



NOV 19 2001

7578 01 401 30 P1 46

Ms. Jeanene Moenckmeier  
Director of Legal Affairs  
Enzymatic Therapy, Inc.  
825 Challenger Drive  
Green Bay, Wisconsin 54311

Phytopharmacia Division of  
Integrative Therapeutics, Inc.  
825 Challenger Drive  
Green Bay, Wisconsin 54311

Dear Ms. Moenckmeier:

This is in response to your letters of October 25, 2001 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 state that Enzymatic Therapy, Inc. and Phytopharmacia Division of Integrative Therapeutics, Inc. are making the following claim, among others, for the products named **Heartburn Free**:

“...decreasing the potential for the highly acidic stomach fluid to splash up in to the esophagus.”

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 statement that you are making for these products, including the use of the term “heartburn” as the name of the product, suggests that they are intended to treat, prevent, or mitigate disease, namely esophageal reflux disease and heartburn<sup>1</sup>. 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

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<sup>1</sup>Although FDA concluded that “occasional heartburn” and “occasional acid indigestion” may be nonspecific symptoms that could be appropriate structure/function claims, the claims for your product are not qualified such that they are not disease claims. Moreover, esophageal reflux disease and its characteristic signs or symptoms are not nonspecific conditions that would be appropriate structure/function claims (see 65 FR 1000 at 1031; Jan. 6, 2000).

975-0163

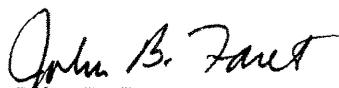
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Page 2 - Ms. Jeanene Moenckmeier

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 you require 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 Compliance, HFR-MW240

**EnzymaticTherapy®**  
NATURAL MEDICINES™

October 25, 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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78372

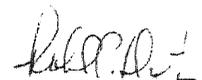
RE: Label Claims/Disclaimers

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.

<b>COMPANY</b>	<b>PRODUCT NAME</b>	<b>DIETARY INGREDIENTS</b>	<b>STATEMENTS</b>
Enzymatic Therapy, Inc.	Heartburn Free*	Orange (Citrus sinensis) Peel Extract, standardized to contain a minimum of 98.5% d-limonene	Heartburn Free supports healthy peristalsis, moving food through the stomach effectively and efficiently.*

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: 10-25-01

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

Heartburn Free8.e

**EnzymaticTherapy®**  
NATURAL MEDICINES™

October 26, 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

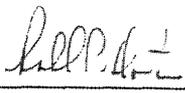
RE: Label Claims/Disclaimers

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<b>COMPANY</b>	<b>PRODUCT NAME</b>	<b>DIETARY INGREDIENTS</b>	<b>STATEMENTS</b>
Enzymatic Therapy, Inc.	Heartburn Free*	Orange (Citrus sinensis) Peel Extract, standardized to contain a minimum of 98.5% d-limonene	In a laboratory study, researchers found that orange peel extract exerts a spasmogenic activity and the spasmogenic activity was associated with the levels of d-limonene in the 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.

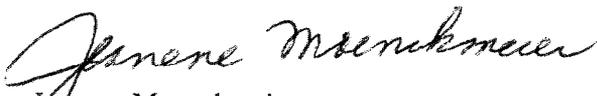
By:   
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 10-26-01

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

Sincerely,

  
Jeanene Moenckmeier  
Director of Legal Affairs

Heartburn Free9.e

# EnzymaticTherapy®

NATURAL MEDICINES™

October 29, 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

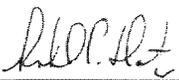
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Enzymatic Therapy, Inc.	Heartburn Free*	Orange (Citrus sinensis) Peel Extract, standardized to contain a minimum of 98.5% d-limonene	Heartburn Free may also work as a surfactant.*

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: 10-29-01

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

Sincerely,

  
Jeanene Moenckmeier  
Director of Legal Affairs

**EnzymaticTherapy**®  
NATURAL MEDICINES™

October 30, 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

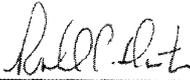
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<b>COMPANY</b>	<b>PRODUCT NAME</b>	<b>DIETARY INGREDIENTS</b>	<b>STATEMENTS</b>
Enzymatic Therapy, Inc.	Heartburn Free*	Orange (Citrus sinensis) Peel Extract, standardized to contain a minimum of 98.5% d-limonene	Heartburn Free reduces the surface tension of the liquid contents in the stomach, decreasing the potential for the highly acidic stomach fluid to splash up into the esophagus.*

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: \_\_\_\_\_

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

Sincerely,



Jeanene Moenckmeier  
Director of Legal Affairs

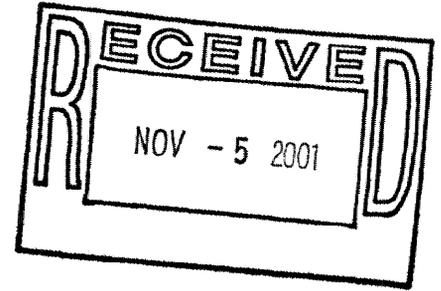
Heartburn Free LLC

825 Challenger Drive  
Green Bay, WI 54311-8328

Ph: 920-469-1313

Fax: 920-469-4400

www.enzy.com



October 25, 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 following labels of its products.

<u>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
PhytoPharmica (A Division of Integrative Therapeutics Inc.)	Heartburn Free*	Orange ( <i>Citrus sinensis</i> ) Peel Extract, patent- pending standardized to contain a minimum of 98.5% d-limonene	Heartburn Free supports healthy peristalsis, moving food through the stomach effectively and efficiently.*

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: 10-25-01

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

Sincerely,

  
Jeanene Moenckmeier  
Director of Legal Affairs

78372

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



October 27, 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

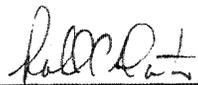
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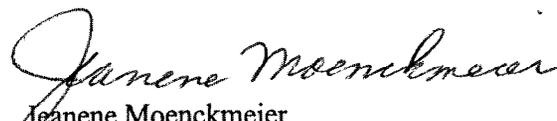
By:   
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 10-27-01

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Sincerely,

  
Jeanene Moenckmeier  
Director of Legal Affairs

HP9p

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October 29, 2001

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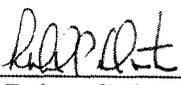
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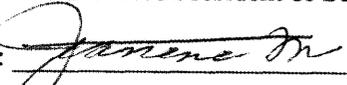
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Title: Senior Vice President of Scientific Affairs

Date:  10-29-01

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Director of Legal Affairs

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October 30, 2001

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By:   
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 10-30-01

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

Sincerely,

  
Jeanene Moenckmeier  
Director of Legal Affairs  
HP11p

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