

# EnzymaticTherapy®

NATURAL MEDICINES™

December 5, 2002

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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

DEC 17 2002

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.	Mega-Zyme®	Pancreatic enzymes 10X, Trypsin, Papain, Bromelain, Amylase, Lipase, Lysozyme, Chymotrypsin,	Helps break down fats, carbohydrates, and proteins in the small 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 C. Doster  
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 12/5/02

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

828 51

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Mega-Zyme 7e

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