



ENZYMATIC THERAPY
INCORPORATED

What Better feels like.™

September 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.

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

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&
PHYTOPHARMICA™

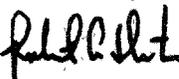
825 Challenger Drive, Green Bay, WI 54311-8328
P: 920.469.1313 ♦ F: 888.570.6460 (Enzymatic)
P: 920.469.9099 ♦ F: 920.469.4418 (Phyto)

0208 5 SEP 22 P2:24

SEP 15 2005

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
OsteoPrime®*	While OsteoPrime contains 23 ingredients associated with bone health benefits, the following 15 vitamins and minerals have been the subject of the most extensive research showing their impact on bone health.*	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), 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, Betaine HCl, Boron (as boron Krebs cycle chelates), Silicon (as magnesium trisilicate), Strontium (as strontium chloride)

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: 

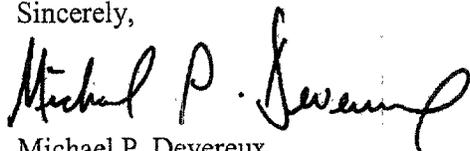
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 9/8/05

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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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
OsteoPrime®*	Combination of 23 bone-supportive ingredients, including five types of calcium and the 15 best studied vitamins and minerals for bone health.*	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), 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, Betaine HCl, Boron (as boron Krebs cycle chelates), Silicon (as magnesium trisilicate), Strontium (as strontium chloride)

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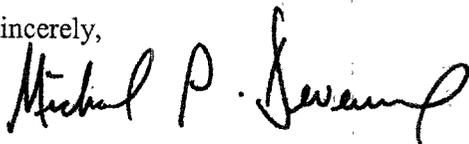
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 9/8/05

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OsteoPrime®*	Supplementation of key nutrients can help ensure strong bones throughout a lifetime.*	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), 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, Betaine HCl, Boron (as boron Krebs cycle chelates), Silicon (as magnesium trisilicate), Strontium (as strontium chloride)

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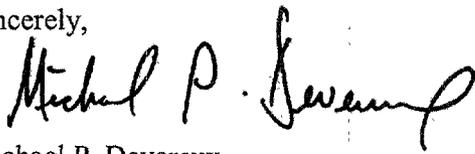
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

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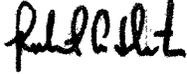
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
OsteoPrime®*	OsteoPrime's ingredients are clinically demonstrated to support and maintain healthy bones and bone structure*	Vitamin C (ascorbic acid), Vitamin D (as 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), 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, 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: 9/8/05

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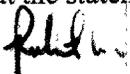
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OsteoPrime®*	OsteoPrime's ingredients are clinically demonstrated to enhance calcium absorption.*	Vitamin C (ascorbic acid), Vitamin D (as cholecalciferol), Vitamin K (as phytonadione), Thiamin (as thiamin HCl) (vitamin B1), Riboflavin (vitamin B2), 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), 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, Betaine HCl, Boron (as boron Krebs cycle chelates), Silicon (as magnesium trisilicate), Strontium (as strontium chloride)

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Date: 9/9/05

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OsteoPrime®*	OsteoPrime's ingredients are clinically demonstrated to 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 tricalcium phosphate, calcium carbonate, calcium lactate, calcium Krebs cycle chelates, and calcium citrate), 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, Betaine HCl, Boron (as boron Krebs cycle chelates), Silicon (as magnesium trisilicate), Strontium (as strontium chloride)

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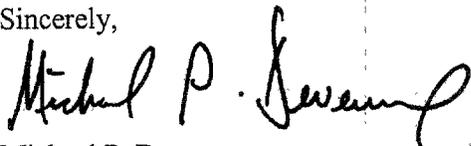
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Title: Senior Vice President of Scientific Affairs

Date: 9/9/05

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OsteoPrime®*	The most abundant mineral in the body, calcium supports bone health, nerve health and healthy heart function.*	Calcium (from tricalcium phosphate, calcium carbonate, calcium lactate, calcium Krebs cycle chelates, and calcium citrate)

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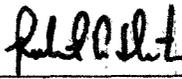
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OsteoPrime®*	There are several calcium salts in nature, each with unique bone supportive benefits.*	Calcium (from tricalcium phosphate, calcium carbonate, calcium lactate, calcium Krebs cycle chelates, and calcium citrate)

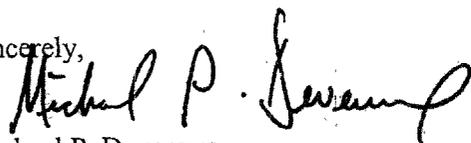
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OsteoPrime®*	Calcium triphosphate is the most prevalent form of calcium in human bone.*	Calcium (from tricalcium phosphate, calcium carbonate, calcium lactate, calcium Krebs cycle chelates, and calcium citrate)

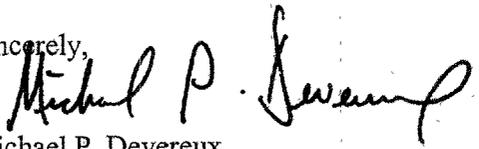
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OsteoPrime®*	Research has suggested that supplemental calcium may have superior benefits for the support of healthy bones.* A review of fifteen trials, representing 1806 participants, demonstrated that calcium was more effective than placebo in supporting healthy bone density.*	Calcium (from tricalcium phosphate, calcium carbonate, calcium lactate, calcium Krebs cycle chelates, and calcium citrate

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: 9/9/05

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P: 920.469.9099 ◊ F: 920.469.4418 (Phyto)

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



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INCORPORATED

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September 9, 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:

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
OsteoPrime®*	More than 50% of the body's magnesium content is in bone; a primary function of magnesium is the regulation of active calcium transport within bone structures.*	Magnesium (as magnesium oxide and magnesium aspartate)

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: 9/9/05

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Sincerely,

Michael P. Devereux

Michael P. Devereux
Chief Financial Officer



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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
OsteoPrime®*	There is also a significant correlation between zinc intake and bone health in both men and women.*	Zinc (as zinc picolinate)

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: 9/9/05

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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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
OsteoPrime®*	Through healthy support of collagen, copper may support mineral bone density over time.*	Copper (as copper gluconate)

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: 9/10/05

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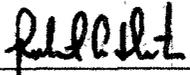
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
OsteoPrime®*	In clinical research, women taking supplemental copper experienced beneficial effects on bone density.*	Copper (as copper gluconate)

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.

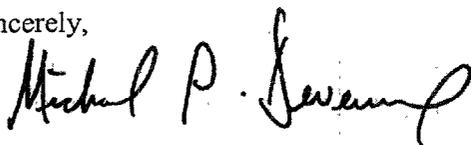
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Robert C. Doster

Title: Senior Vice President of Scientific Affairs

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
OsteoPrime®*	Several trace elements, including manganese, are essential in bone metabolism as cofactors for specific enzymes.*	Manganese (as manganese aspartate)

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: 9/10/05

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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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
OsteoPrime®*	Boron is an essential nutrient for healthy bones and joints.*	Boron (as boron Krebs cycle chelates)

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: 9/10/05

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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September 12, 2005

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
OsteoPrime®*	Clinical research showed boron supplementation supported healthy bone mineral density.*	Boron (as boron Krebs cycle chelates)

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: 9/12/05

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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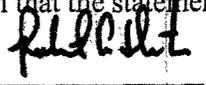
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
OsteoPrime®*	It is thought that this beneficial support is related to interactions between boron and calcium, magnesium and vitamin D, especially the finding that supplemental boron reduced urinary calcium excretion.*	Boron (as boron Krebs cycle chelates)

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: 9/12/05

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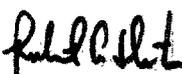
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
OsteoPrime®*	Recent studies of strontium demonstrated it is a bone supportive mineral.*	Strontium (as strontium chloride)

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By: 

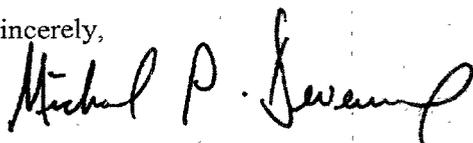
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Title: Senior Vice President of Scientific Affairs

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
OsteoPrime®*	A review of strontium research shows strontium supports healthy bone remodeling, healthy mineralization of bone tissue, and supports healthy distribution of bone mineralization.*	Strontium (as strontium chloride)

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: 9/12/05

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
OsteoPrime®*	Strontium is thought to both support both healthy osteoclasts and healthy osteoblasts in bone.*	Strontium (as strontium chloride)

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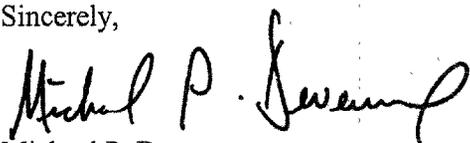
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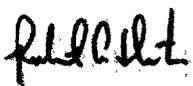
RE: Label Claims/Disclaimers

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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.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
OsteoPrime®*	Important in small amounts for bone health, silicon has recently been recognized as an essential nutrient.*	Silicon (as magnesium trisilicate)

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.

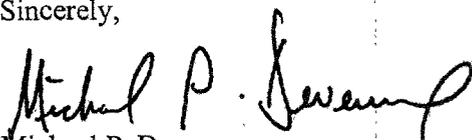
By: 
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 9/12/05

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)

September 12, 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

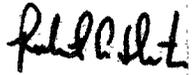
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
OsteoPrime®*	A recent study of over 2800 individuals found that higher dietary silicon intake in men and younger women supports skeletal health, especially the health of cortical bone (dense compact bone in adults).*	Silicon (as magnesium trisilicate)

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: 

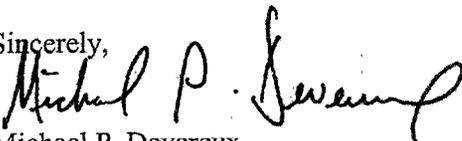
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
OsteoPrime®*	Phosphorus provides nutritional support of healthy bones.*	Phosphorus (from tricalcium phosphate)

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: 9/12/05

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
OsteoPrime®*	Recent research has shown phosphorus and calcium work together to support healthy mineralization of bones.* Additional studies have shown the importance of healthy calcium/phosphorus ratios in bone health support.*	Phosphorus (from tricalcium phosphate)

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.

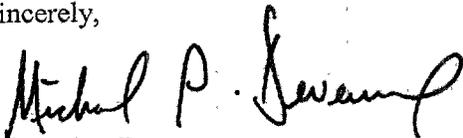
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Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 9/12/05

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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



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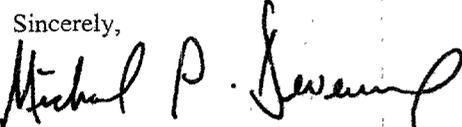
PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
OsteoPrime®*	A research review of over 600 subjects demonstrated that phosphorus supplementation (with calcium) supported healthy bone formation, healthy utilization of vitamin D, and provides nutritional support of healthy bones.*	Phosphorus (from tricalcium phosphate)

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.

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Robert C. Doster
Title: Senior Vice President of Scientific Affairs

Date: 9/12/05

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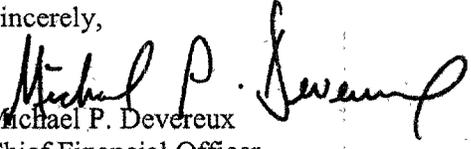
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
OsteoPrime®*	The results of two studies suggest that taking folic acid, vitamin B6, and vitamin B12 may support bone mineral density by reduction of homocysteine levels.*	Vitamin B6 (as pyridoxine HCl), Folic Acid, Vitamin B12 (as cyanocobalamin)

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
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
OsteoPrime®*	Study results show folic acid supports healthy homocysteine levels*	Folic Acid

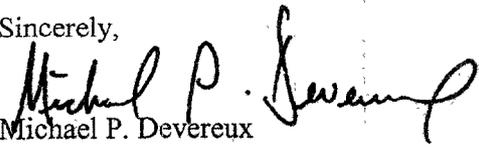
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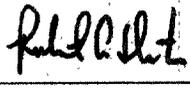
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
OsteoPrime®*	Vitamin B6 may help vitamin K activity in bone metabolism.*	Vitamin B6 (as pyridoxine HCl), Vitamin K (as phytonadione)

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.

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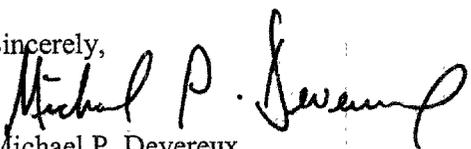
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
OsteoPrime®*	In a double-blind, randomized, placebo controlled trial, vitamin B12 combined with folate reduced homocysteine levels and supported bone health in both men and women.*	Vitamin B12 (as cyanocobalamin),

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By: 
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 9/13/05

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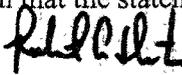
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
OsteoPrime®*	Vitamin C supports the healthy formation of procollagen (a precursor to collagen), supports collagen synthesis, and stimulates healthy bone formation.*	Vitamin C (ascorbic acid)

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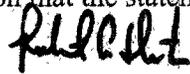
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OsteoPrime®*	Research has demonstrated supplementation with vitamin D3 and calcium may be especially important during the winter months.*	Vitamin D (as cholecalciferol)

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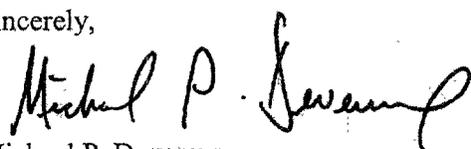
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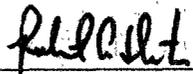
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
OsteoPrime®*	Vitamin K influences osteocalcin, a protein in bone, to attract calcium and support bone mineralization.*	Vitamin K (as phytonadione)

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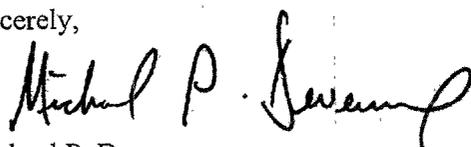
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September 13, 2005

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.

PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
OsteoPrime®*	A 3-year, double-blind, placebo-controlled intervention study of 155 women found that vitamin K1 may substantially support bone density.*	Vitamin K (as phytonadione)

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: 9/13/05

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs, at (920) 406-3608

Sincerely,

Michael P. Devereux
Michael P. Devereux
Chief Financial Officer



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September 14, 2005

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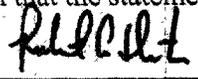
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
OsteoPrime®*	Chromium is an essential trace element required to maintain health and optimal physiologic function in bone.*	Chromium (as chromium aspartate)

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: 

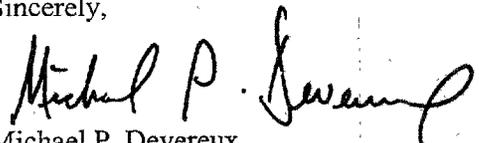
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 9/14/05

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Sincerely,



Michael P. Devereux
Chief Financial Officer

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
OsteoPrime®*	Clinical research has found that chromium supports healthy urinary calcium excretion.*	Chromium (as chromium aspartate)

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: _____

9/14/05

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
OsteoPrime®*	Adequate levels of molybdenum are necessary for nutritional support of healthy bones and teeth.*	Molybdenum (as sodium molybdate)

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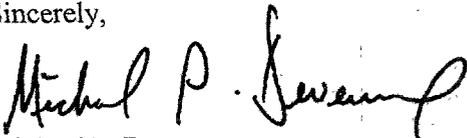
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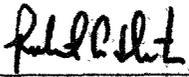
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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
OsteoPrime®*	Betaine is linked to healthy homocysteine levels, a variable in healthy bone metabolism.*	Betaine HCl

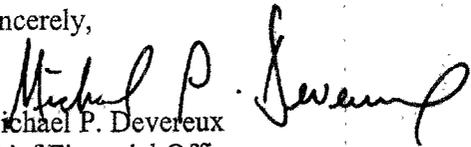
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
OsteoPrime®*	Members of the B vitamin group, pantothenic acid, vitamin B1, and niacinamide support healthy homocysteine levels, a factor associated with support of healthy bone mineral density.*	Thiamin (as thiamin HCl) (vitamin B1), Riboflavin (vitamin B2), Vitamin B6 (as pyridoxine HCl), Vitamin B12 (as cyanocobalamin), Pantothenic Acid (as calcium D-pantothenate), Niacin (as niacinamide)

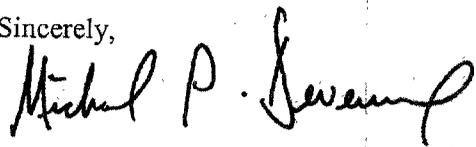
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Robert C. Doster
Title: Senior Vice President of Scientific Affairs

Date: 9/14/05

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 initial "M".

Michael P. Devereux
Chief Financial Officer



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OsteoPrime®*	Riboflavin supports healthy bone cell functioning and has antioxidant activity.*	Riboflavin (vitamin B2)

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OsteoPrime®*	Selenium helps support and maintain physiologic function in bone.*	Selenium (as sodium selenite)

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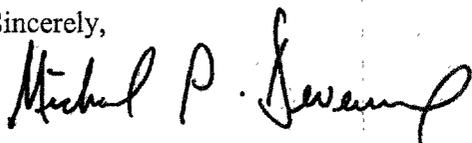
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