

Enzymatic Therapy

NATURAL MEDICINES®

RECEIVED FEB 24 11 50 AM

February 6, 2004

FEB 18 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>
Mega-Zyme®	The Comfort Zone is a simple 3-step system that leads the way to healthy digestion.*	Pancreatic enzyme 10X, Trypsin, Papain, Bromelain (1,200 M.C.U./g), Amylase, Lipase, Lysozyme, Chymotrypsin

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: 2-9-04

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

975 0162

LET 13813

Mega-Zyme 8c

Enzymatic Therapy

NATURAL MEDICINES®

February 7, 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

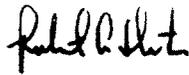
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Mega-Zyme®	The three Comfort Zone products compliment each other and enhance your system for healthy, happy, comfortable digestion.*	Pancreatic enzyme 10X, Trypsin, Papain, Bromelain (1,200 M.C.U./g), Amylase, Lipase, Lysozyme, Chymotrypsin

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: _____

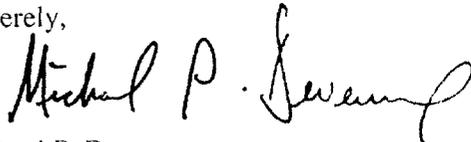
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 2-9-04

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
Mega-Zyme 9c

Enzymatic Therapy

NATURAL MEDICINES®

February 8, 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

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Mega-Zyme®	Mega-Strength Enzymes that break down fats, carbohydrates and proteins to support healthy digestion.*	Pancreatic enzyme 10X, Trypsin, Papain, Bromelain (1,200 M.C.U./g), Amylase, Lipase, Lysozyme, Chymotrypsin

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: 

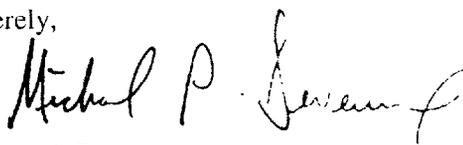
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 2-9-04

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Sincerely,



Michael P. Devereux
Chief Financial Officer

Mega-Zyme 10e

825 Challenger Drive
Green Bay, WI 54311-8328

Ph 920 469-1313

Fax 888 570-6460

www.enzy.com

Enzymatic Therapy

NATURAL MEDICINES®

February 8, 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

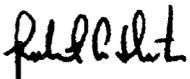
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Mega-Zyme®	Mega-Zyme® provides the highest potency enzyme complex available to promote healthy digestion.*	Pancreatic enzyme 10X, Trypsin, Papain, Bromelain (1,200 M.C.U./g), Amylase, Lipase, Lysozyme, Chymotrypsin

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: 

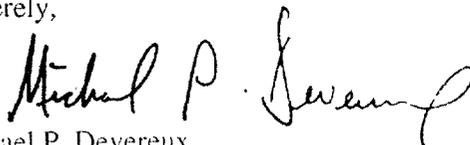
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 2-9-04

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Sincerely,



Michael P. Devereux
Chief Financial Officer
Mega-Zyme Inc

Enzymatic Therapy

NATURAL MEDICINES®

February 9, 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

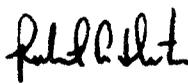
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Mega-Zyme®	Mega-Zyme® is safe, natural way to replenish enzymes, optimize digestion and support better overall health.*	Pancreatic enzyme 10X, Trypsin, Papain, Bromelain (1,200 M.C.U./g), Amylase, Lipase, Lysozyme, Chymotrypsin

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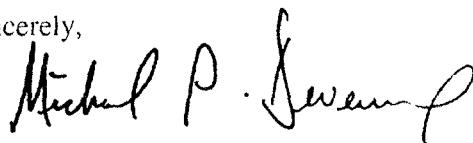
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Michael P. Devereux
Chief Financial Officer
Mega-Zyme 12e