



**ENZYMATIC THERAPY**  
INCORPORATED

*What **Better** feels like.*

**INTEGRATIVE THERAPEUTICS INC.\***  
NF Formulas + PhytoPharmica  
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9755 SW Commerce Circle, Suite B2

Wilsonville, OR 97070

P: 503.582.8386 + F: 503.582.0467

**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)

October 4, 2004

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.

Earth's Promise™	As part of a supplement regimen, the ingredients in Earth's Promise can make an important contribution to the recommended intake of fruit and vegetables, as well as supporting overall health.*	Fiber Blend: inulin from Chicory root, guar gum seed extract Greens Blend: barley grass, alfalfa sprouts, broccoli sprouts, radish sprouts, oat grass, wheat grass, alfalfa juice concentrate, Fruit Blend: mango fruit, kiwi fruit, strawberry fruit, Vegetable Blend: broccoli flower, cabbage leaf, carrot root, collard greens, tomato fruit, mustard greens, kale leaf, spinach leaf, Green Tea Leaf Extract, Seaweed Blend: dulse, blue-green algae, kelp leaf and stem, Stevia Leaf Extract
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14751

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.

*Robert C. Doster*

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

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 10/4/04

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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Earth's Promise™	Natural source of potent and clinical studied antioxidants – lycopene, beta-carotene, lutein and zeaxanthin.*	Fiber Blend: inulin from Chicory root, guar gum seed extract Greens Blend: barley grass, alfalfa sprouts, broccoli sprouts, radish sprouts, oat grass, wheat grass, alfalfa juice concentrate, Fruit Blend: mango fruit, kiwi fruit, strawberry fruit, Vegetable Blend: broccoli flower, cabbage leaf, carrot root, collard greens, tomato fruit, mustard greens, kale leaf, spinach leaf, Green Tea Leaf Extract, Seaweed Blend: dulse, blue-green algae, kelp leaf and stem, Stevia Leaf Extract
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Earth's Promise™	Natural detoxification support*	Fiber Blend: inulin from Chicory root, guar gum seed extract Greens Blend: barley grass, alfalfa sprouts, broccoli sprouts, radish sprouts, oat grass, wheat grass, alfalfa juice concentrate, Fruit Blend: mango fruit, kiwi fruit, strawberry fruit, Vegetable Blend: broccoli flower, cabbage leaf, carrot root, collard greens, tomato fruit, mustard greens, kale leaf, spinach leaf, Green Tea Leaf Extract, Seaweed Blend: dulse, blue-green algae, kelp leaf and stem, Stevia Leaf Extract
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Earth's Promise™	Alkaline-producing ingredients for acid/base balance*	Fiber Blend: inulin from Chicory root, guar gum seed extract Greens Blend: barley grass, alfalfa sprouts, broccoli sprouts, radish sprouts, oat grass, wheat grass, alfalfa juice concentrate, Fruit Blend: mango fruit, kiwi fruit, strawberry fruit, Vegetable Blend: broccoli flower, cabbage leaf, carrot root, collard greens, tomato fruit, mustard greens, kale leaf, spinach leaf, Green Tea Leaf Extract, Seaweed Blend: dulse, blue-green algae, kelp leaf and stem, Stevia Leaf Extract
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Date: 10/4/04

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October 6, 2004

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Earth's Promise™	Lycopene (tomatoes) provides support for prostate gland health, and has been shown to support cardiovascular health by preventing the oxidation of LDL cholesterol.*	Tomato Fruit
------------------	--	--------------

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By:   
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 10/6/04

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Sincerely,



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Chief Financial Officer



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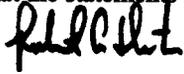
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<p>Earth's Promise™</p>	<p>Lutein and zeaxanthin (spinach and other dark green leafy vegetables) are deposited in high concentrations in the macular region of the retina. It is believed that these antioxidants play an important supportive role in eye health by supporting macular pigment development.* Macular pigment absorbs ultraviolet radiation from the sun, among other functions.*</p>	<p>Fiber Blend: inulin from Chicory root, guar gum seed extract Greens Blend: barley grass, alfalfa sprouts, broccoli sprouts, radish sprouts, oat grass, wheat grass, alfalfa juice concentrate, Fruit Blend: mango fruit, kiwi fruit, strawberry fruit, Vegetable Blend: broccoli flower, cabbage leaf, carrot root, collard greens, tomato fruit, mustard greens, kale leaf, spinach leaf, Green Tea Leaf Extract, Seaweed Blend: dulse, blue-green algae, kelp leaf and stem, Stevia Leaf Extract</p>
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Earth's Promise™	In laboratory tests, spinach extract shows greater free radical quenching activity than green tea, N-acetylcysteine (NAC), or vitamin E.*	Spinach Leaf
------------------	---	--------------

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By: *Robert C. Doster*  
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 10/6/04

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Sincerely,

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Michael P. Devereux  
Chief Financial Officer



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Earth's Promise™	Green tea has been shown in research studies to both increase the activity of the glutathione peroxidase and superoxide dismutase enzyme systems, as well as protect lipids and proteins from oxidation.*	Green Tea Leaf Extract
------------------	---	------------------------

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

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 10/7/04

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Earth's Promise™	Carrot contains high levels of the antioxidant beta-carotene, and has been found in research studies to increase plasma antioxidant levels.*	Carrot Root
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Earth's Promise™	The inulin and fructooligosaccharides in Earth's Promise also support calcium absorption, a crucial factor in maintaining healthy bone density.* And, kale also supports the absorption of magnesium, another crucial mineral for healthy bones.*	Inulin from chicory root, Guar Gum Seed Extract
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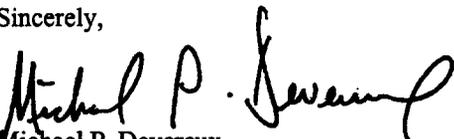
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Earth's Promise™	Chlorophyll, responsible for sustaining the life of plants through photosynthesis, is also rich in enzymes and magnesium. It is found in barley, wheat and oat grasses, as well as alfalfa sprouts and kelp. Chlorophyll has been extensively researched for its support of the immune system.*	Barley Grass, Alfalfa Sprouts, Oat, Wheat Grass, Kelp Leaf and Stem
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Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 10/7/04

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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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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.

Earth's Promise™	Certain carotenoids such as beta-carotene and lycopene are thought to regulate the immune response.*	Tomato Fruit, Carrot Root
------------------	--	---------------------------

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: 10/8/04

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)

October 8, 2004

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

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Earth's Promise™	Carrots have high levels of beta-carotene, which has been shown to enhance natural killer cell activity.* And tomatoes have high concentrations of lycopene, which has shown to support the immune system, prostate health, and macular health.*	Tomato Fruit, Carrot Root
------------------	--	---------------------------

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

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Earth's Promise™	Kelp, alfalfa sprouts and wheat, barley and oat grass provide magnesium. Magnesium is associated with energy production at a cellular level, and has been studied for its role supporting the immune system.*	Kelp Leaf and Stem, Alfalfa Sprouts, Wheat Grass, Barley Grass, Oat Grass
------------------	---	---

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Robert C. Doster

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Earth's Promise™	Blue-green algae, a water-borne plant, naturally has vitamin A, essential amino acids and zinc. Zinc has been studied for its association with natural killer cell activity.*	Blue-green algae
------------------	---	------------------

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By: \_\_\_\_\_  
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 10/9/04

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Earth's Promise™	Both broccoli and broccoli sprouts are a source of sulforaphanes. Sulforaphanes are associated with immune health support.*	Broccoli Flower, Broccoli Sprouts
------------------	---	-----------------------------------

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Robert C. Doster

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Earth's Promise™	The polyphenols in green tea, specifically EGCG, have been the subject of many scientific studies showing their antioxidant and immune support activity. EGCG has been shown to support colon, breast and prostate health.*	Green Teal Leaf Extract
------------------	---	-------------------------

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: 10/9/04

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Earth's Promise™	Green tea has been shown to support the immune system and T-cell formation.*	Green Teal Leaf Extract
------------------	--	-------------------------

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Robert C. Doster

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October 10, 2004

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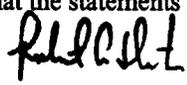
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Earth's Promise™	Inulin fiber acts as a prebiotic in the digestive tract, promoting bile excretion and helping foster a healthy climate for probiotic beneficial bacteria. They also aid in the absorption of minerals such as calcium, magnesium and zinc.*	Inulin from chicory root
------------------	---	--------------------------

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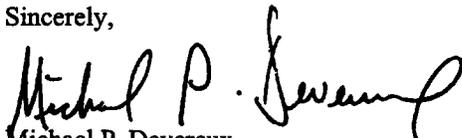
By:   
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 10/10/04

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October 11, 2004

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

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Earth's Promise™	Soluble and insoluble fiber from inulin also supports healthy digestion and colon function, by safely absorbing and eliminating toxins.*	Inulin from chicory root, Guar Gum Seed Extract
------------------	--	---

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

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 10/11/04

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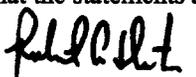
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Earth's Promise™	Fiber promotes bowel movements and modulates gastric and intestinal physiology.*	Inulin from chicory root, Guar Gum Seed Extract
------------------	--	---

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Title: Senior Vice President of Scientific Affairs

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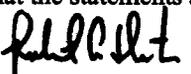
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Earth's Promise™	Fiber has been demonstrated in numerous clinical studies to provide support of gastrointestinal, cardiovascular, immune, and endocrine function health.*	Inulin from chicory root, Guar Gum Seed Extract
------------------	--	---

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Earth's Promise™	Current research also indicates that wheat grass, one of the three grasses in Earth's Promise, may support gastric and colonic health.*	Wheat Grass
------------------	---	-------------

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October 12, 2004

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Earth's Promise™	Many of the ingredients in Earth's Promise are associated with the retention of healthy cholesterol levels that are already within normal range.* Inulin and oligofructose, guar gum, barley, carrot, broccoli, cabbage, and green tea have been clinically studied for this benefit.*	Inulin from chicory root, Guar Gum Seed Extract, Barley Grass, Carrot Root, Broccoli Sprouts, Broccoli Flower, Cabbage Leaf, Green Tea Leaf Extract
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By: \_\_\_\_\_  
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 10/12/04

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



**ENZYMATIC THERAPY**  
INCORPORATED

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**INTEGRATIVE THERAPEUTICS INC.™**  
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P: 920.469.1313 ♦ F: 888.570.6460 (Enzymatic)  
P: 920.469.9099 ♦ F: 920.469.4418 (Phyto)

October 12, 2004

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

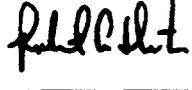
RE: Label Claims/Disclaimers

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.

Earth's Promise™	In a scientific study, adding guar gum to a healthy diet supported the retention of healthy cholesterol levels already within normal limits.*	Guar Gum Seed Extract
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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: 10/12/04

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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Earth's Promise™	The broccoli and cabbage found in Earth's Promise may also support the retention of healthy cholesterol levels already within normal limits.* A randomized, double-blind clinical study found that a broccoli and cabbage combination supported healthy HDL and LDL levels in just 9 weeks.*	Broccoli Sprouts, Broccoli Flower, Cabbage Leaf
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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: 10/12/04

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