

# EnzymaticTherapy®

NATURAL MEDICINES™

January 11, 2003

1170 30 FEB -6 2003

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 811  
Food and Drug Administration  
Attention: Robert Moore  
5100 Paint Branch Parkway  
College Park, MD 20740

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. 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>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	Acidophilus Pearls™	Proprietary Probiotic Blend Lactobacillus acidophilus and Bifidobacterium longum	The patented seamless pearl capsule of Acidophilus Pearls™ assures that virtually all the bacteria remain uninjured and healthy to colonize in the intestine.*

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

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/11/03

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

Sincerely,

*Michael P. Devereux*

Michael P. Devereux  
Chief Financial Officer

Acidophilus Pearls with patented True Delivery Technology 24e

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**EnzymaticTherapy**®  
NATURAL MEDICINES™

January 9, 2003

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 811  
Food and Drug Administration  
Attention: Robert Moore  
5100 Paint Branch Parkway  
College Park, MD 20740

JAN 9 2 003

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. 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.

COMPANY	PRODUCT NAME	DIETARY INGREDIENTS	STATEMENTS
Enzymatic Therapy, Inc.	Acidophilus Pearls™	Proprietary Probiotic Blend Lactobacillus acidophilus and Bifidobacterium longum	Lactobacillus acidophilus and Bifidobacterium longum also help support the better utilization and bioavailability of nutrients, including vitamins, minerals, proteins, fats, and carbohydrates.*

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.

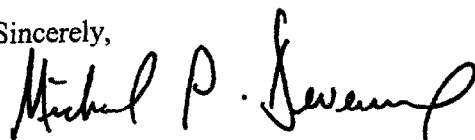
By:   
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/9/03

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

Sincerely,



Michael P. Devereux  
Chief Financial Officer

Acidophilus Pearls with patented True Delivery Technology 22c

# EnzymaticTherapy®

NATURAL MEDICINES™

January 10, 2003

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 811  
Food and Drug Administration  
Attention: Robert Moore  
5100 Paint Branch Parkway  
College Park, MD 20740

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. 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>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	Acidophilus Pearls™	Proprietary Probiotic Blend Lactobacillus acidophilus and Bifidobacterium longum	Probiotics have been shown to help retain healthy levels of C. albicans that are already within normal limits.*

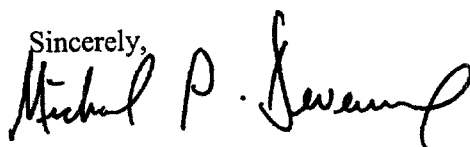
I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By: Robert Doster  
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/10/03

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

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

Acidophilus Pearls with patented True Delivery Technology 23e

# EnzymaticTherapy®

NATURAL MEDICINES™

January 8, 2003

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 811  
Food and Drug Administration  
Attention: Robert Moore  
5100 Paint Branch Parkway  
College Park, MD 20740

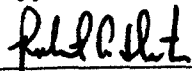
RE: Label Claims/Disclaimers

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. 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>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	Acidophilus Pearls™	Proprietary Probiotic Blend Lactobacillus acidophilus and Bifidobacterium longum	Oral ingestion of probiotics produces a stabilizing effect on the gut flora.*

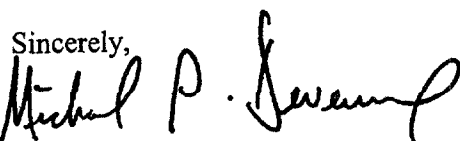
I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By:   
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/8/03

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

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

Acidophilus Pearls with patented True Delivery Technology 21e

# Enzymatic Therapy®

NATURAL MEDICINES™

January 7, 2003

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 811  
Food and Drug Administration  
Attention: Robert Moore  
5100 Paint Branch Parkway  
College Park, MD 20740

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. 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>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	Acidophilus Pearls™	Proprietary Probiotic Blend Lactobacillus acidophilus and Bifidobacterium longum	In an open, randomized, controlled trial, Lactobacillus acidophilus and Bifidobacterium bifidum were supportive of colon health in older adults.* In addition, B cell (important antibody producing immune cells) levels increased as compared with the untreated group.*

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.

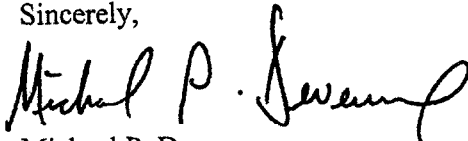
By:   
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/7/03

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

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

Acidophilus Pearls with patented True Delivery Technology 20c

# EnzymaticTherapy®

NATURAL MEDICINES™

January 6, 2003

Office of Nutritional Products, Labeling &  
 Dietary Supplements, HFS 811  
 Food and Drug Administration  
 Attention: Robert Moore  
 5100 Paint Branch Parkway  
 College Park, MD 20740


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. 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>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	Acidophilus Pearls™	Proprietary Probiotic Blend Lactobacillus acidophilus and Bifidobacterium longum	Lactobacillus acidophilus and Bifidobacterium longum have been shown to possess immunoprotective/immunomodulatory properties.* These benefits include modulation of: cytokine and various interleukin production, autoimmunity, natural killer cell cytotoxicity, lymphocyte proliferation, and antibody production.*

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.

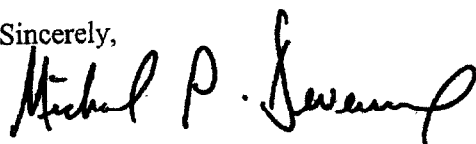
By:   
 Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/16/03

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

Sincerely,



Michael P. Devereux  
 Chief Financial Officer

Acidophilus Pearls with patented True Delivery Technology 19e

# EnzymaticTherapy®

NATURAL MEDICINES™

January 5, 2003

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 811  
Food and Drug Administration  
Attention: Robert Moore  
5100 Paint Branch Parkway  
College Park, MD 20740

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. 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>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	Acidophilus Pearls™	Proprietary Probiotic Blend Lactobacillus acidophilus and Bifidobacterium longum	In a randomized, controlled clinical trial, Bifidobacterium longum was shown to support the breakdown of lactose and reduce the symptoms of lactose intolerance (flatulence) in people with lactose intolerance.*

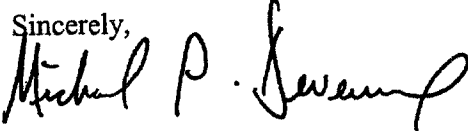
I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

By:   
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/5/03

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

Sincerely,  


Michael P. Devereux  
Chief Financial Officer

Acidophilus Pearls with patented True Delivery Technology 18c

825 Challenger Drive  
Green Bay, WI 54311-8328

Ph: 920-469-1313

Fax: 888-570-6460

www.enzy.com

# EnzymaticTherapy®

NATURAL MEDICINES™

January 4, 2003

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 811  
Food and Drug Administration  
Attention: Robert Moore  
5100 Paint Branch Parkway  
College Park, MD 20740

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. 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>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	Acidophilus Pearls™	Proprietary Probiotic Blend Lactobacillus acidophilus and Bifidobacterium longum	Probiotics do not permanently colonize in the body. Therefore, they need to be ingested regularly for their health-promoting effects to persist.*

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  
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/4/03

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

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

Acidophilus Pearls with patented True Delivery Technology 17e



# Enzymatic Therapy®

NATURAL MEDICINES™

January 3, 2003

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 811  
Food and Drug Administration  
Attention: Robert Moore  
5100 Paint Branch Parkway  
College Park, MD 20740

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. 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>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	Acidophilus Pearls™	Proprietary Probiotic Blend Lactobacillus acidophilus and Bifidobacterium longum	Additionally, the patented True Delivery™ Technology pearl capsule protects the bacteria from harsh stomach acid so they can be released live and intact in the intestines, where they need to arrive in live form to perform their beneficial function.*

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 of Scientific Affairs

Date: 1/3/03

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

Sincerely,

  
Michael P. Devereux  
Chief Financial Officer

Acidophilus Pearls with patented True Delivery Technology 16e

**EnzymaticTherapy**®  
NATURAL MEDICINES™

January 2, 2003

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 811  
Food and Drug Administration  
Attention: Robert Moore  
5100 Paint Branch Parkway  
College Park, MD 20740

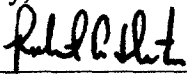
RE: Label Claims/Disclaimers

Dear Sir/Madam:

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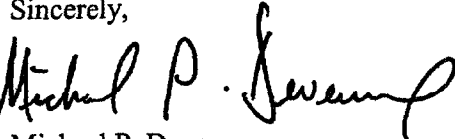
<u>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	Acidophilus Pearls™	Proprietary Probiotic Blend Lactobacillus acidophilus and Bifidobacterium longum	It provides a combination of two different active, live cultures to support the overall health of the intestinal tract.*

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 of Scientific Affairs

Date: 1/2/03

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

Sincerely,  
  
Michael P. Devereux  
Chief Financial Officer

# EnzymaticTherapy®

NATURAL MEDICINES™

January 1, 2003

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 811  
Food and Drug Administration  
Attention: Robert Moore  
5100 Paint Branch Parkway  
College Park, MD 20740

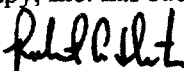
RE: Label Claims/Disclaimers

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. 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>COMPANY</u>	<u>PRODUCT NAME</u>	<u>DIETARY INGREDIENTS</u>	<u>STATEMENTS</u>
Enzymatic Therapy, Inc.	Acidophilus Pearls™	Proprietary Probiotic Blend Lactobacillus acidophilus and Bifidobacterium longum	Acidophilus Pearls™ is a probiotic dietary supplement designed to help support digestion and a healthy intestinal system.*

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.

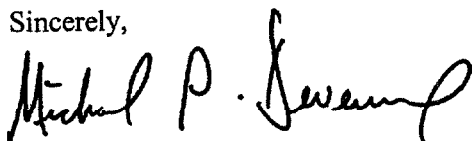
By:   
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/1/03

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

Sincerely,



Michael P. Devereux  
Chief Financial Officer

Acidophilus Pearls with patented True Delivery Technology 14e