

# Enzymatic Therapy

NATURAL MEDICINES®

November 5, 2003

DEC 1 2003

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>INGREDEINT(S) TO WHICH THE CLAIM REFERS</u>
OsteoPrime®*	OsteoPrime® provides a balanced combination of important nutrients to support and maintain healthy bones in women and is targeted to work especially well for women during post-menopausal years.*	Vitamin C, Vitamin D, Vitamin K, Thiamin, Riboflavin, Niacin, Vitamin B6, Folic Acid, Vitamin B12, Pantothenic Acid, Calcium, Magnesium, Zinc, Selenium, Copper, Manganese, Chromium, Molybdenum, Sodium, Betaine HCl, Silicon, Boron, Strontium

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: 11/5/03

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www.enzy.com

975 0162 LET 13391

OsteoPrime 8e

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