

# Enzymatic Therapy

NATURAL MEDICINES®

MAR 13 2004

March 11, 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>
Echinacea Vitamin C with Elderberry Extract	Dietary Supplement supports healthy immune function*	Vitamin A (as vitamin A palmitate and 50% from natural beta carotene with mixed carotenoids), Vitamin C (65% as ascorbic acid and 35% as sodium ascorbate), Vitamin B6 (as pyridoxine HCl), Zinc (as zinc gluconate), Echinacea Proprietary Blend Echinacea purpurea whole plant extract 4:1 and Echinacea angustifolia root extract 4:1, European Elder (Sambucus nigra) Fruit Extract 5:1

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: 3/11/04

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Green Bay, WI 54311-8328  
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Fax 888-570-6460  
www.enzy.com

Echinacea Vitamin C with Elderberry Extract 1c (BW)

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