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NUTRITIONALS, HFS-450

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March 14, 1997

0057 '97 SEP 19 P1 32

James Tanner, PhD
Acting Director, Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
HFS-450
200 C Street SW
Washington DC 20204

Re: *Submission of Structure/Function Claims*

Dear Dr Tanner:

After an audit of our files, we are submitting structure/function claims which may not have been previously filed with your office or may have been reworked with wording changes and substantiation verification. Enclosed are the structure/function claims for the following nutrients, as generated by Dr. Luke Bucci:

- 1) Critical Mass Drink
- 2) Water Balance Equilibrium Formula
- 3) Body Sculpt
- 4) VitaliRest
- 5) St. John's Wort
- 6) Megabolic Mega-Paks

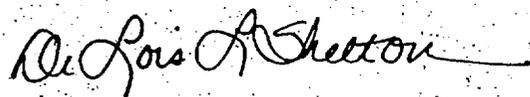
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We welcome the opportunity to receive feedback from your office as we continue to interpret how to write structure/function claims as allowed by the Dietary Supplement Health and Education Act. There are some areas of overlap between nutrient functions or their effects on body structure and health claims. We anticipate that we will continue to fully comply with your interpretation of health claims.

Please feel free to contact me if you have further questions or comments.

Respectfully,

A handwritten signature in black ink that reads "De Lois L. Shelton". The signature is written in a cursive style with a long horizontal flourish at the end.

De Lois L. Shelton, Regulatory Compliance

cc: Dave Mastroianni; Luke R. Bucci

STRUCTURE / FUNCTION CLAIMS

NUTRIENT: Megabolic Mega-Paks

DATE: March 3, 1997
Document Name: sf01mega.wpd

BY: Luke R. Bucci, Ph.D.

0058 '97 SEP 19 P1:33

BRAND, CODE # & PRODUCT NAME(S): Weider Nutrition Group Megabolic Mega-Pak

NUTRIENT AMOUNT:

STRUCTURE/FUNCTION CLAIM:

When it comes to vitamins, conservative physicians argue that they rarely see inadequate intakes of vitamins in our society, but not so with minerals. Few would disagree with the statement that minerals such as calcium and iron are deficient in the diet of many people. Lack of minerals affects the working of vitamins may also perform poorly. Result: we may not be getting our fair share of nutrients.

What has compounded the problem is the quality of our food supply. Due to over processing and refinement, food may no longer provide the same quality of minerals it used to contain. The soil, rivers, and oceans contain minerals, as do plants, sea creatures, and algae. But availability of these minerals for us has decreased and continues to decrease. Megabolic can help replace the minerals that are essential to your diet which may have been deleted by food processing methods.

THE VITAL MINERALS IN MEGABOLIC: As a group of compounds, minerals (including metal and non-metal trace elements) are vital because:

They maintain both electrical and acid-based balances.

They maintain proper pressure and solubility.

They assist in conducting nerve impulses.

They stimulate and inhibit enzymes.

They are actual structural elements in the body, in bones, teeth, tendons and cartilage.

THE NEED TWO TYPES OF MINERALS:

Major (also called inorganic elements) which are needed in quantities greater than 100 milligrams per day. Examples are calcium, phosphorous, magnesium, sodium, potassium, sulfur and chloride.

TRACE ELEMENTS which are just as vital although required in much smaller quantities include iron, copper, manganese, zinc, iodine, chromium, molybdenum and selenium.

-IRON-One of the most abundant elements in the earth crust, iron is found in the body in hemoglobin (a storage form of oxygen in muscles), transferrin (a principal carrier of iron in the blood), (mainly a storage form of iron). There are certain foods which are excellent

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sources of iron such as liver, egg yolks, pork and beef. Unfortunately these foods are also high in cholesterol and should be eaten sparingly. Therefore, it may be difficult for athletes, women, and adolescents to meet their daily nutritional needs for iron. MEGABOLIC supplies 100% of your iron needs.

CALCIUM- The news is out that your need for calcium extends far beyond your formative years. Calcium participates in all muscle contractions and is vital for the functioning of nerve cells and enzyme activity. It is also responsible for transmission of impulses from nerves to muscles. As a component of bones, calcium is required throughout your life cycle since bone tissue is constantly being formed. MEGABOLIC's got the calcium active men and women need.

PHOSPHORUS- Besides being involved in energy metabolism, phosphorus is a main component of bone and other body structures. The many B-complex vitamins that are involved in energy production will only become effective when combined with phosphorus. On the cell level, ATP (the form of energy used by muscles) contains phosphorus.

ZINC- Many enzymes (such as carbonic anhydrase and lactated dehydrogenase) that prevent the buildup of lactic-acid in muscles (a major cause of sports fatigue) requires zinc for their action. Because many fitness-conscious people have reduced their intake of animal products, they may not be getting enough zinc, since vegetable and plant foods are lesser sources of zinc than animal foods. Refining our foods lowers our zinc intake even more. MEGABOLIC has 200% of your daily requirement for zinc.

MAGNESIUM- All enzymes needed for the metabolism of ATP for energy require magnesium. This essential mineral also regulates body heat, the contraction of muscles and the synthesis of body proteins. Athletic and active people should be aware that magnesium deficiency symptoms are muscular tremors, twitching, quivering and cramping.

SELENIUM- Selenium is an essential trace mineral for humans. It helps detoxify contaminants in the environment (such as mercury found in fish from contaminated water) and is a component of red blood cells.

IODINE- Iodine is an essential component of the thyroid gland which controls protein synthesis, carbohydrate absorption and the basal metabolic rate. Now that Americans have reduced their intake of salt (the principal source of iodine), their iodine intake may also drop.

POTASSIUM- Deficiencies of this essential mineral are particularly serious to people working out. Irregular heart beat, cessation of muscle contractions and the abnormal conduction of nerve impulses will devastate your training program. Since active people have greater needs for potassium (because potassium is lost in sweat), they should be aware that continued or frequent muscle cramping can be an early sign of a deficiency.

COPPER- Many environmental pollutants (such as cadmium) decrease copper absorption. Severe copper deficiency can disrupt the building of connective tissue and cause bones to become weakened.

MANGANESE- Enzymes containing manganese are very active in the mitochondria, the 'powerhouse' of the cell where ATP production occurs. Is a vital component of enzymes involved in carbohydrate metabolism.

CHROMIUM- Identified as the ingredient in torula yeast which improved glucose

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metabolism , chromium is an essential mineral for humans. It is involved in the breakdown of proteins and fats. A lowered chromium intake is thought to be a consequence of food processing and refining.

VITAMINS

The vitamins found in MEGABOLIC MEGA-PAKS also have many important functions.

Among these are :

- Vitamin A- Maintenance of the normal condition of mucous membranes.
- Vitamin C- Essential for the formation of collagen protein in our body.
- Vitamin D- Helps promote intestinal absorption of calcium and phosphate.
- Vitamin E- Can enhance the absorption, transport and storage of vitamins.
- Thiamine(Vitamin B1) Essential for the key reactions in carbohydrate metabolism.
- Riboflavin (Vitamin B2) Necessary for fat synthesis and tissue respiration.
- Folic Acid- Essential for the normal metabolism of certain amino acids.

Approved by / Date

REFERENCES:

1. *Modern Nutrition in Health and Disease*, 8th ed., Shils, M.E., J.A. Olson, M. Shike, Eds., Lea & Febiger, Philadelphia, 1994.
2. *Nutritional Biochemistry of the Vitamins*, Bender DA, Cambridge University Press, Cambridge, 1992.
3. *Handbook of Vitamins*, 2nd ed, LJ Machlin, Ed., Marcel Dekker, Inc. New York and Basel. 1992.
4. *The Vitamins Fundamental Aspects in Nutrition and Health*, GF Combs, Jr. Ed. Academic Press, Inc. 1993
5. *Present Knowledge in Nutrition*, 6th ed. ML Brown, Ed. International Life Sciences Institute, Nutrition Foundations Washington, D.C. 1990.

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STRUCTURE / FUNCTION CLAIMS

NUTRIENT: Water Balance Equilibrium Formula

DATE: March 3, 1997
Document Name: sf01water.wpd

BY: Luke R. Bucci, Ph.D.

BRAND, CODE # & PRODUCT NAME(S): Schiff 12725 Water Balance Equilibrium Formula

NUTRIENT AMOUNT: 50 Tablets

STRUCTURE/FUNCTION CLAIM:

A gentle, natural means of maintaining a normal water balance. Formulated by Dr. Lark with essential vitamins and minerals additional herbal concentrates:

- B-Complex vitamins with extra B-6 and pantothenic acid
- Antioxidant vitamins C and E
- Potassium, a mineral vital to maintaining water balance
- Parsley, Horsetails and Uva Ursi, herbs which help the body achieve normal water balance.

The Water Balance Nutritional System was developed based upon the latest scientific findings in the area of nutrition and human health and reflects Dr. Lark's 10 year Clinical experience with thousands of women patients.


Approved by / Date

REFERENCES:

1. Lark, S.M. Premenstrual Syndrome. In *Women's Health Companion Self Help Nutrition Guide and Cookbook*. Celestial Arts Publishing Berkeley, CA. 1995, 85-95.
2. Lark, S.M. Part II: Alternatives to Hormone Replacement Therapy. In *The Estrogen Decision Self Help Book*. Celestial Arts Publishing, Berkeley, CA. 1995. 123-304.

STRUCTURE / FUNCTION CLAIMS

NUTRIENT: Critical Mass Drink

DATE: March 5, 1997
Document Name: sf01mass.wpd

BY: Luke R. Bucci, PhD

BRAND, CODE # & PRODUCT NAME(S): American Body Building 08000 Critical Mass Drink

NUTRIENT AMOUNT: 18.0 FL. OZ. (532 ml)

STRUCTURE/FUNCTION CLAIM:

Glucose replenishes muscle glycogen, maximizes recovery, and enhances growth following a demanding workout- especially after an anaerobic or a weight lifting workout.

LR Bucci 3/6/97
Approved by / Date

REFERENCES:

1. Valeriani, A. The need for carbohydrate intake during endurance exercise, *Sports Med.*, 1991 (12) 349.
2. Costill, D.L. and Hargreaves, M. Carbohydrate nutrition and fatigue. *Sports Med* 1992 (13) 86.
3. Liebman, M. , Wilkinson, J.G. Carbohydrate metabolism and exercise in *Nutrition in Exercise and Sport* Wolinsky, I. And Hickson, J.F. Jr., Eds. CRC Press, Boca Raton, FL, 1994, 15.
4. Miller, G.D. Carbohydrates in ultra-endurance exercise and athletic performance, in *Nutrition in Exercise and Sport*, Wolinsky, I. And Hickson, J.F. Jr., Eds. CRC Press, Boca Raton, FL, 1994, 65.
5. Walber-Rankin, J. Dietary carbohydrate as an ergogenic aid for prolonged and brief competitions in sport, *Int. J. Sports Nutr.* 5 (Suppl.) S13, 1995.
6. Bucci, L.R. , Nutritional ergogenic aids, in *Nutrition in Exercise and Sport* Wolinsky, I. And Hickson, J.F. Jr., Eds. CRC Press, Boca Raton, FL, 1994, 295.
7. Friedman, J.E., Neuffer, P.D. and Dohm, G.L. Regulation of glycogen resynthesis following exercise. Dietary considerations, *Sports Med* 1991 (11) 232.1

STRUCTURE / FUNCTION CLAIMS

NUTRIENT: Body Sculpt

DATE: March 6, 1997
Document Name: sf01body.wpd

BY: Luke R. Bucci

BRAND, CODE # & PRODUCT NAME(S): Great American Nutrition 50276 Body Sculpt
Designed for Women's Health

NUTRIENT AMOUNT: 60 tabs

STRUCTURE/FUNCTION CLAIM:

Three key ingredients in the Body Sculpt Multi Vitamin:

- Antioxidants: Vitamins C,E, and Beta Carotene help delay the oxidation of biomolecules due to exposure to free radicals which may contribute to the aging process.
 - Chaste Tree Berry (Vitex)- traditionally used by women to encourage menstrual health.
 - Dong Quai- used in traditional Chinese medicine this herb is thought to provide vitality and support to female hormones.
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Approved by / Date

REFERENCES:

Vitamin C(see vitamin C file for references) .

1. Jacob, R.A., Vitamin C, in *Modern Nutrition in Health and Disease*, 8th ed., Shils, M.E., J.A. Olson, M. Shike, Eds., Lea & Febiger, Philadelphia, 1994, 432-448.
2. Englard, S. And S. Seifter, The biochemical functions of ascorbic acid. *Ann. Rev. Nutr.*, 1986; 6: 365-406.
3. Bender, D.A., Vitamin C, in *Nutritional Biochemistry of the Vitamins*, Cambridge University Press, Cambridge, 1992, 223-245.
4. Skelton, W.P. and N.K. Skelton, Deficiency of vitamins A, B and C: something to watch for, *Postgraduate Med.* 1990; 87(4): 293-310.

Vitamin E (see vitamin E file for references)

1. Farrell, P.M. and R.J. Roberts, Vitamin E, in *Modern Nutrition in Health and Disease*, 8th ed., Shils, M.E., J.A. Olson, M. Shike, Eds., Lea & Febiger, Philadelphia, 1994, 326-341.
2. Bieri, J.G., Vitamin E, in *Present Knowledge in Nutrition*, 6th ed., Brown, M.L., Ed., International Life Sciences Foundation, Washington, D.C., 1990, 117-121.

Beta Carotene (see Beta Carotene file for references)

1. Pennington, J.A.T., *Bowes and Church's Food Values of Portions Commonly Used*, 15th ed., J.B. Lippincott, Philadelphia, 1989, 193.
2. Olson, J.A., Vitamin A, retinoids, and carotenoids, in *Modern Nutrition in Health and Disease*, 8th ed., Shils, M.E., J.A. Olson, M. Shike, Eds., Lea & Febiger, Philadelphia, 1994, 287-307.

Chaste Tree Berry (*Vitex agnus-castus*)

1. Jary, H., Leonhardt, S., Gorkow, C., and Wuttke, W. In vitro prolactin but not LH and FSH release is inhibited by compounds in extracts of *Agnus castus*: direct evidence for a dopaminergic principle by the dopamine receptor assay. *Exp. Clin. Endocrinol* 1994, 102, 448-454.
2. Milewicz, A., Gejdel E, et al. *Vitex agnus-castus* extract in the treatment of luteal phase defects due to latent hyperprolactinemia: Results of a randomized placebo-controlled double blind study. *Arzneim-Forsch Drug Res* 1993, 43(7), 752-6.
3. Sliutz, G., Speiser, P., Schultz, AM, Spona, J, and Zeillinger, R. *Ahnus castus* extracts inhibit prolactin secretion of rat pituitary cells. *Horm. Metab. Res.* 1993, 25, 253-255.

Dong Quai (*Angelica sinensis*)

1. He, ZP, Wang DZ, Shi, LY, Wang, SX. Treating amenorrhea in vital energy-deficient patients with *angelica sinensis*-*astragalus membranaceus* menstruation-regulating decoction. *J Tradit Chin Med* 1986, 6(3) 187-90.
2. Mei, QB, Tao, JY, Cui, B. Advances in the pharmacological studies of *radix Angelica sinensis* (Oliv) Diels (Chinese Danggui). *Chin Med J Engl* 1991, 104(9), 776-81.

STRUCTURE / FUNCTION CLAIMS

NUTRIENT: VitaliRest

DATE: March 7, 1997
Document Name: sf01rest.wpd

BY: Luke R. Bucci, Ph.D.

BRAND, CODE # & PRODUCT NAME(S): Great American Nutrition 52080
VitaliRest Energy for Life

NUTRIENT AMOUNT: 60 tablets

STRUCTURE/FUNCTION CLAIM:

VITALIREST for men and women is a natural nighttime formula which allows you to normalize your body's natural dieting process. Here's how: A good diet program includes: Exercise, Nutrition and REST. VITALIREST contains the ingredient Melatonin, that is designed to induce complete rest, which is essential to every diet program.

VITALIREST also contains two key ingredients essential to dieter's needs: Chromium Picolinate and Citrimax. These combined ingredients help to decrease body fat percentage, control hunger and improve blood sugar metabolism.

By taking VITALIREST in combination with daily exercise and good nutrition, you will have the rest you need for a perfect diet program. VITALIREST is the perfect extension of the VITALISLIM supplement and VITALISLIM shake to complete the ultimate diet regimen.

THE THREE KEY INGREDIENTS AND HOW THEY WORK: Chromium Picolinate is a trace mineral essential for carbohydrate and fat metabolism. It normalizes blood glucose and optimizes insulin efficiency.

CITRIMAX is a fruit from India that changes the way the body stores and provides fat. It suppresses the appetite without nervous system side effects. CITRIMAX also known as Garcinia cambogia, contains Hydroxycitric Acid (HCA).

Melatonin is a substance produced by the pineal gland that regulates circadian rhythms. It helps induce rest and acts as an antioxidant, free-radical scavenger and immune supporter.

Approved by / Date

REFERENCES:

Melatonin (see Melatonin file for references)

1. Reiter RJ, Melchiorri D, Sewerynek E, Poeggler B, Barlow-Wilder LR, Chuang JI, Ortiz

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- GG, Acuña-Castroviejo D. A review of the evidence supporting melatonin's role as an antioxidant. *J Pineal Res* 1995; 18:1-11.
2. Morrey KM, McLachlan JA, Bakouche O. Activation of human monocytes by the pineal hormone melatonin. *J Immunol* 1994; 153: 2671-80.
 3. Maestroni GJ, Conti A, Pierpaoli W. Pineal melatonin, its fundamental immunoregulatory role in aging and cancer. *Ann NY Acad Sci* 1988; 521:140-8.
 4. Maestroni GJ. The immunoneuroendocrine role of melatonin. *J Pineal Res* 1993; 14:1-10.
 5. Dawson D, Encel N. Melatonin and sleep in humans. *J Pineal Res* 1993; 15:1-12.
 6. Arendt J, et al. Alleviation of jet lag by melatonin: preliminary results of a controlled double blind study. *Br Med J* 1986; 292:1170.

Citrimax (see Citrimax file for references)

1. Majeed M, Rosen, R, McCary M, Conte A, Patil, D, Butrym E. *Citrin A Revolutionary, Herbal Approach to Weight Management*. New Editions Publishing Burlingame, CA.
2. *Journal of Lipid Research* 1981 22:753-762.
3. *Diabetes* 1994; 43:878-883.

Chromium Picolinate (see Chromium Picolinate file for references)

1. Evans, G.W., The effect of chromium picolinate on insulin controlled parameters in humans, *Int. J. Biosocial Res.*, 1989; 11: 163-180.
2. Kaats, G.R., Fisher, J.A., and Blum, K., The effects of chromium picolinate supplementation on body composition in different age groups, *Age*, 1991; 14: 138.
3. Hasten, D.L., Rome, E.P., Franks, B.D., and Hegsted, M., Anabolic effects of chromium picolinate on beginning weight training students, *Int. J. Sport Nutr.*, 1992; 2: 343-350.
4. Evans, G.W., and Pouchnik, D.J., Composition and biological activity of chromium-pyridine carboxylate complexes, *J. Inorg. Biochem.*, 1993; 49: 177-187.
5. Hallmark, M.A., Reynolds, T.H., DeSouza, C.A., et al., Effects of chromium supplementation and resistive training on muscle strength and body composition, *Med. Sci. Sports Exerc.*, 1996;28,139-144.

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6. Clancy, S., Clarkson, P.M., DeCheke, M., et al., Chromium supplementation in football players, *Int. J. Sport Nutr.*, 1994; 4: 142-153.
7. Bahadori, B., Habersack, S., Schneider, H., et al., Treatment with chromium-picolinate improves lean muscle mass in patients following weight reduction, *Int. J. Obesity*, 1995; 19(Suppl. 1): 38.

STRUCTURE / FUNCTION CLAIMS

NUTRIENT: St. John's Wort

DATE: March 7, 1997
Document Name: sf01stjn.wpd

BY: Luke R. Bucci, Ph.D.

BRAND, CODE # & PRODUCT NAME(S): Schiff 12013 St. John's Wort

NUTRIENT AMOUNT: 300 mg (60 tablets)

STRUCTURE/FUNCTION CLAIM:

St. John's Wort is a flowering bush found throughout the world.

It has compounds that may influence the brain's ability to make neurotransmitters, which control mood.

Schiff St. John's Wort products are standardized to contain reproducible and consistent amount of active substances. (0.3% Hypericin)

Standardized St. John's Wort may help maintain feelings of well-being and normal, healthy mood.

St. John's Wort is commonly used in Germany where millions of people enjoy its benefits.

Approved by / Date

REFERENCES:

1. Linde K, Ramirez G, Mulrow CD, Pauls A, Weidenhammer W, Melchart D. St. John's Wort for depression- an overview and meta-analysis of randomised clinical trials. *British Medical Journal* 1996;313, 253-258.
2. Payk TR. Treatment of Depression. *J Geriatr Psychiatry Neurol* 1994, 7,(suppl 1)S3-S5.
3. Murray MT. St. john's wort in *The Healing Power of Herbs*. Prima publishing, Rocklin, CA. 294-301
4. Harrer G, Schulz V. Clinical investigation of the antidepressant effectiveness of hypericum. *J Geriatr PsNeurol* 1994; 7(suppl 1) S6-S8.
5. Holzl J, Demisch L, Gollnik B. Investigations about antidepressive and mood changing effects of Hypericum perforatum. *Planta Medica* 1989;55, 643.
6. Suzuki O, etal. Inhibition of monamine oxidase by hypericin. *Planta Medica* 1984; 50: 272-4.