

# Enzymatic Therapy

NATURAL MEDICINES®

January 16, 2004

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Heartburn Free®*	Heartburn Free reduces the surface tension of the liquid contents in the stomach, further decreasing the potential for occasional heartburn.*	Orange (Citrus sinensis) Peel Extract standardized to contain a minimum of 98.5% d-limonene

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: 1/16/04

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

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13645

Heartburn Free 21e

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Heartburn Free®*	In a clinical setting, participants were asked to take one 1000 mg capsule of Heartburn Free every day or every other day. About 32% of participants achieved relief as early as day 2 of their regimen, with a gradual increase in percentage to 89% of participants achieving relief by day 14*	Orange (Citrus sinensis) Peel Extract standardized to contain a minimum of 98.5% d-limonene

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Heartburn Free 22c

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs, at (920) 406-3608.

Sincerely,

A handwritten signature in black ink that reads "Michael P. Devereux". The signature is written in a cursive style with a large, prominent initial "M".

Michael P. Devereux  
Chief Financial Officer

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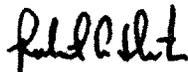
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Heartburn Free®*	In a double blind placebo controlled study, participants were randomized to an every day or every other day regimen, with half the participants taking Heartburn Free and the other half taking a placebo capsule of soy bean oil. The percentage of participants who reported relief was much higher in the group receiving Heartburn Free than that in the placebo group.*	Orange ( <i>Citrus sinensis</i> ) Peel Extract standardized to contain a minimum of 98.5% d-limonene

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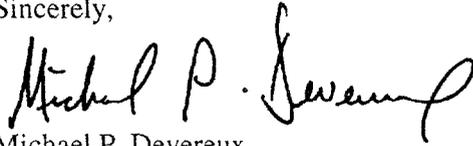
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Heartburn Free 23c

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Chief Financial Officer

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Heartburn Free®*	As demonstrated in clinical trials, the beneficial effects of Heartburn Free®* appear to develop over time, with the best results attained after following a ten capsule regimen. As with other dietary supplements (such as garlic or glucosamine sulfate [whose beneficial results are generally not experienced until after 6 weeks of regular ingestion]) there is a lag time before optimal relief of occasional heartburn is achieved.* However, after completing the initial regimen, most persons experience a decrease of their occasional heartburn symptoms as well as a longer duration of time between occurrence of occasional symptoms.*	Orange (Citrus sinensis) Peel Extract standardized to contain a minimum of 98.5% d-limonene

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Green Bay, WI 54311-8328

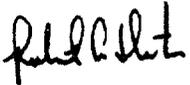
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Fax: 888-570-6460

www.enzy.com

Heartburn Free 24e

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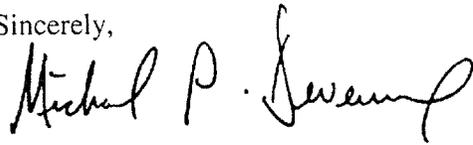
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/18/04

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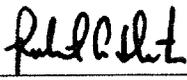
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Heartburn Free®*	The key ingredient in Heartburn Free, d-limonene, has also been well studied for its support of healthy cell development.*	Orange (Citrus sinensis) Peel Extract standardized to contain a minimum of 98.5% d-limonene

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Heartburn Free 25c

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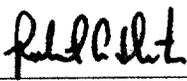
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Heartburn Free®*	d-Limonene is a farnesyl transferase inhibitor that has shown support of healthy cell development.*	Orange (Citrus sinensis) Peel Extract standardized to contain a minimum of 98.5% d-limonene

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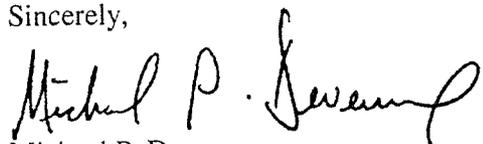
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Heartburn Free 26e

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Heartburn Free®*	Several laboratory studies have suggested d-limonene supports healthy cellular communication.*	Orange (Citrus sinensis) Peel Extract standardized to contain a minimum of 98.5% d-limonene

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