



**INTEGRATIVE THERAPEUTICS INC.™**

NF Formulas ◊ PhytoPharmica  
Tyler Encapsulations ◊ Vitaline Formulas

9755 SW Commerce Circle, Suite B2  
Wilsonville, OR 97070  
P: 503.582.8386 ◊ F: 503.582.0467

**ENZYMATIC THERAPY®  
&  
PHYTOPHARMICA®**

825 Challenger Drive, Green Bay, WI 54311-8328  
P: 920.469.1313 ◊ F: 888.570.6460 (Enzymatic)  
P: 920.469.9099 ◊ F: 920.469.4418 (Phyto)

**ENZYMATIC THERAPY**

INCORPORATED

What *Better* feels like.™

0249 5 APR -7 P2:29

March 24, 2005

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

MAR 30 2005

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>
ORGANICran™	ORGANICran provides nutritional support for bladder and urinary tract health.*	Organic Cranberry (Vaccinium macrocarpon) standardized to contain 6% quinic acid

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: 3/24/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 469-3608.

Sincerely,  
Michael P. Devereux  
Mike Devereux  
Chief Financial Officer

975 0162 LET 15923



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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
ORGANICran™	ORGANICran is standardized to contain 6% quinic acid, a natural fruit acid extensively studied for its health supportive benefits.*	Organic Cranberry (Vaccinium macrocarpn) standardized to contain 6% quinic acid

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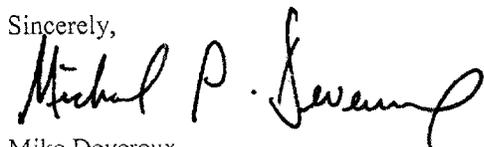
By:   
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 3/24/05

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Sincerely,



Mike Devereux  
Chief Financial Officer



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March 25, 2005

Office of Nutritional Products, Labeling &  
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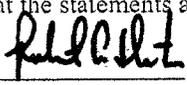
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
ORGANICran™	Specialized urinary system cells called uroepithelial cells are vital to the health of the ureters, urinary bladder, and urethra, and also benefit from support from the compounds in cranberry.* In fact, extensive laboratory and clinical research has demonstrated that quinic acid and other cranberry compounds support the health of uroepithelial cells.*	Organic Cranberry (Vaccinium macrocarpn) standardized to contain 6% quinic acid

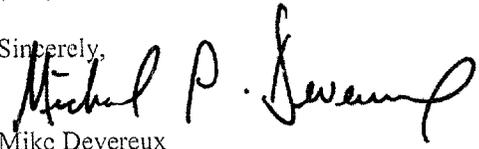
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 Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 3/25/05

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Sincerely,  
  
 Mike Devereux  
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
ORGANICran™	In one clinical trial, 153 elderly women were randomized to receive either cranberry or placebo. Baseline urine samples and six clean-voided study urine samples were collected at approximately 1-month intervals. The women in the cranberry group experienced 73 percent more urinary tract health support than women in the placebo group.* A clinical study of 150 women found that 84 percent of the participants taking cranberry had urinary tract support compared to 61 percent taking a lactobacillus drink, and 64 percent taking placebo.*	Organic Cranberry (Vaccinium macrocarpn) standardized to contain 6% quinic acid

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By: \_\_\_\_\_

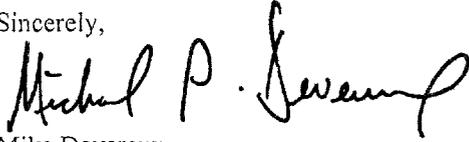
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 3/25/05

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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".

Mike Devereux  
Chief Financial Officer



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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
ORGANICran™	To determine effective support of urinary tract health, 150 sexually active women were randomized for one year to one of three groups: placebo juice + placebo tablets versus placebo juice + cranberry tablets, versus cranberry juice + placebo tablets. Tablets were taken twice daily, juice three times daily. While both cranberry juice and cranberry tablets statistically significantly supported urinary tract health, cranberry tablets provided the most cost-effective support.*	Organic Cranberry (Vaccinium macrocarpn) standardized to contain 6% quinic acid

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