



# ENZYMATIC THERAPY

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&  
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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)

0718 6 JAN 23 P2:05

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 17 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®* Plus	The most abundant mineral in the body, calcium supports bone health, nerve health, and healthy heart function.* There are several calcium salts in nature, each with unique bone supportive benefits.* Calcium triphosphate is the most prevalent form of calcium in human bone.*	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 17174

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.

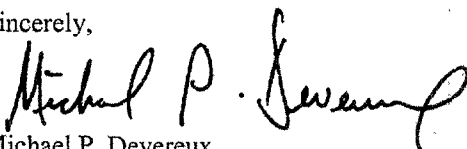
By: Robert C. Doster

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

Date: 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 Operations Officer



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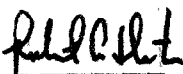
RE: Label Claims/Disclaimers

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
OsteoPrime®* Plus	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.* A Harvard study that tracked 78,000 women over a decade demonstrated that those who had higher intakes of dietary calcium were more likely to experience support for bone health than those whose dietary calcium intake was lower.*	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)

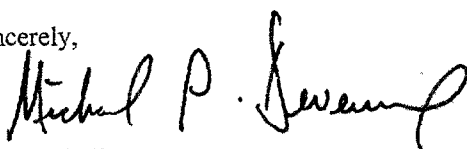
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Robert C. Doster  
Title: Senior Vice President of Scientific Affairs

Date: 1/4/06

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
OsteoPrime®* Plus	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

Title: Senior Vice President of Scientific Affairs

Date: \_\_\_\_\_

1/4/06

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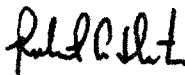
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
OsteoPrime®* Plus	In a study of women taking supplemental magnesium for two years, significant support for healthy bone density was demonstrated.*	Magnesium (as magnesium 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  
Title: Senior Vice President of Scientific Affairs

Date: 1/4/06

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PRODUCT NAME	STATEMENTS	INGREDIENT(S) TO WHICH THE CLAIM REFERS
OsteoPrime®* Plus	Studies have shown that the zinc content in bones declines as people age. There is also a significant correlation between zinc intake and bone health in both men and women.*	Zinc (as zinc picolinate)

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By: Robert C. Doster

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/4/06

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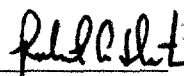
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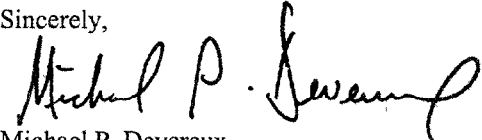
<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
OsteoPrime®* Plus	Through healthy support of collagen, copper may support bone mineral density over time.* In clinical research, women taking supplemental copper experienced beneficial effects on bone density.*	Copper (as copper gluconate)

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Date: 1/4/06

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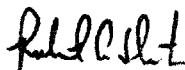
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OsteoPrime®* Plus	Several trace elements, including manganese are essential in bone metabolism as cofactors for specific enzymes.*	Manganese (as manganese aspartate)

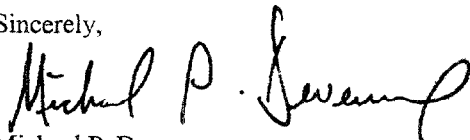
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OsteoPrime®* Plus	In a 16-week randomized, double-blind, placebo-controlled crossover trial, manganese provided nutritional support for the bones in the low back and the knee joint.*	Manganese (as manganese aspartate)

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Title: Senior Vice President of Scientific Affairs

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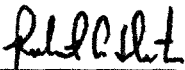
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OsteoPrime®* Plus	Boron is an essential nutrient for healthy bones and joints.*	Boron (as boron Krebs cycle chelates)

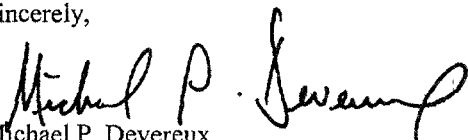
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OsteoPrime®* Plus	Clinical research showed boron supplementation supported healthy bone mineral density.	Boron (as boron Krebs cycle chelates)

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Robert C. Doster  
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P: 920.469.9099 ◊ F: 920.469.4418 (Phyto)

January 5, 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

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®* Plus	It is thought that this beneficial support is related to interactions between boron and calcium, magnesium and vitamin D, which is supported by 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  
Robert C. Doster  
Title: Senior Vice President of Scientific Affairs

Date: 1/5/06

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 Operations Officer



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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
OsteoPrime®* Plus	Recent studies of strontium demonstrated it is a bone supportive mineral.* A review of strontium research shows the mineral supports healthy bone remodeling, healthy mineralization of bone tissue, and supports healthy distribution of bone mineralization.* <sup>23</sup> Strontium is thought to both support both healthy osteoclasts and healthy osteoblasts in bone.*	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: 1/5/06

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OsteoPrime®* Plus	Silicon has recently been recognized as an key nutrient that is important in small amounts for bone health.* A recent study of over 2800 individuals found that higher dietary silicon intake in men and women supports skeletal health, especially the health of cortical bone (dense compact bone in adults).*	Silicon (as magnesium trisilicate)

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

Date: 1/5/06

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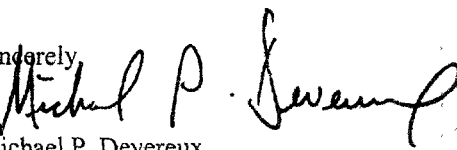
<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
OsteoPrime®* Plus	Phosphorus provides nutritional support of healthy bones.*	Phosphorus (as tricalcium phosphate)

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: 1/5/06

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OsteoPrime®* Plus	Recent research has shown phosphorus and calcium work together to support healthy mineralization of bones.* A research review of over 600 subjects demonstrated the importance of healthy calcium/phosphorus ratios in bone health support.* Phosphorus supplementation (when bound to calcium) supports healthy bone formation and soft tissue health.*	Phosphorus (as 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  
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/5/06

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
OsteoPrime®* Plus	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), Vitamin B12 (as cyanocobalamin), Folic Acid

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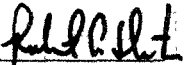
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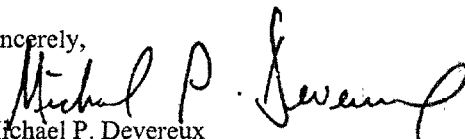
<b>PRODUCT NAME</b>	<b>STATEMENTS</b>	<b>INGREDIENT(S) TO WHICH THE CLAIM REFERS</b>
OsteoPrime®* Plus	Study results show folic acid supports healthy homocysteine levels.*	Folic Acid

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: 1/5/06

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

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: 1/5/06

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Michael P. Devereux  
Chief Operations Officer



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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
OsteoPrime®* Plus	Combined with folate, reduced homocysteine levels and supported bone health in both men and women.*	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

Title: Senior Vice President of Scientific Affairs

Date: 1/5/06

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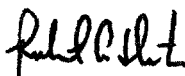
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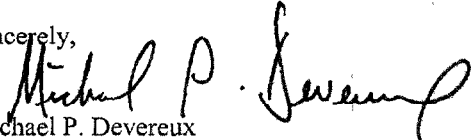
<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
OsteoPrime®* Plus	Vitamin C supports the healthy formation of procollagen (a precursor to collagen), supports collagen synthesis, and stimulates healthy bone formation.*	Vitamin C (ascorbic acid)

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OsteoPrime®* Plus	Clinical research demonstrates that vitamin C supplement use supports healthy bone mineral density.* A study of 770 women who took at least 500mg of calcium and vitamin C had support of healthy bone mineral density in the lumbar spine (lower back).*	Vitamin C (ascorbic acid)

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
OsteoPrime®* Plus	Research has demonstrated supplementation with vitamin D3 and calcium may be especially important during the winter months.*	Vitamin D3 (as cholecalciferol)

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: 1/5/06

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 Operations Officer





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P: 920.469.9099 • F: 920.469.4418 (Phyto)

January 5, 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

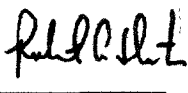
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
OsteoPrime®* Plus	Vitamin K influences osteocalcin, a protein in bone, to attract calcium and support bone mineralization.*	Vitamin K (as phytonadione)

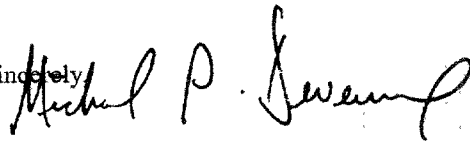
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
OsteoPrime®* Plus	A 3-year, double-blind, placebo-controlled intervention study of 155 women found that vitamin K1 may substantially support bone density.*	Vitamin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

Title: Senior Vice President of Scientific Affairs

Date: \_\_\_\_\_

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
OsteoPrime®* Plus	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: 1/6/06

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

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: \_\_\_\_\_

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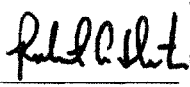
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
OsteoPrime®* Plus	Betaine is linked to healthy homocysteine levels, a variable in healthy bone metabolism.*	Betaine HCl

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: 

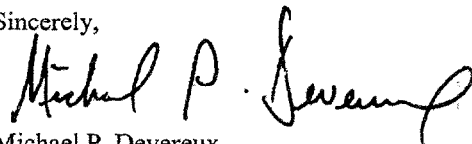
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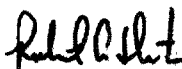
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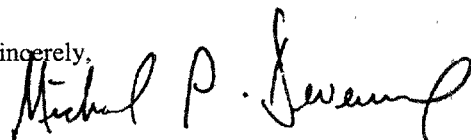
<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
OsteoPrime®* Plus	Members of the B vitamin group, pantothenic acid, vitamin B1, and niacinamide support healthy homocysteine levels, a factor associated with healthy bone mineral density.*	Thiamin (as thiamin HCl) (vitamin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

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: 1/6/06

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

Sincerely,  


Michael P. Devereux  
Chief Operations Officer



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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
OsteoPrime®* Plus	Supports healthy bone cell functioning and has antioxidant activity.*	Riboflavin (vitamin B2)

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By: \_\_\_\_\_

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: \_\_\_\_\_

1/6/06

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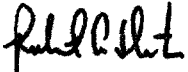
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
OsteoPrime®* Plus	Helps support and maintain physiologic function in bone.*	Selenium (as sodium selenite)

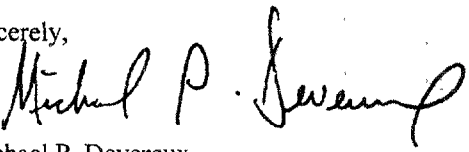
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OsteoPrime®* Plus	The exclusive formulation is ideal for women in perimenopause and menopause, phases critical to the lifelong health of bones.*	Vitamin C (ascorbic acid), Vitamin D (as cholecalciferol), Vitamin K (as phytonadione), Thiamin (as thiamin 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)

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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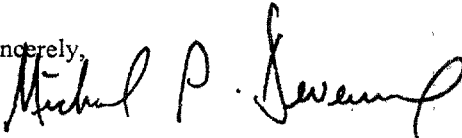
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
OsteoPrime®* Plus	Helps keep bones strong and resilient.*	Vitamin C (ascorbic acid), Vitamin D (as cholecalciferol), Vitamin K (as phytonadione), Thiamin (as thiamin 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)

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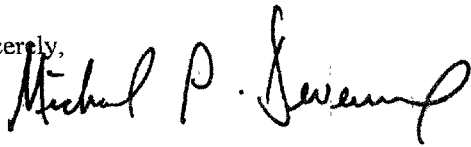
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