DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

6388 '02 MAR 26 P2:20

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.

Please contact us if we may be of further assistance.

Sincerely,

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

PhytoPharmica
NATURAL MEDICINES™

RECEIVED
JAN - 2 2002

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.

COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	STATEMENTS
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.

78755

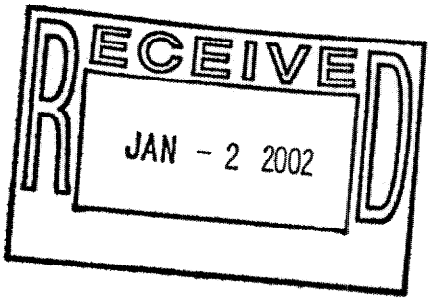
Sincerely,

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

PhytoPharmica®
NATURAL MEDICINES™



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

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.

COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	STATEMENTS
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.

18755

Sincerely,

Jeanene Moenckmeier
Director of Legal Affairs

FlexAgility1p

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®
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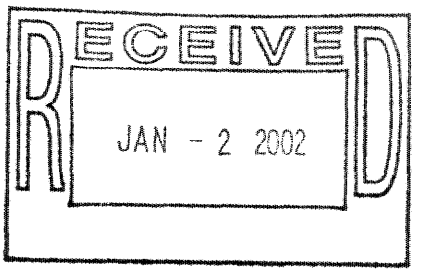

December 13, 2001

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.

COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	STATEMENTS
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
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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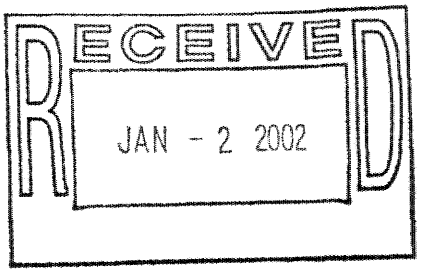

December 12, 2001

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

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.

COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	STATEMENTS
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

FlexAgility1e

78755

EnzymaticTherapy®
NATURAL MEDICINES™

RECEIVED
FEB 22 2002
BY:

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

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.

COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	STATEMENTS
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

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

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

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.

COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	STATEMENTS
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

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

PhytoPharmica®
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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:

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.

COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	STATEMENTS
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

PhytoPharmica®
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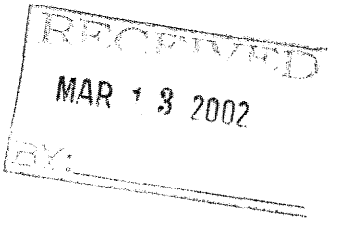
March 9, 2002

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



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.

COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	STATEMENTS
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

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

PhytoPharmica®
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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 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.

COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	STATEMENTS
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: 3/12/02

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

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

PhytoPharmica®
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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

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.

COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	STATEMENTS
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: 3/14/02

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
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

PhytoPharmica®
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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

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.

COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	STATEMENTS
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

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

PhytoPharmica®
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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.

COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	STATEMENTS
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
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®
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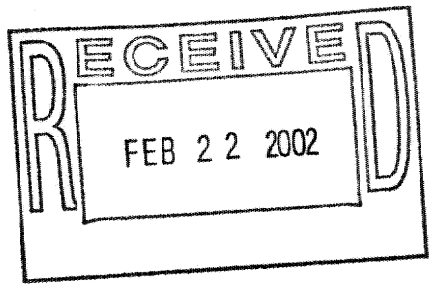

February 1, 2002

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.

COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	STATEMENTS
Enzymatic Therapy, Inc.	MygraClear™ with patented Petadolex	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

79338

EnzymaticTherapy®
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

RECEIVED
FEB 22 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.

COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	STATEMENTS
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

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

79338

EnzymaticTherapy®
NATURAL MEDICINES™

RECEIVED
MAR 13 2002
BY:

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

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.

COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	STATEMENTS
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
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

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

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EnzymaticTherapy®
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MAR 12 2002
BY:

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

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.

COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	STATEMENTS
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: 3/6/02

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
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EnzymaticTherapy®
NATURAL MEDICINES™

March 10, 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.

COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	STATEMENTS
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

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EnzymaticTherapy®
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MAR 13 2002
BY:

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

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.

COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	STATEMENTS
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
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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EnzymaticTherapy®
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March 13, 2002

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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:

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COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	STATEMENTS
Enzymatic Therapy, Inc.	MygraClear™ with Patented Petadolex	Purple Butterbur (Petasites hybridus) Root Extract	71% improvement reported.*

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

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Green Bay, WI 54311-8328
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EnzymaticTherapy®
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March 13, 2002

RECEIVED
MAR 18 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.

COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	STATEMENTS
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

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Green Bay, WI 54311-8328
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