



NF Formulas



PhytoPharmica



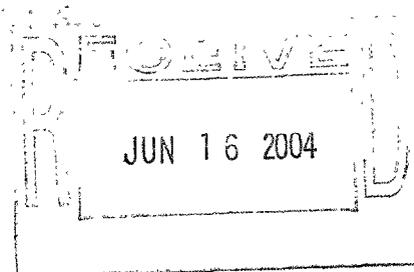
Tyler Encapsulations



Vitaline Formulas

June 11, 2004

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740



**Notification of structure-function claims**

Dear Sir:

This letter is to notify you that the following product manufactured, packed, and/or distributed by Integrative Therapeutics Inc. (9755 SW Commerce Circle, Suite B2, Wilsonville, OR 97070) has a label that contains a statement provided for by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Integrative Therapeutics Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and complies 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	Statement	Ingredient(s) to which claim refers		
Mega MultiVitamin Drink Mix	Supports healthy metabolism of calcium and phosphorus; supports the absorption of vitamin A; supports bone mineralization. †	Vitamin A (50% as beta carotene and as retinyl acetate) Vitamin C (as ascorbic acid) <b>Vitamin D (as cholecalciferol)</b> Vitamin E (as d-alpha tocopheryl acetate) Thiamin (as thiamine HCl) (Vitamin B1) Riboflavin (vitamin B2) Niacin (as niacinamide) Vitamin B6 (as pyridoxine HCl) Folic Acid Vitamin B12 (as cyanocobalamin) Biotin Pantothenic Acid (as calcium D-pantothenate) Calcium (as calcium lactate) Iodine (as potassium iodide) Magnesium (as magnesium glycinate) Zinc (as zinc sulfate) Selenium (as L-selenomethionine) Copper (as copper gluconate) Manganese (as manganese citrate) Chromium (as chromium picolinate) Molybdenum (as sodium molybdate) Sodium Potassium (from whey protein, guar gum, potassium citrate and potassium iodide)	Malic Acid Betaine Inositol Inulin (from chicory root) Hesperidin 50% (from citrus fruits) Taurine Glycine L-Tyrosine N-Acetylcysteine (NAC) L-Serine Stevia (Stevia rebaudiana) Leaf Extract Sour Cherry (Prunus cerasus) Fruit Extract Cranberry (Vaccinium macrocarpon) Fruit Extract Bilberry (Vaccinium myrtillus) Fruit Extract Boron (as sodium borate) Lutein (from Calendula officinalis) Zeaxanthin (from Calendula officinalis) Whey Protein Concentrate	

I certify that the information contained in this notice is complete and accurate, and that Integrative Therapeutics Inc. has substantiation that the statement is truthful and not misleading.

Mario Roxas, N.D.  
Director of Scientific and Technical Affairs

Date 6/11/04

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LET 14/150



NF Formulas



PhytoPharmica



Tyler Encapsulations



Vitaline Formulas

June 10, 2004

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Product Name	Statement	Ingredient(s) to which claim refers	
Mega MultiVitamin Drink Mix	Beta-carotene is an antioxidant and free radical fighter. †	<b>Vitamin A (50% as beta carotene and as retinyl acetate)</b> Vitamin C (as ascorbic acid) Vitamin D (as cholecalciferol) Vitamin E (as d-alpha tocopheryl acetate) Thiamin (as thiamine HCl) (Vitamin B1) Riboflavin (vitamin B2) Niacin (as niacinamide) Vitamin B6 (as pyridoxine HCl) Folic Acid Vitamin B12 (as cyanocobalamin) Biotin Pantothenic Acid (as calcium D-pantothenate) Calcium (as calcium lactate) Iodine (as potassium iodide) Magnesium (as magnesium glycinate) Zinc (as zinc sulfate) Selenium (as L-selenomethionine) Copper (as copper gluconate) Manganese (as manganese citrate) Chromium (as chromium picolinate) Molybdenum (as sodium molybdate) Sodium Potassium (from whey protein, guar gum, potassium citrate and potassium iodide)	Malic Acid Betaine Inositol Inulin (from chicory root) Hesperidin 50% (from citrus fruits) Taurine Glycine L-Tyrosine N-Acetylcysteine (NAC) L-Serine Stevia (Stevia rebaudiana) Leaf Extract Sour Cherry (Prunus cerasus) Fruit Extract Cranberry (Vaccinium macrocarpon) Fruit Extract Bilberry (Vaccinium myrtillus) Fruit Extract Boron (as sodium borate) Lutein (from Calendula officinalis) Zeaxanthin (from Calendula officinalis) Whey Protein Concentrate

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 Mario Roxas, N.D.  
 Director of Scientific and Technical Affairs

6/20/04  
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 Date



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Vitaline Formulas

June 13, 2004

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Product Name	Statement	Ingredient(s) to which claim refers
Mega MultiVitamin Drink Mix	In lipid metabolism, supports healthy cholesterol production and assists in triglyceride breakdown to retain healthy cholesterol levels that are already within normal limits. †	Vitamin A (50% as beta carotene and as retinyl acetate) Vitamin C (as ascorbic acid) Vitamin D (as cholecalciferol) Vitamin E (as d-alpha tocopheryl acetate) Thiamin (as thiamine HCl) (Vitamin B1) Riboflavin (vitamin B2) <b>Niacin (as niacinamide)</b> Vitamin B6 (as pyridoxine HCl) Folic Acid Vitamin B12 (as cyanocobalamin) Biotin Pantothenic Acid (as calcium D-pantothenate) Calcium (as calcium lactate) Iodine (as potassium iodide) Magnesium (as magnesium glycinate) Zinc (as zinc sulfate) Selenium (as L-selenomethionine) Copper (as copper gluconate) Manganese (as manganese citrate) Chromium (as chromium picolinate) Molybdenum (as sodium molybdate) Sodium Potassium (from whey protein, guar gum, potassium citrate and potassium iodide)
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Director of Scientific and Technical Affairs

Date 6/13/04





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June 13, 2004

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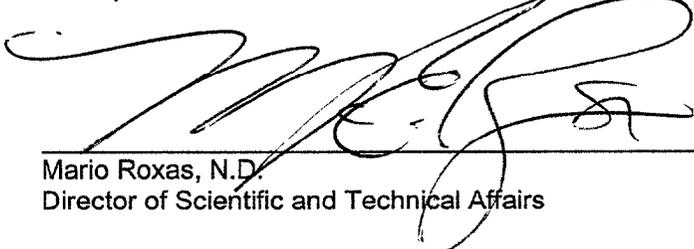
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Product Name	Statement	Ingredient(s) to which claim refers
Mega MultiVitamin Drink Mix	In clinical studies, riboflavin has shown significant benefit for heart health, and functions synergistically with other heart healthy nutrients. †	Vitamin A (50% as beta carotene and as retinyl acetate) Vitamin C (as ascorbic acid) Vitamin D (as cholecalciferol) Vitamin E (as d-alpha tocopheryl acetate) Thiamin (as thiamine HCl) (Vitamin B1) <b>Riboflavin (vitamin B2)</b> Niacin (as niacinamide) Vitamin B6 (as pyridoxine HCl) Folic Acid Vitamin B12 (as cyanocobalamin) Biotin Pantothenic Acid (as calcium D-pantothenate) Calcium (as calcium lactate) Iodine (as potassium iodide) Magnesium (as magnesium glycinate) Zinc (as zinc sulfate) Selenium (as L-selenomethionine) Copper (as copper gluconate) Manganese (as manganese citrate) Chromium (as chromium picolinate) Molybdenum (as sodium molybdate) Sodium Potassium (from whey protein, guar gum, potassium citrate and potassium iodide)
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Mario Roxas, N.D.  
Director of Scientific and Technical Affairs

Date

6/13/04



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Tyler Encapsulations



Vitaline Formulas

June 10, 2004

Office of Nutritional Products, Labeling &  
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Product Name	Statement	Ingredient(s) to which claim refers
Mega MultiVitamin Drink Mix	Antioxidant, free radical fighter. †	Vitamin A (50% as beta carotene and as retinyl acetate) <b>Vitamin C (as ascorbic acid)</b> Vitamin D (as cholecalciferol) Vitamin E (as d-alpha tocopheryl acetate) Thiamin (as thiamine HCl) (Vitamin B1) Riboflavin (vitamin B2) Niacin (as niacinamide) Vitamin B6 (as pyridoxine HCl) Folic Acid Vitamin B12 (as cyanocobalamin) Biotin Pantothenic Acid (as calcium D-pantothenate) Calcium (as calcium lactate) Iodine (as potassium iodide) Magnesium (as magnesium glycinate) Zinc (as zinc sulfate) Selenium (as L-selenomethionine) Copper (as copper gluconate) Manganese (as manganese citrate) Chromium (as chromium picolinate) Molybdenum (as sodium molybdate) Sodium Potassium (from whey protein, guar gum, potassium citrate and potassium iodide)
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 Mario Roxas, N.D. Date 6/10/04  
 Director of Scientific and Technical Affairs



NF Formulas



PhytoPharmica



Tyler Encapsulations



Vitaline Formulas

June 10, 2004

Office of Nutritional Products, Labeling &  
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Product Name	Statement	Ingredient(s) to which claim refers
Mega MultiVitamin Drink Mix	Necessary for the proper functioning of the immune system. †	Vitamin A (50% as beta carotene and as retinyl acetate) <b>Vitamin C (as ascorbic acid)</b> Vitamin D (as cholecalciferol) Vitamin E (as d-alpha tocopheryl acetate) Thiamin (as thiamine HCl) (Vitamin B1) Riboflavin (vitamin B2) Niacin (as niacinamide) Vitamin B6 (as pyridoxine HCl) Folic Acid Vitamin B12 (as cyanocobalamin) Biotin Pantothenic Acid (as calcium D-pantothenate) Calcium (as calcium lactate) Iodine (as potassium iodide) Magnesium (as magnesium glycinate) Zinc (as zinc sulfate) Selenium (as L-selenomethionine) Copper (as copper gluconate) Manganese (as manganese citrate) Chromium (as chromium picolinate) Molybdenum (as sodium molybdate) Sodium Potassium (from whey protein, guar gum, potassium citrate and potassium iodide)
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 \_\_\_\_\_  
 Mario Roxas, N.D. Date 2/10/04  
 Director of Scientific and Technical Affairs



NF Formulas



PhytoPharmica



Tyler Encapsulations



Vitaline Formulas

June 9, 2004

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

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Product Name	Statement	Ingredient(s) to which claim refers
Mega MultiVitamin Drink Mix	Help support healthy skin and mucous membrane integrity; supports healthy immune system responses; supports healthy bone growth and healthy reproductive processes. †	<b>Vitamin A (50% as beta carotene and as retinyl acetate)</b> Vitamin C (as ascorbic acid) Vitamin D (as cholecalciferol) Vitamin E (as d-alpha tocopheryl acetate) Thiamin (as thiamine HCl) (Vitamin B1) Riboflavin (vitamin B2) Niacin (as niacinamide) Vitamin B6 (as pyridoxine HCl) Folic Acid Vitamin B12 (as cyanocobalamin) Biotin Pantothenic Acid (as calcium D-pantothenate) Calcium (as calcium lactate) Iodine (as potassium iodide) Magnesium (as magnesium glycinate) Zinc (as zinc sulfate) Selenium (as L-selenomethionine) Copper (as copper gluconate) Manganese (as manganese citrate) Chromium (as chromium picolinate) Molybdenum (as sodium molybdate) Sodium Potassium (from whey protein, guar gum, potassium citrate and potassium iodide)
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Mario Roxas, N.D.  
Director of Scientific and Technical Affairs

Date

6/9/04



NF Formulas



PhytoPharmica



Tyler Encapsulations



Vitaline Formulas

June 12, 2004

Office of Nutritional Products, Labeling &  
Dietary Supplements, HFS 810  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

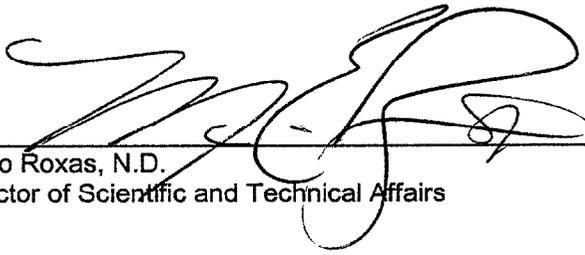
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Product Name	Statement	Ingredient(s) to which claim refers
Mega MultiVitamin Drink Mix	Helps oxygen circulation; supports healthy nerve transmissions; supports healthy leg nerves and muscles; helps boost energy levels. †	Vitamin A (50% as beta carotene and as retinyl acetate) Vitamin C (as ascorbic acid) Vitamin D (as cholecalciferol) <b>Vitamin E (as d-alpha tocopheryl acetate)</b> Thiamin (as thiamine HCl) (Vitamin B1) Riboflavin (vitamin B2) Niacin (as niacinamide) Vitamin B6 (as pyridoxine HCl) Folic Acid Vitamin B12 (as cyanocobalamin) Biotin Pantothenic Acid (as calcium D-pantothenate) Calcium (as calcium lactate) Iodine (as potassium iodide) Magnesium (as magnesium glycinate) Zinc (as zinc sulfate) Selenium (as L-selenomethionine) Copper (as copper gluconate) Manganese (as manganese citrate) Chromium (as chromium picolinate) Molybdenum (as sodium molybdate) Sodium Potassium (from whey protein, guar gum, potassium citrate and potassium iodide)
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6/12/04

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Mario Roxas, N.D. Date  
 Director of Scientific and Technical Affairs



NF Formulas



PhytoPharmica



Tyler Encapsulations



Vitaline Formulas

June 14, 2004

Office of Nutritional Products, Labeling &  
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Product Name	Statement	Ingredient(s) to which claim refers
Mega MultiVitamin Drink Mix	In clinical studies, niacin, when combined with other heart healthy nutrients, supported the muscle strength of the heart. †	Vitamin A (50% as beta carotene and as retinyl acetate) Vitamin C (as ascorbic acid) Vitamin D (as cholecalciferol) Vitamin E (as d-alpha tocopheryl acetate) Thiamin (as thiamine HCl) (Vitamin B1) Riboflavin (vitamin B2) Niacin (as niacinamide) Vitamin B6 (as pyridoxine HCl) Folic Acid Vitamin B12 (as cyanocobalamin) Biotin Pantothenic Acid (as calcium D-pantothenate) Calcium (as calcium lactate) Iodine (as potassium iodide) Magnesium (as magnesium glycinate) Zinc (as zinc sulfate) Selenium (as L-selenomethionine) Copper (as copper gluconate) Manganese (as manganese citrate) Chromium (as chromium picolinate) Molybdenum (as sodium molybdate) Sodium Potassium (from whey protein, guar gum, potassium citrate and potassium iodide)
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6/14/04

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Mario Roxas, N.D. Date  
 Director of Scientific and Technical Affairs





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Product Name	Statement	Ingredient(s) to which claim refers
Mega MultiVitamin Drink Mix	Through peripheral vasodilatation, niacin supports the retention of healthy blood pressure that is already within normal limits. †	Vitamin A (50% as beta carotene and as retinyl acetate) Vitamin C (as ascorbic acid) Vitamin D (as cholecalciferol) Vitamin E (as d-alpha tocopheryl acetate) Thiamin (as thiamine HCl) (Vitamin B1) Riboflavin (vitamin B2) <b>Niacin (as niacinamide)</b> Vitamin B6 (as pyridoxine HCl) Folic Acid Vitamin B12 (as cyanocobalamin) Biotin Pantothenic Acid (as calcium D-pantothenate) Calcium (as calcium lactate) Iodine (as potassium iodide) Magnesium (as magnesium glycinate) Zinc (as zinc sulfate) Selenium (as L-selenomethionine) Copper (as copper gluconate) Manganese (as manganese citrate) Chromium (as chromium picolinate) Molybdenum (as sodium molybdate) Sodium Potassium (from whey protein, guar gum, potassium citrate and potassium iodide)
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This letter is to notify you that the following product manufactured, packed, and/or distributed by Integrative Therapeutics Inc. (9755 SW Commerce Circle, Suite B2, Wilsonville, OR 97070) has a label that contains a statement provided for by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Integrative Therapeutics Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and complies 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	Statement	Ingredient(s) to which claim refers
Mega MultiVitamin Drink Mix	Acts as a coenzyme for many different enzymes that break carbon-to-carbon bonds and are involved in carbohydrate and metabolism of pyruvic acid to CO <sub>2</sub> and H <sub>2</sub> O.†	Vitamin A (50% as beta carotene and as retinyl acetate) Vitamin C (as ascorbic acid) Vitamin D (as cholecalciferol) Vitamin E (as d-alpha tocopheryl acetate) <b>Thiamin (as thiamine HCl) (Vitamin B1)</b> Riboflavin (vitamin B2) Niacin (as niacinamide) Vitamin B6 (as pyridoxine HCl) Folic Acid Vitamin B12 (as cyanocobalamin) Biotin Pantothenic Acid (as calcium D-pantothenate) Calcium (as calcium lactate) Iodine (as potassium iodide) Magnesium (as magnesium glycinate) Zinc (as zinc sulfate) Selenium (as L-selenomethionine) Copper (as copper gluconate) Manganese (as manganese citrate) Chromium (as chromium picolinate) Molybdenum (as sodium molybdate) Sodium Potassium (from whey protein, guar gum, potassium citrate and potassium iodide)
		Malic Acid Betaine Inositol Inulin (from chicory root) Hesperidin 50% (from citrus fruits) Taurine Glycine L-Tyrosine N-Acetylcysteine (NAC) L-Serine Stevia (Stevia rebaudiana) Leaf Extract Sour Cherry (Prunus cerasus) Fruit Extract Cranberry (Vaccinium macrocarpon) Fruit Extract Bilberry (Vaccinium myrtillus) Fruit Extract Boron (as sodium borate) Lutein (from Calendula officinalis) Zeaxanthin (from Calendula officinalis) Whey Protein Concentrate

I certify that the information contained in this notice is complete and accurate, and that Integrative Therapeutics Inc. has substantiation that the statement is truthful and not misleading.

  
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 Mario Roxas, N.D.

Director of Scientific and Technical Affairs

  
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 Date