

Enzymatic Therapy

NATURAL MEDICINES®

December 9, 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®*	Take Control of: <ul style="list-style-type: none">• Vitamin imbalances• Irregular or difficult periods• Troubled sleep-no energy• Occasional flushing or hot flashes• Brain fog• Mood swings• Abdominal weight gain• Calcium levels*	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: 12/9/03

825 Challenger Drive
Green Bay, WI 54311-8328
Ph: 920-469-1313
Fax: 888-570-6460
www.enzy.com

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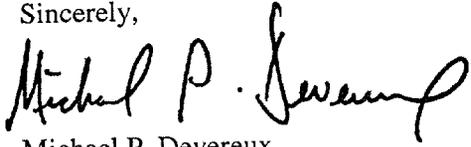
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OsteoPrime 12e

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, appearing to read "Michael P. Devereux". The signature is written in a cursive style with a large, prominent initial "M".

Michael P. Devereux
Chief Financial Officer

Enzymatic Therapy

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
OsteoPrime®*	Take Control of: <ul style="list-style-type: none">• Hot flashes• Night sweats• Low energy• Mood swings• Irritability• Calcium needs• Inadequate vitamin levels*	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

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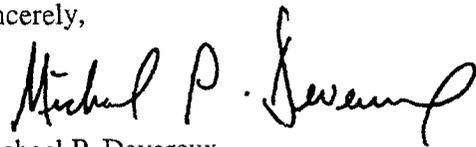
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Michael P. Devereux
Chief Financial Officer