



APR - 9 2002

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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 March 14, 2002 and March 25, 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 submissions were for the products **Enzymatic Therapy Migracare®** and **PhytoPharmica MygraFree™**.

The products **Enzymatic Therapy Migracare®** and **PhytoPharmica MygraFree™** use the claim "Dietary supplement to support healthy circulation in the brain." This claim, used in conjunction with the names of the products, **Mygracare®** and **MygraFree™** is an implied claim 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 **Migracare®** and **MygraFree™** 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

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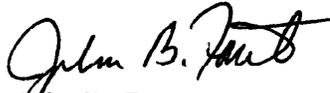
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are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation 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

EnzymaticTherapy®

NATURAL MEDICINES™

March 14, 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



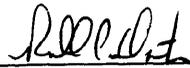
RE: Label Claims/Disclaimers

Dear Sir/Madam:

This letter is to notify you that Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 is a distributor 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.	Migracare®	Feverfew (Tanacetum parthenium) Flower and Leaf	Dietary supplement supports healthy circulation of 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 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

825 Challenger Drive
Green Bay, WI 54311-8328

Ph: 920-469-1313

Fax: 888-570-6460

www.enzy.com

Migracare 1c

79932

March 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

RECEIVED
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RE: Label Claims/Disclaimers

Dear Sir/Madam:

This letter is to notify you that PhytoPharmica at 825 Challenger Drive, Green Bay, Wisconsin 54311 is a distributor 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>
Phyto-Pharmica (a Division of Integrative Therapeutics Inc.)	MygraFree™	Feverfew (Tanacetum parthenium) Flower and Leaf	Dietary supplement to support healthy circulation in the brain*

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

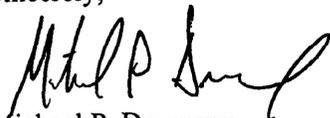
By: 
 Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 3/25/02

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

79930

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