

# Enzymatic Therapy

NATURAL MEDICINES®

April 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

APR 20 2004

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>
Chewable Echinacea with Vitamin C & Elderberry	Selected synergistic nutrients that support the immune system in a convenient chewable tablet.*	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 pupurea 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 Doster

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 4/7/04

975 0162

LET

13928

825 Challenger Drive

Green Bay, WI 54311-8328

Ph 920-469-1313

Fax 888-570-6460

www.enzy.com

Echinacea Vitamin C with Elderberry Extract 2e-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, stylized "M" and "D".

Michael P. Devereux  
Chief Financial Officer

# Enzymatic Therapy

NATURAL MEDICINES®

April 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

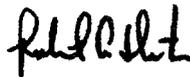
RE: Label Claims/Disclaimers

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Chewable Echinacea with Vitamin C & Elderberry	Vitamin C acts as an antioxidant*	Vitamin C (65% as ascorbic acid and 35% as sodium ascorbate)

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: \_\_\_\_\_

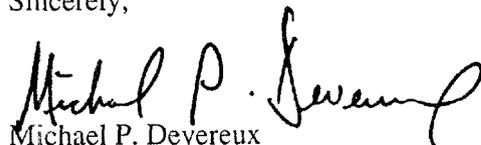
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 4/8/04

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

Echinacea Vitamin C with Elderberry Extract 3e-BW

# Enzymatic Therapy

NATURAL MEDICINES®

April 9, 2004

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Center for Food Safety and Applied Nutrition  
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College Park, MD 20740

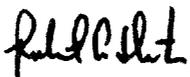
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Chewable Echinacea with Vitamin C & Elderberry	Shown to enhance immune function.*	European Elder (Sambucus nigra) Fruit Extract 5:1

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: 

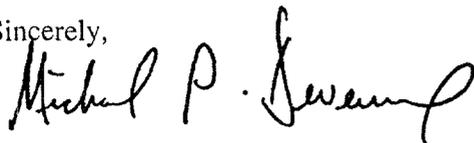
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 4/9/04

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

Echinacea Vitamin C with Elderberry Extract 4e-BW

825 Challenger Drive  
Green Bay, WI 54311-8328

Ph 920-469-1313

Fax 888-570-6460

www.enzy.com

# Enzymatic Therapy

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April 9, 2004

Office of Nutritional Products, Labeling &  
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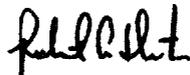
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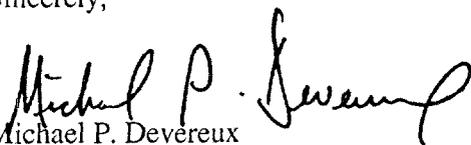
<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Chewable Echinacea with Vitamin C & Elderberry	Vitamin A has antioxidant properties, and promotes healthy cellular growth.* It works synergistically with vitamin C.*	Vitamin A (as vitamin A palmitate and 50% from natural beta carotene with mixed carotenoids)

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: 4/9/04

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

Echinacea Vitamin C with Elderberry Extract 5c-BW

# Enzymatic Therapy

NATURAL MEDICINES®

April 9, 2004

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
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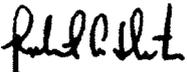
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Chewable Echinacea with Vitamin C & Elderberry	Zinc boots immunity, helps health cells reproduce and protects against free radicals.*	Zinc (as zinc gluconate)

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: 

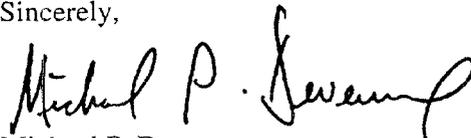
Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 4/9/04

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

825 Challenger Drive

Green Bay, WI 54311-8328

Ph. 920-469-1313

Fax: 888-570-6460

www.enzy.com

Echinacea Vitamin C with Elderberry Extract 6e-BW

# Enzymatic Therapy

NATURAL MEDICINES®

April 10, 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

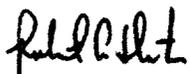
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
Chewable Echinacea with Vitamin C & Elderberry	Features supplements that work together synergistically to boost the immune system during times of stress.*	Vitamin 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 pupurea whole plant extract 4:1 and Echinacea angustifolia root extract 4:1, European Elder (Sambucus nigra) Fruit Extract 5:1

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By: 

Robert Doster  
Title: Senior Vice President of Scientific Affairs

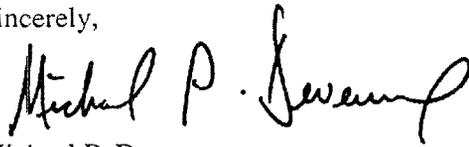
Date: 4/10/04

825 Challenger Drive  
Green Bay, WI 54311-8328  
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Echinacea Vitamin C with Elderberry Extract 7e-BW

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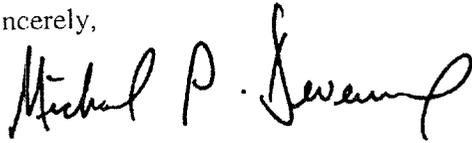
Sincerely,

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

Michael P. Devereux  
Chief Financial Officer

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

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Michael P. Devereux  
Chief Financial Officer

# Enzymatic Therapy

NATURAL MEDICINES®

April 11, 2004

Office of Nutritional Products, Labeling &  
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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>
Chewable Echinacea with Vitamin C & Elderberry	This potent formula is a great tasting chewable tablet, proven safe and effective for children, which boosts the immune system and strengthens the body's natural defense mechanisms.*	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 pupurea whole plant extract 4:1 and Echinacea angustifolia root extract 4:1, European Elder (Sambucus nigra) Fruit Extract 5:1

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By: Robert Doster

Robert Doster  
Title: Senior Vice President of Scientific Affairs

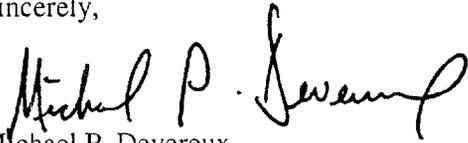
Date: 4/11/04

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