



**ENZYMATIC THERAPY**  
INCORPORATED

What **Better** feels like.™

**INTEGRATIVE THERAPEUTICS INC.™**  
NF Formulas • PhytoPharmica  
Tyler Encapsulations ◀ Vitaline Formulas

9755 SW Commerce Circle, Suite B2  
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**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)

0502 6 JAN 12 P2:39

January 4, 2006

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

JAN - 8 2006

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>
OsteoPrime®* Ultra	The ingredients in OsteoPrime Ultra clinically demonstrated to support and maintain healthy bones and bone structure, enhance calcium absorption, and help keep bones strong and resilient.*	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 calcium carbonate, tricalcium phosphate, calcium lactate, calcium Krebs cycle chelates, and calcium citrate), Phosphorus (from tricalcium phosphate), Phosphorus (from tricalcium phosphate), 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, Natto K2 (fermented soybeans containing vitamin K2 as menaquinone-7), Betaine HCl, Strontium (as strontium chloride), Silicon (as sodium metasilicate), Boron (as boron Krebs cycle chelates)

975 0162 LET 17165

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: 1-4-06

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