



January 10, 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 PhytoPharmica, (a Division of Integrative Therapeutics, 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. PhytoPharmica 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.

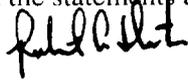
<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
End Fatigue™ Daily Energy Enfusion™*	Mitochondrial energy production follows precise metabolic pathways and requires specific molecules, cofactors, and enzymes. The resulting product is the special carrier for cellular energy, adenosine, triphosphate (ATP). The energy release from ATP powers all physiologic functions.*	Vitamin A (as 50% beta carotene and as retinyl acetate), Vitamin C (ascorbic acid), Vitamin D (as cholecalciferol), Vitamin E (as d-alpha tocopheryl acetate), Biotin, Iodine (as potassium iodide), Magnesium (as magnesium glycinate), Zinc (as zinc oxide), Selenium (as L-selenomethionine), Copper (as copper gluconate), Manganese (as manganese citrate), Chromium (as chromium picolinate), Molybdenum (as sodium molybdate), Sodium, Potassium (as potassium citrate), Whey Protein, Malic Acid, Inositol, Inulin (from chicory root), Hesperidin 50% (from citrus fruit), Taurine, Glycine, L-Tyrosine, N-Acetylcysteine (NAC), L-Serine, Boron (as sodium borate)

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LET 13629

825 CHALLENGER DRIVE
 GREEN BAY, WI 54311-8328
 920-469-9099
 TOLL FREE 800-553-2370
 FAX 920-469-4418
 FAX TOLL FREE 888-311-5657
 WWW.PHYTOPHARMICA.COM

I certify that the information contained in this notice is complete and accurate and that PhytoPharmica has substantiation that the statements are truthful and not misleading.



By: _____
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/10/04

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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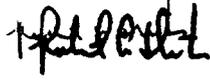
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
End Fatigue™ Daily Energy Enfusion™*	Any dysfunction along the complex and multi-stepped process of cellular energy metabolism may result in insufficient ATP production. Consequently, physiologic functions may be significantly affected. Muscle contractions may be weak, ions and molecules may not be transported effectively, and enzymatic reactions may be insufficient. The result is often fatigue, that state following a period of mental or bodily activity, characterized by a lessened capacity for work and reduced efficiency of accomplishment, usually accompanied by a feeling of occasional weariness, sleepiness, or irritability.* Healthy human energy metabolism is crucial to sufficient ATP production.*	Vitamin A (as 50% beta carotene and as retinyl acetate), Vitamin C (ascorbic acid), Vitamin D (as cholecalciferol), Vitamin E (as d-alpha tocopheryl acetate), Biotin, Iodine (as potassium iodide), Magnesium (as magnesium glycinate), Zinc (as zinc oxide), Selenium (as L-selenomethionine), Copper (as copper gluconate), Manganese (as manganese citrate), Chromium (as chromium picolinate), Molybdenum (as sodium molybdate), Sodium, Potassium (as potassium citrate), Whey Protein, Malic Acid, Inositol, Inulin (from chicory root), Hesperidin 50% (from citrus fruit), Taurine, Glycine, L-Tyrosine, N-Acetylcysteine (NAC), L-Serine, Boron (as sodium borate)

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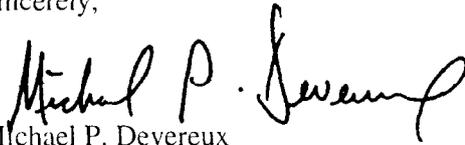
Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/10/04

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Michael P. Devereux
Chief Financial Officer

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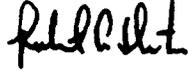
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
End Fatigue™ Daily Energy Enfusion™*	Adequate nutrition is, in turn, crucial to healthy human energy metabolism.*	Vitamin A (as 50% beta carotene and as retinyl acetate), Vitamin C (ascorbic acid), Vitamin D (as cholecalciferol), Vitamin E (as d-alpha tocopheryl acetate), Biotin, Iodine (as potassium iodide), Magnesium (as magnesium glycinate), Zinc (as zinc oxide), Selenium (as L-selenomethionine), Copper (as copper gluconate), Manganese (as manganese citrate), Chromium (as chromium picolinate), Molybdenum (as sodium molybdate), Sodium, Potassium (as potassium citrate), Whey Protein, Malic Acid, Inositol, Inulin (from chicory root), Hesperidin 50% (from citrus fruit), Taurine, Glycine, L-Tyrosine, N-Acetylcysteine (NAC), L-Serine, Boron (as sodium borate)

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
End Fatigue™ Daily Energy Enfusion™*	Vitamin A (as 50% beta carotene and as retinyl acetate): Helps support healthy skin and mucous membrane integrity.*	Vitamin A (as 50% beta carotene and as retinyl acetate)

I certify that the information contained in this notice is complete and accurate and that PhytoPharmica has substantiation that the statements are truthful and not misleading.

By: _____

Robert C. Doster

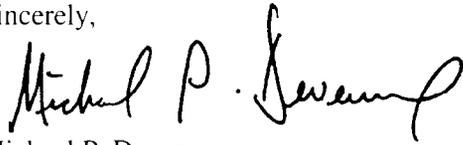
Title: Senior Vice President of Scientific Affairs

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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



PhytoPharmica[®]

NATURAL MEDICINES™

January 11, 2004

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
End Fatigue™ Daily Energy Enfusion™*	Vitamin A (as 50% beta carotene and as retinyl acetate): Supports healthy immune system responses*	Vitamin A (as 50% beta carotene and as retinyl acetate)

I certify that the information contained in this notice is complete and accurate and that PhytoPharmica has substantiation that the statements are truthful and not misleading.

By: _____

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 1-21-04

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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>
End Fatigue™ Daily Energy Enfusion™*	Vitamin A (as 50% beta carotene and as retinyl acetate): Supports healthy bone growth and healthy reproductive processes*	Vitamin A (as 50% beta carotene and as retinyl acetate)

I certify that the information contained in this notice is complete and accurate and that PhytoPharmica has substantiation that the statements are truthful and not misleading.

By: _____

Robert C. Doster

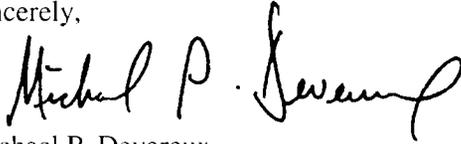
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Michael P. Devereux
Chief Financial Officer



January 12, 2004

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
End Fatigue™ Daily Energy Enfusion™*	Vitamin C (ascorbic acid): Antioxidant, free radical fighter*	Vitamin C (ascorbic acid)

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Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 1-21-04

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
End Fatigue™ Daily Energy Enfusion™*	Biotin: Supports healthy hair and scalp tissue*	Biotin

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Robert C. Doster

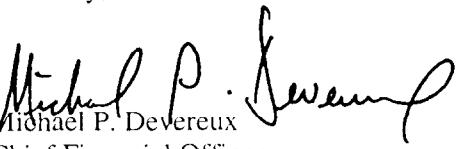
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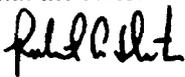
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
End Fatigue™ Daily Energy Enfusion™*	Biotin: Helps healthy skin and muscles*	Biotin

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Robert C. Doster

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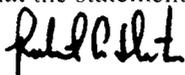
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
End Fatigue™ Daily Energy Enfusion™*	Magnesium (as magnesium glycinate): Supports enzyme activity involved in energy production*	Magnesium (as magnesium glycinate)

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
End Fatigue™ Daily Energy Enfusion™*	Magnesium (as magnesium glycinate): Supports healthy nerve and muscle function*	Magnesium (as magnesium glycinate)

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Robert C. Doster

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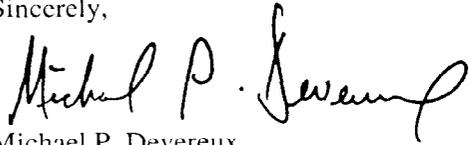
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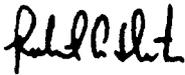
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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
End Fatigue™ Daily Energy Enfusion™*	Magnesium (as magnesium glycinate): Supports healthy immune system functions*	Magnesium (as magnesium glycinate)

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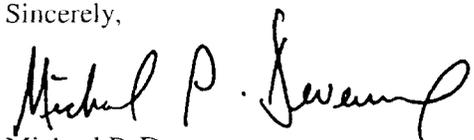
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RE: Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by PhytoPharmica, (a Division of Integrative Therapeutics, 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. PhytoPharmica 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>
End Fatigue™ Daily Energy Entusion™*	Chromium (as chromium picolinate): Supports fat metabolism by insulin*	Chromium (as chromium picolinate)

I certify that the information contained in this notice is complete and accurate and that PhytoPharmica has substantiation that the statements are truthful and not misleading.

By: _____

Robert C. Doster

Title: Senior Vice President of Scientific Affairs

Date: 1-21-04

825 CHALLENGER DRIVE
GREEN BAY, WI 54311-8328
920-469-9099
TOLL FREE 800-553-2370
FAX 920-469-4418
FAX TOLL FREE 888-311-5657
WWW.PHYTOPHARMICA.COM

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, prominent initial "M".

Michael P. Devereux
Chief Financial Officer



January 14, 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

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
End Fatigue™ Daily Energy Enfusion™*	Chromium (as chromium picolinate): Helps turn protein into muscle*	Chromium (as chromium picolinate)

I certify that the information contained in this notice is complete and accurate and that PhytoPharmica 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: 1-21-04

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<u>PRODUCT NAME</u>	<u>STATEMENTS</u>	<u>INGREDIENT(S) TO WHICH THE CLAIM REFERS</u>
End Fatigue™ Daily Energy Enfusion™*	Chromium (as chromium picolinate): Supports healthy glucose conversion into energy*	Chromium

I certify that the information contained in this notice is complete and accurate and that PhytoPharmica has substantiation that the statements are truthful and not misleading.

By: 

Robert C. Doster

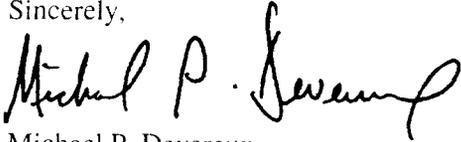
Title: Senior Vice President of Scientific Affairs

Date: 1/14/04

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