



P.O. Box 3749 • Batesville, Arkansas 72503 800-572-8446 Bus. FAX 870-698-2379 Order/Apps FAX 1-800-959-2777

September 29, 2005

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C. St., SW
Washington, DC 20204

Re: Statement of Nutritional Support Notification

To Whom It May Concern:

Pursuant to Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 343(r)(6), and implementing Food and Drug Administration regulation 21 C.F.R. 101.93 (62 Fed.Reg. 49886 (Sept. 23, 1997)), Life Plus International submits this notification on the following dietary supplements:

Men's Bronze Formula, a dietary supplement containing Ascorbic Acid (Vitamin C), Microcrystalline Cellulose, Zinc Gluconate, Niacin (Nicotinamide), Vitamin E (D Alpha Succinate), Green Tea Leaves and Tender Shoots (98% Polyphenols), Boron Chelate proprietary blend (Boron Citrate, Boron Acetate, and Boron Glycinate), Mixed Tocopherols, Calcium D Pantothenate, Carotenoids (Palm/Carrot Oil), Manganese Gluconate, Hydroxypropyl Methylcellulose, Vitamin B-6 (Pyridoxine HCl), Stearic Acid, PhytoZyme™ proprietary blend (Bromelain, Papain, Aloe Vera, Alfalfa, Parsley, and vegetable and fruit concentrates from Carrots, Broccoli, Spinach, Cauliflower, Asparagus, Celery, Beet, Chili Pepper, Green Bean, Pea, Sweet Potato, Cucumber, Pumpkin, Snow Pea, Tomato, Zucchini, Lima Beans, Mushroom, Banana, Cantaloupe, Cranberry, Guava, Lemon, Mango, Orange, Papaya, Peach, Pineapple and Grapefruit), Niacin (Nicotinic Acid), Titanium Dioxide, Thiamin (Vitamin B-1), Vitamin A Acetate, Magnesium Stearate, Riboflavin (Vitamin B-2), Chromium Polynicotinate, Copper Gluconate, Silica, Glyceryl Triacetate, Silicic Acid, Vitamin K-1 (Phytomenadione), Vitamin D-3 (Cholecalciferol), Chromium Picolinate, Folic Acid, Biotin, Sodium Selenite, Carmine, Sodium Molybdate, Carnauba Wax, Potassium Iodide, Curcumin, and Vitamin B-12 (Cyanocobalamin).

Labeling for this product contains the following claims:

1. Vitamins, Minerals and Herbs to Support Wellness
2. Vitamin D is not only important for proper absorption of calcium and bone health, but also for maintaining healthy joints, a healthy cardiovascular system and healthy moods.
3. Iodine is necessary for the body to make thyroid hormone, while selenium is necessary for proper function of the enzyme that converts thyroid hormone to its biologically active form.
4. The trace mineral chromium plays an essential role in the metabolism of carbohydrates and fats.

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5. Boron exerts much of its influence by playing an integrative role in the areas of bone metabolism, joint health, mental acuity and proper functioning of hormones.
6. Boron appears to support bone health, as well as joint health.
7. Folic acid, vitamin B-12 and vitamin B-6 help lower homocysteine levels.
8. Folic acid, vitamin B-12 and betaine are included in the BodySMART Cellular Nutrition formulas for their role in methylation reactions (essential to maintain healthy DNA), and for the role folic acid plays in maintaining and strengthening healthy chromosomes. Vitamin B-6 also supports amino acid metabolism in general. Vitamin B-12 and folic acid support healthy DNA synthesis and cell division as well.
9. Every cell of the body contains biotin which supports the health of hair, skin, nerves, sex glands and sebaceous glands. It is essential for carbohydrate metabolism and the synthesis of fatty acids.
10. Niacinamide, folic acid, ascorbic acid (vitamin C), beta-carotene, vitamin A and vitamin E are major protectors against oxidative stress. Studies indicate that, by maintaining diets high in such antioxidants, individuals can protect their brain cells against free radical attack, thus helping to retain mental focus, sharpness and acuity as they age.
11. Green tea extract is rich in polyphenols (epigallocatechin gallate, or EGCG), as well as caffeine, and may be useful in supporting a weight-loss program by increasing energy expenditure. A clinical study of healthy young men who routinely took two green tea capsules (containing 50 mg of caffeine and 90 mg of EGCG) three times a day showed a significantly greater oxidation of fat and energy expenditure compared to those who took the same amount of caffeine alone or a placebo. Green tea extracts may also support cardiovascular health by maintaining cholesterol levels already in the normal range.
12. Iodine and Selenium for Healthy Thyroid Function.
13. Selenium is also essential for healthy immune function.

Men's Silver Formula, a dietary supplement containing Saw Palmetto Berry, Microcrystalline Cellulose, Ascorbic Acid (Vitamin C), Zinc Gluconate, Niacin (Nicotinamide), Boron Chelate proprietary blend (Boron Citrate, Boron Acetate, and Boron Glycinate), Vitamin E (D Alpha Succinate), L-Carnitine L-Tartrate, Green Tea Leaves and Tender Shoots (98% Polyphenols), Mixed Tocopherols, Alpha Lipoic Acid, Lutein Extract, Croscarmellose Sodium, Hydroxypropyl Methylcellulose, Calcium D Pantothenate, Carotenoids (Palm/Carrot Oil), Stearic Acid, Vitamin B-6 (Pyridoxine HCl), Manganese Gluconate, Titanium Dioxide, Soy Phospholipid Complex, Magnesium Stearate, PhytoZyme™ proprietary blend (Bromelain, Papain, Aloe Vera, Alfalfa, Parsley, and vegetable and fruit concentrates from Carrots, Broccoli, Spinach, Cauliflower, Asparagus, Celery, Beet, Chili Pepper, Green Bean, Pea, Sweet Potato, Cucumber, Pumpkin, Snow Pea, Tomato, Zucchini, Lima Beans, Mushroom, Banana, Cantaloupe, Cranberry, Guava, Lemon, Mango, Orange, Papaya, Peach, Pineapple and Grapefruit), Riboflavin (Vitamin B-2), Policosanol, Niacin (Nicotinic Acid), Glyceryl Triacetate, Thiamin (Vitamin B-1), Silica, Vitamin A Acetate, Vitamin K-1 (Phytomenadione), Chromium Polynicotinate, Copper Gluconate, Vitamin D-3 (Cholecalciferol), Silicic Acid, Chromium Picolinate, Folic Acid, Sodium Selenite, Biotin, Carnauba Wax, Sodium Molybdate, Vitamin B-12 (Cyanocobalamin), and Potassium Iodide.

Labeling for this product contains the following claims:

1. Vitamins, Minerals and Herbs to Support Wellness
2. Vitamin D is not only important for proper absorption of calcium and bone health, but also for maintaining healthy joints, a healthy cardiovascular system and healthy moods.
3. Iodine is necessary for the body to make thyroid hormone, while selenium is necessary for proper function of the enzyme that converts thyroid hormone to its biologically active form.
4. The trace mineral chromium plays an essential role in the metabolism of carbohydrates and fats.
5. Boron exerts much of its influence by playing an integrative role in the areas of bone metabolism, joint health, mental acuity and proper functioning of hormones.
6. Boron appears to support bone health, as well as joint health.
7. Folic acid, vitamin B-12 and vitamin B-6 help lower homocysteine levels.
8. Folic acid, vitamin B-12 and betaine are included in the BodySMART Cellular Nutrition formulas for their role in methylation reactions (essential to maintain healthy DNA), and for the role folic acid plays in maintaining and strengthening healthy chromosomes. Vitamin B-6 also supports amino acid metabolism in general. Vitamin B-12 and folic acid support healthy DNA synthesis and cell division as well.
9. Every cell of the body contains biotin which supports the health of hair, skin, nerves, sex glands and sebaceous glands. It is essential for carbohydrate metabolism and the synthesis of fatty acids.
10. Niacinamide, folic acid, ascorbic acid (vitamin C), beta-carotene, vitamin A and vitamin E are major protectors against oxidative stress. Studies indicate that, by maintaining diets high in such antioxidants, individuals can protect their brain cells against free radical attack, thus helping to retain mental focus, sharpness and acuity as they age.
11. Green tea extract is rich in polyphenols (epigallocatechin gallate, or EGCG), as well as caffeine, and may be useful in supporting a weight-loss program by increasing energy expenditure. A clinical study of healthy young men who routinely took two green tea capsules (containing 50 mg of caffeine and 90 mg of EGCG) three times a day showed a significantly greater oxidation of fat and energy expenditure compared to those who took the same amount of caffeine alone or a placebo. Green tea extracts may also support cardiovascular health by maintaining cholesterol levels already in the normal range.
12. ALA supports liver and brain health.
13. Saw Palmetto Berry is the most studied, well-known and widely used natural product for supporting prostate health. A 3-year study in Germany showed signs that saw palmetto significantly promoted prostate health in 73 percent of the participants.
14. Lutein is a specific carotenoid recently highlighted in eye research and found to be particularly important to eye health as we get older.
15. A great deal of clinical trial evidence suggests that policosanol supports heart health in a variety of ways, including potent antioxidant activity and maintaining cholesterol levels already in the normal range.
16. Iodine and Selenium for Healthy Thyroid Function.
17. Selenium is also essential for healthy immune function.

18. Phosphatidyl serine: supports healthy brain function as we age
19. Alpha-Lipoic Acid: Premier protection from oxidative stress in all body tissues.
20. Alpha-Lipoic Acid (ALA) is the most effective nutritional antioxidant in bolstering cellular and tissue levels of glutathione, a master physiological antioxidant that orchestrates the biological interaction of many other antioxidants.
21. Increased energy with L-carnitine
22. L-carnitine is an amino acid-derived compound necessary for transport of fatty acids as fuel into mitochondria, the "furnaces" of the cell. L-carnitine's central role in muscle function and fat metabolism has drawn the attention of clinicians and researchers to clinical applications related to these roles. L-carnitine also helps support healthy immune function as we get older.
23. Healthy prostate
24. Lutein for healthy vision

Men's Gold Formula, a dietary supplement containing Saw Palmetto Berry, Microcrystalline Cellulose, Zinc Gluconate, Ascorbic Acid (Vitamin C), Boron Chelate proprietary blend (Boron Citrate, Boron Acetate, and Boron Glycinate), L-Carnitine L-Tartrate, Niacin (Nicotinamide), Vitamin E (D Alpha Succinate), Green Tea Leaves and Tender Shoots (98% Polyphenols), Alpha Lipoic Acid, Lutein Extract, Mixed Tocopherols, Croscarmellose Sodium, Hydroxypropyl Methylcellulose, Vitamin B-6 (Pyridoxine HCl), Calcium D Pantothenate, Carotenoids (Palm/Carrot Oil), Stearic Acid, Soy Phospholipid Complex, Policosanol, Manganese Gluconate, Riboflavin (Vitamin B-2), Titanium Dioxide, Magnesium Stearate, PhytoZyme™ proprietary blend (Bromelain, Papain, Aloe Vera, Alfalfa, Parsley, and vegetable and fruit concentrates from Carrots, Broccoli, Spinach, Cauliflower, Asparagus, Celery, Beet, Chili Pepper, Green Bean, Pea, Sweet Potato, Cucumber, Pumpkin, Snow Pea, Tomato, Zucchini, Lima Beans, Mushroom, Banana, Cantaloupe, Cranberry, Guava, Lemon, Mango, Orange, Papaya, Peach, Pineapple and Grapefruit), Niacin (Nicotinic Acid), Vitamin K-1 (Phytomenadione), Glycerol Triacetate, Thiamin (Vitamin B-1), Silica, Vitamin A Acetate, Vitamin D-3 (Cholecalciferol), Chromium Polynicotinate, Copper Gluconate, Silicic Acid, Chromium Picolinate, Biotin, Folic Acid, Curcumin, Sodium Selenite, Vitamin B-12 (Cyanocobalamin), Carnuba Wax, Sodium Molybdate and Carmine.

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3. Iodine is necessary for the body to make thyroid hormone, while selenium is necessary for proper function of the enzyme that converts thyroid hormone to its biologically active form.
4. The trace mineral chromium plays an essential role in the metabolism of carbohydrates and fats.
5. Boron exerts much of its influence by playing an integrative role in the areas of bone metabolism, joint health, mental acuity and proper functioning of hormones.
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9. Every cell of the body contains biotin which supports the health of hair, skin, nerves, sex glands and sebaceous glands. It is essential for carbohydrate metabolism and the synthesis of fatty acids.
10. Niacinamide, folic acid, ascorbic acid (vitamin C), beta-carotene, vitamin A and vitamin E are major protectors against oxidative stress. Studies indicate that, by maintaining diets high in such antioxidants, individuals can protect their brain cells against free radical attack, thus helping to retain mental focus, sharpness and acuity as they age.
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14. Lutein is a specific carotenoid recently highlighted in eye research and found to be particularly important to eye health as we get older.
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23. Healthy prostate
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Women's Bronze Formula, a dietary supplement containing Ascorbic Acid (Vitamin C), Ferrous Gluconate, Microcrystalline Cellulose, Zinc Gluconate, Niacin (Nicotinamide), Vitamin E (D Alpha Succinate), Green Tea Leaves and Tender Shoots (98% Polyphenols), Boron Chelate proprietary blend (Boron Citrate, Boron Acetate, and Boron Glycinate), Mixed Tocopherols, Calcium D Pantothenate, Carotenoids (Palm/Carrot Oil), Manganese Gluconate, Hydroxypropyl Methylcellulose, Vitamin B-6 (Pyridoxine HCl), Croscarmellose Sodium, Stearic Acid, PhytoZyme™ proprietary blend (Bromelain, Papain, Aloe Vera, Alfalfa, Parsley, and vegetable and fruit concentrates from Carrots, Broccoli, Spinach, Cauliflower, Asparagus, Celery, Beet, Chili Pepper, Green Bean, Pea, Sweet Potato, Cucumber, Pumpkin, Snow Pea, Tomato, Zucchini, Lima Beans, Mushroom, Banana, Cantaloupe, Cranberry, Guava, Lemon, Mango, Orange, Papaya, Peach, Pineapple and Grapefruit), Titanium Dioxide, Niacin (Nicotinic Acid), Magnesium Stearate, Thiamin (Vitamin B-1), Vitamin A Acetate, Riboflavin (Vitamin B-2), Chromium Polynicotinate, Copper Gluconate, Glyceryl Triacetate, Silica, Silicic Acid, Vitamin K-1 (Phytomenadione), Vitamin D-3 (Cholecalciferol), Chromium Picolinate, Folic Acid, Biotin, Sodium Selenite, Carmine, Sodium Molybdate, Carnauba Wax, Potassium Iodide, Curcumin, and Vitamin B-12 (Cyanocobalamin).

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10. Green tea extract is rich in polyphenols (epigallocatechin gallate, or EGCG), as well as caffeine, and may be useful in supporting a weight-loss program by increasing energy expenditure.
11. Several randomized trials of women with menopausal symptoms have shown increased dietary intake (40-160 mg a day) of isoflavone-rich foods and/or

supplements has resulted in improved vasomotor stability, as well as overall improved quality of life.

12. Black cohosh does not contain isoflavones or any compounds with estrogenic activity, but rather appears to help support already healthy neurotransmitter levels in the brain and has been associated with well being in women of middle age.
13. ALA supports liver and brain health.
14. L-carnitine's central role in muscle function and fat metabolism has drawn the attention of clinicians and researchers to clinical applications related to these roles. L-carnitine also helps support healthy immune function as we get older.
15. Lutein is a specific carotenoid recently highlighted in eye research and found to be particularly important to eye health as we get older.
16. Lutein is highly concentrated in the macula of healthy retinas and appears to neutralize free radicals generated when ultraviolet light strikes the retina.
17. A great deal of clinical trial evidence suggests policosanol supports heart health in a variety of ways, including potent antioxidant activity and maintaining cholesterol levels already in the normal range.
18. Iodine and Selenium for Healthy Thyroid Function
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20. Alpha Lipoic Acid – Premier protection from oxidative stress in all body tissues
21. Increased energy with L-Carnitine
22. Lutein for healthy vision
23. Phosphatidyl serine: supports healthy brain function as we age.
24. Researchers have linked societies with high dietary intake of isoflavone containing soy products to a lower incidence of hot flashes during menopause.

Women's Gold Formula, a dietary supplement containing Zinc Gluconate, Ascorbic Acid (Vitamin C), Microcrystalline Cellulose, Boron Chelate proprietary blend (Boron Citrate, Boron Acetate, and Boron Glycinate), Soy Isoflavones Isolate, L-Carnitine L-Tartrate, Niacin (Nicotinamide), Vitamin E (D Alpha Succinate), Green Tea Leaves and Tender Shoots (98% Polyphenols), Alpha Lipoic Acid, Lutein Extract, Mixed Tocopherols, Croscarmellose Sodium, Sage Leaf Extract, Vitamin B-6 (Pyridoxine HCl), Hydroxypropyl Methylcellulose, Calcium D Pantothenate, Carotenoids (Palm/Carrot Oil), Stearic Acid, Soy Phospholipid Complex, Policosanol, Manganese Gluconate, Riboflavin (Vitamin B-2), Titanium Dioxide, Vitamin K-1 (Phytomenadione), PhytoZyme™ proprietary blend (Bromelain, Papain, Aloe Vera, Alfalfa, Parsley, and vegetable and fruit concentrates from Carrots, Broccoli, Spinach, Cauliflower, Asparagus, Celery, Beet, Chili Pepper, Green Bean, Pea, Sweet Potato, Cucumber, Pumpkin, Snow Pea, Tomato, Zucchini, Lima Beans, Mushroom, Banana, Cantaloupe, Cranberry, Guava, Lemon, Mango, Orange, Papaya, Peach, Pineapple and Grapefruit), Magnesium Stearate, Niacin (Nicotinic Acid), Thiamin (Vitamin B-1), Glyceryl Triacetate, Vitamin A Acetate, Vitamin D-3 (Cholecalciferol), Chromium Polynicotinate, Copper Gluconate, Silica, Silicic Acid, Chromium Picolinate, Biotin, Folic Acid, Sodium Selenite, Curcumin, Vitamin B-12 (Cyanocobalamin), Carnauba Wax, Sodium Molybdate, Carmine, and Potassium Iodide.

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16. Lutein is highly concentrated in the macula of healthy retinas and appears to neutralize free radicals generated when ultraviolet light strikes the retina.
17. A great deal of clinical trial evidence suggests policosanol supports heart health in a variety of ways, including potent antioxidant activity and maintaining cholesterol levels already in the normal range.
18. Checking the writings of herbalists working four centuries ago, scientists at the northern English universities of Newcastle and Northumbria found a marked improvement in the memory capabilities of people taking sage leaf extract.
19. Iodine and Selenium for Healthy Thyroid Function
20. Selenium is also essential for healthy immune function

21. Alpha Lipoic Acid – Premier protection from oxidative stress in all body tissues
22. Increased energy with L-Carnitine
23. Lutein for healthy vision
24. Phosphatidyl serine: supports healthy brain function as we age.
25. Researchers have linked societies with high dietary intake of isoflavone containing soy products to a lower incidence of hot flashes during menopause.
26. Sage leaf has been widely used to support health and well-being in women during the menopausal years.

EnerXan, a dietary supplement containing Green Tea Extract (40% Polyphenols), L-Tyrosine, Guarana Seed Extract, Microcrystalline Cellulose, Cinnamon Bark, Damiana (*Turnera aphrodisiaca*) Whole Herb Extract, Yerba Maté Leaf Extract, Croscarmellose Sodium, Stearic Acid, Hydroxypropyl Methylcellulose, Cocoa (Processed With Alkali), Magnesium Stearate, Caffeine Extracted from Coffee Beans, Titanium Dioxide, PhytoZyme™ proprietary blend (Bromelain, Papain, Aloe Vera, Alfalfa, Parsley, and vegetable and fruit concentrates from Carrots, Broccoli, Spinach, Cauliflower, Asparagus, Celery, Beet, Chili Pepper, Green Bean, Pea, Sweet Potato, Cucumber, Pumpkin, Snow Pea, Tomato, Zucchini, Lima Beans, Mushroom, Banana, Cantaloupe, Cranberry, Guava, Lemon, Mango, Orange, Papaya, Peach, Pineapple and Grapefruit), Glyceryl Triacetate, Silica, Carnauba Wax, Chromium Polynicotinate, Chromium Picolinate, and Annatto.

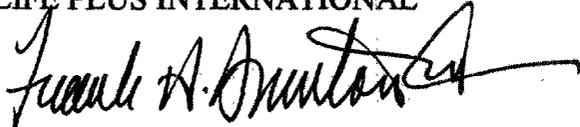
Labeling for this product contains the following claims:

1. Chromium and Herbal Tablets Help Support Energy
2. **EnerXan** is a unique energy supporting formula.
3. In addition to the Green Tea Leaf, Guarana Seed, and Yerba Maté Leaf extracts, **EnerXan** contains Dutch cocoa extract, and cinnamon bark along with the amino acid L-tyrosine and the trace-mineral chromium. These synergistic ingredients help support feelings of energy and vitality.
4. The polyphenols, which are potent antioxidants, are believed to be responsible for most of green tea's roles in supporting good health.
5. Guaraná is an evergreen vine indigenous to the Amazon basin, and the crushed seeds of the plant have long been used as an energy supporting beverage or extract.
6. One of the polyphenols in cinnamon, known as methylhydroxy chalcone polymer, provides particularly strong nutritional support for the body's ability to furnish a steady fuel supply to the brain and body.
7. Chromium nutritionally supports the activity of important enzymes in the body.
8. Cocoa contains lots of polyphenols—the antioxidants of red wine and grape seeds that provide super antioxidant protection and support a healthy heart.
9. L-tyrosine is an amino acid (protein building block) that is important to the structure of almost all proteins in the body, and also supports healthy moods and energy.
10. Most people who drink 1-4 cups of coffee a day will find that 1-3 EnerXan before breakfast and 1-3 before lunch, as part of a sensible program of diet and exercise, as outlined in the Life Plus HealthSmart Weight Management Program, will provide good, stable energy levels throughout the day.
11. Energy support for weight management

12. Dutch cocoa is a particularly rich source of the mineral magnesium, and the amino acid L-tryptophan which helps supports healthy moods.
13. Other substances found in cocoa powder, such as phenylethylamine, theobromine, and anandamide, have also been associated with supporting healthy moods.

I, Frank H. Newton at LIFE PLUS INTERNATIONAL, 267 E. Main Street, Batesville, Arkansas, am authorized to certify this Notification on behalf of the Company. I certify that the information presented and contained in this Notification is complete and accurate and that the Office of Regulatory Affairs at Life Plus International has substantiation that each statement is truthful and not misleading.

LIFE PLUS INTERNATIONAL

A handwritten signature in black ink, appearing to read "Frank H. Newton III", with a long, sweeping horizontal stroke extending to the right.

Frank H. Newton III, Vice President of Regulatory Affairs