



**ENZYMATIC THERAPY**  
INCORPORATED

*What **Better** feels like.™*

March 8, 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

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.

MAR 15 2005

**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)

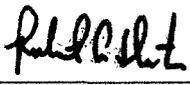
<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
OsteoPrime®*	Preserves mineral mass*	Vitamin C (ascorbic acid), Vitamin D (as cholecalciferol), Vitamin K (as phytonadione), Thiamin (as thiamin HCl) (vitamin B1), Riboflavin (vitamin B2), Niacin (as niacinamide), Vitamin B6 (as pyridoxine HCl), Folic Acid, Vitamin B12 (as cyanocobalamin), Pantothenic Acid (as calcium D-pantothenate), Calcium (from tricalcium phosphate, calcium carbonate, calcium lactate, calcium Krebs cycle chelates, and calcium citrate), Magnesium (as magnesium oxide and magnesium aspartate), Zinc (as zinc picolinate), Selenium (as sodium selenite), Copper (as copper gluconate), Manganese (as manganese aspartate), Chromium (as chromium aspartate), Molybdenum (as sodium molybdate), Sodium, Betaine HCl, Boron (as boron Krebs cycle chelates), Silicon (as magnesium trisilicate), Strontium (as strontium chloride)

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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: 3/8/05

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



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P: 920.469.9099 ♦ F: 920.469.4418 (Phyto)

March 9, 2005

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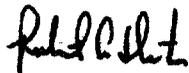
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
OsteoPrime®*	Promotes bone repair functions*	Vitamin C (ascorbic acid), Vitamin D (as cholecalciferol), Vitamin K (as phytonadione), Thiamin (as thiamin HCl) (vitamin B1), Riboflavin (vitamin B2), Niacin (as niacinamide), Vitamin B6 (as pyridoxine HCl), Folic Acid, Vitamin B12 (as cyanocobalamin), Pantothenic Acid (as calcium D-pantothenate), Calcium (from tricalcium phosphate, calcium carbonate, calcium lactate, calcium Krebs cycle chelates, and calcium citrate), Magnesium (as magnesium oxide and magnesium aspartate), Zinc (as zinc picolinate), Selenium (as sodium selenite), Copper (as copper gluconate), Manganese (as manganese aspartate), Chromium (as chromium aspartate), Molybdenum (as sodium molybdate), Sodium, Betaine HCl, Boron (as boron Krebs cycle chelates), Silicon (as magnesium trisilicate), Strontium (as strontium chloride)

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By:   
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 3/9/05

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Michael P. Devereux  
Chief Financial Officer