inc.)	FlexAgility	Ginger (Zingiber officinale), Greater Galangal (Alpinia galanga)	Reduces joint pain and stiffness due to occasional overuse*

I certify that the information contained in this notice is complete and accurate and that PhytoPharmica (A Division of Integrative Therapeutics, Inc.) has substantiation that the statements are truthful and not misleading.

By:   
 Cheryl Myers  
 Title: Director of Product Development

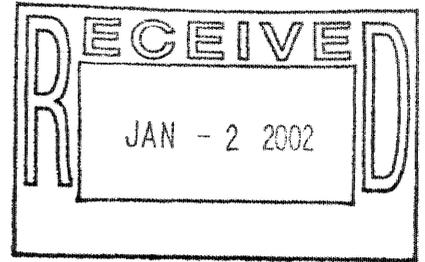
Date: 12-12-01

If you have any questions, please contact Jeanene Moenckmeier, Director of Legal Affairs at (920) 469-4440.

Sincerely,  
  
 Jeanene Moenckmeier  
 Director of Legal Affairs  
 FlexAgilitylp

78755  
 825 CHALLENGER DRIVE  
 GREEN BAY, WI 54311-8328  
 920-469-9099  
 TOLL FREE 800-553-2370  
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**EnzymaticTherapy®**  
NATURAL MEDICINES™



December 13, 2001

Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C St. SW  
Washington, DC 20204

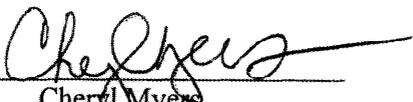
RE: Label Claims/Disclaimers

Dear Sir/Madam:

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.

<u>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	FlexAgility	Ginger (Zingiber officinale), Greater Galangal (Alpinia galanga)	Reduces joint pain and stiffness due to everyday activity*

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:   
Cheryl Myers  
Title: Director of Product Development

Date: 12-13-01

If you have any questions, please contact Jeanene Moenckmeier, Director of Legal Affairs at (920) 469-4440.

Sincerely,  
  
Jeanene Moenckmeier  
Director of Legal Affairs

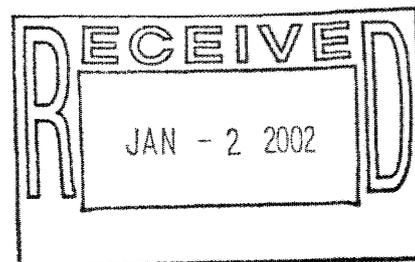
825 Challenger Drive  
Green Bay, WI 54311-8328  
Ph: 920-469-1313  
Fax: 920-469-4400  
www.enzy.com

FlexAgility 2e

78755

**EnzymaticTherapy®**  
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December 12, 2001



Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C St. SW  
Washington, DC 20204

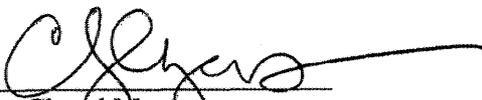
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<u>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	FlexAgility	Ginger (Zingiber officinale), Greater Galangal (Alpinia galanga)	Reduces joint pain and stiffness due to occasional overuse*

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.

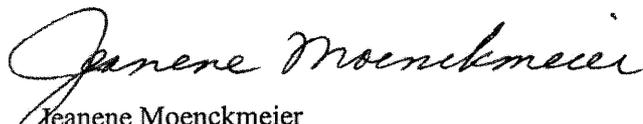
By:   
Cheryl Myers

Title: Director of Product Development

Date: 12-12-01

If you have any questions, please contact Jeanene Moenckmeier, Director of Legal Affairs at (920) 469-4440.

Sincerely,

  
Jeanene Moenckmeier  
Director of Legal Affairs

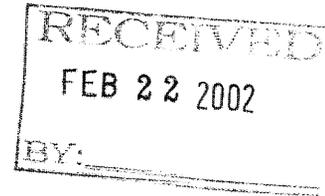
825 Challenger Drive  
Green Bay, WI 54311-8328  
Ph: 920-469-1313  
Fax: 920-469-4400  
www.enzy.com

FlexAgility®

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**EnzymaticTherapy**<sup>®</sup>  
NATURAL MEDICINES™

January 24, 2002



Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
U. S. Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740-3835

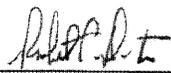
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<u>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	FlexAgility	Proprietary Herbal Extract Blend: Ginger (Zingiber officinale) rhizome extract, Greater Galangal (Alpinia galanga) rhizome extract	This unique combination gives FlexAgility the triple-action power to reduce joint pain and stiffness due to occasional overuse, and protect the integrity of cartilage.*

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 Scientific Affairs

Date: 1/24/02

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 469-3608.

Sincerely,



Michael P. Devereux  
Chief Financial Officer

FlexAgility 3e

**EnzymaticTherapy**®  
NATURAL MEDICINES™

January 25, 2002

Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
U. S. Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740-3835

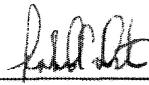
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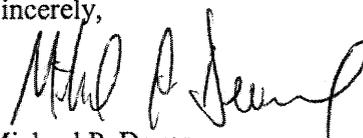
<u>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	FlexAgility	Proprietary Herbal Extract Blend: Ginger (Zingiber officinale) rhizome extract, Greater Galangal (Alpinia galanga) rhizome extract	Clinical studies have shown significant effects after two weeks of using this formula, and even more significant results after six weeks of use.*

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 Scientific Affairs

Date: 1/25/02

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 469-3608

Sincerely,  
  
Michael P. Devereux  
Chief Financial Officer  
FlexAgility 4e

79745

March 8, 2002

Office of Special Nutritionals (HFS-450)  
 Center for Food Safety and Applied Nutrition  
 U. S. Food and Drug Administration  
 5100 Paint Branch Parkway  
 College Park, MD 20740-3835

RECEIVED  
 MAR 13 2002  
 BY:

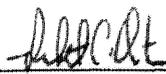
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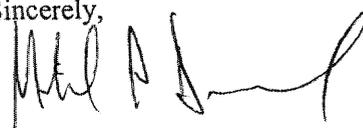
<u>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
PhytoPharmica (A Division of Integrative Therapeutics, Inc.)	MygraPreve with Patented Petadolex	Purple Butterbur (Petasites hybridus) Root Extract	Dietary Supplement for healthy blood vessel tone in the brain*

I certify that the information contained in this notice is complete and accurate and that PhytoPharmica (A Division of Integrative Therapeutics, Inc.) has substantiation that the statements are truthful and not misleading.

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

Date: 3/8/02

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 469-3608.

Sincerely,  
  
 Michael P. Devereux  
 Chief Financial Officer  
 MygraPreve with Patented Petadolex 1p

825 CHALLENGER DRIVE  
 GREEN BAY, WI 54311-8328  
 920-469-9099  
 TOLL FREE 800-553-2370  
 FAX 920-469-4418  
 FAX TOLL FREE 888-311-5657  
 WWW.PHYTOPHARMICA.COM

March 9, 2002

Office of Special Nutritionals (HFS-450)  
 Center for Food Safety and Applied Nutrition  
 U. S. Food and Drug Administration  
 5100 Paint Branch Parkway  
 College Park, MD 20740-3835

RECEIVED  
 MAR 13 2002  
 BY: \_\_\_\_\_

RE: Label Claims/Disclaimers

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<u>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
PhytoPharmica (A Division of Integrative Therapeutics, Inc.)	MygraPreve with Patented Petadolex	Purple Butterbur (Petasites hybridus) Root Extract	Dietary Supplement for healthy blood vessel tone and blood flow in the brain*

I certify that the information contained in this notice is complete and accurate and that PhytoPharmica (A Division of Integrative Therapeutics, Inc.) has substantiation that the statements are truthful and not misleading.

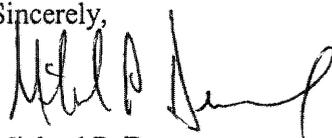
By:   
 Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 3/9/02

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 469-3608.

Sincerely,



Michael P. Devereux  
 Chief Financial Officer

MygraPreve with Patented Petadolex 2p

825 CHALLENGER DRIVE  
 GREEN BAY, WI 54311-8328  
 920-469-9099  
 TOLL FREE 800-553-2370  
 FAX 920-469-4418  
 FAX TOLL FREE 888-311-5657  
 WWW.PHYTOPHARMICA.COM

March 10, 2002

Office of Special Nutritionals (HFS-450)  
 Center for Food Safety and Applied Nutrition  
 U. S. Food and Drug Administration  
 5100 Paint Branch Parkway  
 College Park, MD 20740-3835

RECEIVED  
 MAR 13 2002  
 BY: \_\_\_\_\_

RE: Label Claims/Disclaimers

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<u>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
PhytoPharmica (A Division of Integrative Therapeutics, Inc.)	MygraPreve with Patented Petadolex	Purple Butterbur (Petasites hybridus) Root Extract	Studies demonstrate MygraPreve with Petadolex is safe and well tolerated.*

I certify that the information contained in this notice is complete and accurate and that PhytoPharmica (A Division of Integrative Therapeutics, Inc.) has substantiation that the statements are truthful and not misleading.

By:   
 Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 3/10/02

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 469-3608.

Sincerely,



Michael P. Devereux  
 Chief Financial Officer

MygraPreve with Patented Petadolex 5p

825 CHALLENGER DRIVE  
 GREEN BAY, WI 54311-8328  
 920-469-9099  
 TOLL FREE 800-553-2370  
 FAX 920-469-4418  
 FAX TOLL FREE 888-311-5657  
 WWW.PHYTOPHARMICA.COM



79715

March 11, 2002

Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
U. S. Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740-3835

RECEIVED  
MAR 13 2002  
BY: \_\_\_\_\_

RE: Label Claims/Disclaimers

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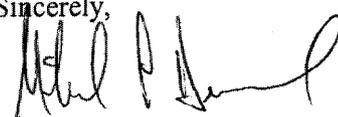
<u>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
PhytoPharmica (A Division of Integrative Therapeutics, Inc.)	MygraPreve with Patented Petadolex	Purple Butterbur (Petasites hybridus) Root Extract	Dietary Supplement for proper blood vessel structure and blood flow in the brain*

I certify that the information contained in this notice is complete and accurate and that PhytoPharmica (A Division of Integrative Therapeutics, Inc.) has substantiation that the statements are truthful and not misleading.

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

Date: 3/11/02

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 469-3608.

Sincerely,  


Michael P. Devereux  
Chief Financial Officer  
MygraPreve with Patented Petadolex 3p

825 CHALLENGER DRIVE  
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March 11, 2002

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RE: Label Claims/Disclaimers

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<u>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
PhytoPharmica (A Division of Integrative Therapeutics, Inc.)	MygraPreve with Patented Petadolex	Purple Butterbur (Petasites hybridus) Root Extract	Doctor recommended MygraPreve with Petadolex features a patented extract of butterbur to support healthy blood vessel tone in the brain, as well as healthy blood flow in the brain*

I certify that the information contained in this notice is complete and accurate and that PhytoPharmica (A Division of Integrative Therapeutics, Inc.) has substantiation that the statements are truthful and not misleading.

By:   
Robert C. Doster  
Title: Senior Vice President of Scientific Affairs  
Date: 3/11/02

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 469-3608.

Sincerely,



Michael P. Devereux  
Chief Financial Officer

MygraPreve with Patented Petadolex 4p

825 CHALLENGER DRIVE  
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FAX 920-469-4418  
FAX TOLL FREE 888-311-5657  
WWW.PHYTOPHARMICA.COM

March 12, 2002

Office of Special Nutritionals (HFS-450)  
 Center for Food Safety and Applied Nutrition  
 U. S. Food and Drug Administration  
 5100 Paint Branch Parkway  
 College Park, MD 20740-3835

RECEIVED  
 3/18/02

RE: Label Claims/Disclaimers

Dear Sir/Madam:

This letter is to notify you that PhytoPharmica (A Division of Integrative Therapeutics, 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.

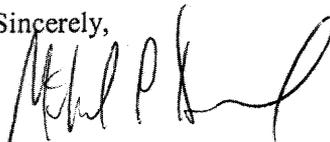
<u>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
PhytoPharmica (A Division of Integrative Therapeutics, Inc.)	MygraHealth with Patented Petadolex	Purple Butterbur (Petasites hybridus) Root Extract	62% improvement reported*

I certify that the information contained in this notice is complete and accurate and that PhytoPharmica (A Division of Integrative Therapeutics, Inc.) has substantiation that the statements are truthful and not misleading.

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

Date: 3/12/02

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 469-3608.

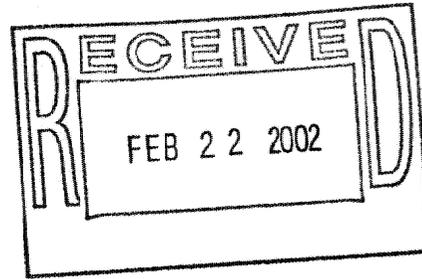
Sincerely,  
  
 Michael P. Devereux  
 Chief Financial Officer  
 MygraHealth with Patented Petadolex 6p

79710  
 825 CHALLENGER DRIVE  
 GREEN BAY, WI 54311-8328  
 920-469-9099  
 TOLL FREE 800-553-2370  
 FAX 920-469-4418  
 FAX TOLL FREE 888-311-5657  
 WWW.PHYTOPHARMICA.COM

**EnzymaticTherapy**<sup>®</sup>  
NATURAL MEDICINES™

February 1, 2002

Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
U. S. Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740-3835



RE: Label Claims/Disclaimers

Dear Sir/Madam:

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.

<u>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	MygraClear™ with patented Petadox	Purple Butterbur (Petasites hybridus)	Dietary Supplement for proper blood vessel structure and blood flow 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 C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 2/1/02

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 469-3608.

Sincerely,  


Mike Devereux  
Chief Financial Officer

825 Challenger Drive  
Green Bay, WI 54311-8328

Ph: 920-469-1313

Fax: 888-570-6460

www.enzy.com

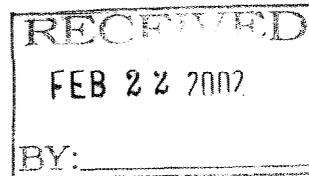
MygraClear 1c

79338

**EnzymaticTherapy**<sup>®</sup>  
NATURAL MEDICINES™

February 2, 2002

Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
U. S. Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740-3835



RE: Label Claims/Disclaimers

Dear Sir/Madam:

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.

<u>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	MygraClear™ with patented Petadolex	Purple Butterbur (Petasites hybridus)	Doctor recommended MygraClear with Petadolex features a patented extract of butterbur to support healthy blood vessel tone in the brain, as well as healthy blood flow 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 C. Doster  
Title: Senior Vice President of Scientific Affairs

Date: 2/2/02

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 469-3608.

Sincerely,

  
Mike Devereux  
Chief Financial Officer  
MygraClear 2e

79338

**EnzymaticTherapy**®  
NATURAL MEDICINES™

March 8, 2002

RECEIVED  
MAR 13 2002  
BY:

Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
U. S. Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740-3835

RE: Label Claims/Disclaimers

Dear Sir/Madam:

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.

<u>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	MygraClear™ with Patented Petadolex	Purple Butterbur (Petasites hybridus) Root Extract	Dietary Supplement 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 C. Doster  
Robert C. Doster  
Title: Senior Vice President of Scientific Affairs

Date: 3/8/02

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 469-3608.

Sincerely,  
Michael P. Devereux  
Michael P. Devereux  
Chief Financial Officer

825 Challenger Drive  
Green Bay, WI 54311-8328  
Ph: 920-469-1313  
Fax: 888-570-6460  
www.enzy.com

MygraClear with Patented Petadolex 3c

79741

**EnzymaticTherapy**<sup>®</sup>  
NATURAL MEDICINES™

19741

March 9, 2002

RECEIVED  
MAR 12 2002  
BY: \_\_\_\_\_

Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
U. S. Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740-3835

RE: Label Claims/Disclaimers

Dear Sir/Madam:

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<u>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	MygraClear™ with Patented Petadolex	Purple Butterbur (Petasites hybridus) Root Extract	Dietary Supplement for healthy blood vessel tone and blood flow in the brain*

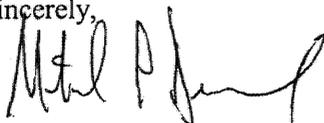
I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By:   
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 3/9/02

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 469-3608.

Sincerely,  


Michael P. Devereux  
Chief Financial Officer

825 Challenger Drive  
Green Bay, WI 54311-8328

Ph: 920-469-1313

Fax: 888-570-6460

www.enzy.com

MygraClear with Patented Petadolex 4e

**EnzymaticTherapy**<sup>®</sup>  
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March 10, 2002

Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
U. S. Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740-3835

RECEIVED  
MAR 13 2002  
BY: \_\_\_\_\_

RE: Label Claims/Disclaimers

Dear Sir/Madam:

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.

<u>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	MygraClear™ with Patented Petadolex	Purple Butterbur (Petasites hybridus) Root Extract	Studies demonstrate MygraClear with Petadolex is safe and well tolerated*

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.

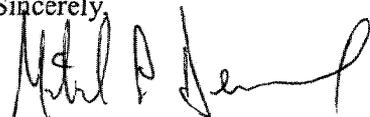
By:   
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 3/10/02

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 469-3608.

Sincerely,



Mike Devereux  
Chief Financial Officer

825 Challenger Drive  
Green Bay, WI 54311-8328

Ph: 920-469-1313

Fax: 888-570-6460

www.enzy.com

MygraClear with Patented Petadolex 5e

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**EnzymaticTherapy®**  
NATURAL MEDICINES™

March 12, 2002

RECEIVED  
MAR 13 2002  
BY: \_\_\_\_\_

Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
U. S. Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740-3835

RE: Label Claims/Disclaimers

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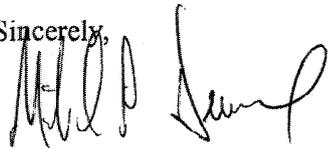
<u>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	MygraClear™ with Patented Petadolex	Purple Butterbur (Petasites hybridus) Root Extract	It has been the subject of two placebo-controlled clinical studies. In the most recent, participants reported a 71% improvement*

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 C. Doster  
Title: Senior Vice President of Scientific Affairs

Date: 3/12/02

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 469-3608.

Sincerely,  
  
Mike Devereux  
Chief Financial Officer

825 Challenger Drive  
Green Bay, WI 54311-8328  
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MygraClear with Patented Petadolex 5e

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**EnzymaticTherapy**<sup>®</sup>  
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March 13, 2002

RECEIVED  
MAR 13 2002  
BY: \_\_\_\_\_

Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
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5100 Paint Branch Parkway  
College Park, MD 20740-3835

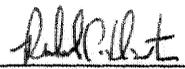
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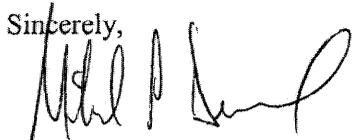
I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By:   
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 3/13/02

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 469-3608.

Sincerely,  
  
Mike Devereux  
Chief Financial Officer

825 Challenger Drive  
Green Bay, WI 54311-8328  
Ph: 920-469-1313  
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MygraClear with Patented Petadolex 5e

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**EnzymaticTherapy**®  
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March 13, 2002

Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
U. S. Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740-3835

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MAR 18 2002  
BY: \_\_\_\_\_

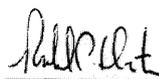
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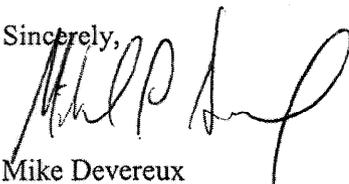
<u>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	MygraClear™ with Patented Petadolex	Purple Butterbur (Petasites hybridus) Root Extract	It has been the subject of two placebo-controlled clinical studies. In the most recent, participants reported a 62% improvement*

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 C. Doster  
Title: Senior Vice President of Scientific Affairs

Date: 3/13/02

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 469-3608.

Sincerely,  
  
Mike Devereux  
Chief Financial Officer

825 Challenger Drive  
Green Bay, WI 54311-8328  
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Fax: 888-570-6460  
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MygraClear with Patented Petadolex 9e