



FEB - 3 1998
0558 '98 MAR 24 P2:43

Mr. Eric Baker
Director of Sales and Marketing
UltraVit Enterprises, Inc.
116 W. Del Mar Boulevard
Pasadena, California 91105

Dear Mr. Baker:

This is in response to your letter of December 18, 1997 to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act). Your submission states UltraVit Enterprises, Inc. is making the following statements, among others, for the following products:

Hi-Pot FOS - 800 mg, GREENLINE

“...has a protective action against the overgrowth of harmful bacteria”
“...protect the internal environment of the body from the overgrowth of pathogenic bacteria”

Hi-Pot. Acidophilus w/FOS, GREENLINE

“...decrease susceptibility of the body to invasion of pathogenic bacteria”
“...prevent the overgrowth of harmful organisms in the intestine following antibiotic therapy”

Natural Premium E 400 I.U., GREENLINE, Dry E 400 I.U., GREENLINE, and Natural E D-alpha tocopherol 400 I.U. GREENLINE

“...normalizes abnormal hormone levels”

Glucosamine sulfate - 750 mg, GREENLINE

“Normalizes connective tissue metabolism including cartilage and joints”
“...Disturbances of the metabolism of the matrix of the connective tissue can cause articular pain, joint tenderness, joint swelling, and restriction of active and passive movements^{1,2,3,4,5,6}”

975-0163

LET128

Garlic (Pure-Gar) - 500 mg, GREENLINE

“Garlic has been shown to have antifungal properties^{2,3} and may aid in neutralizing the toxic effects of certain chemicals^{2,3}.”

“The vasodilative constituents in garlic have cholesterol and lipid lowering effects⁴; reduce blood platelet aggregation; and contribute to a more rapid dissolution of coagulated blood, plaques, and clots to maintain fluidity of the blood³.”

Garlic, hawthorne, mistletoe, GREENLINE

“...participates in stabilizing the blood pressure”

“...stabilizes lipid metabolism and blood pressure^{1,2,3}”

Ultramune, GREENLINE

“...helps the body fight infection”

CoQ10 (30 mg, 50 mg, and 100 mg), GREENLINE

“Improves cardiac function² stabilizes the heart rhythmic action¹, and supports energy supply from foods³.”

These claims suggest that these products are intended to treat, prevent, or mitigate disease.

Your submission also states that UltraVit Enterprises, Inc. is making numerous claims on the labels of its products that contain, as a part of the claims, citations to one or more articles published in research journals or other sources. Many of these citations suggest that these products are intended to treat, prevent, or mitigate disease. For example, claims for the product **Phosphatidylserine - ginkgo biloba complex** suggest that the product is intended to treat, cure, prevent, or mitigate Alzheimer's disease or other mental diseases associated with aging. These claims include: (1) a statement that the product is to “improve short term memory⁵” and that contains the citation “Palmieri, G. et al. (1987). Double-blind controlled trial of phosphatidylserine in subjects with senile mental deterioration. Clin Trials J. 24:73-83;” and (2) a statement that the product is to “improve mental alertness²” and that contains the citation “Crook, T.H. et al. (1991) Effects of phosphatidylserine in age-associated memory impairment. Neurol. 41:644-649.”

In addition, the use of citations that contain references to their role in treating, preventing, curing, or mitigating diseases such as periodontal disease and atherosclerosis (**Ultrabones**), cancer (**Ultragevity, beta-carotene 25, 1000 IU, Deluxe anti-oxidant/ultra anti-oxidant**), cataracts (**Ultra Eyes**), peripheral arterial insufficiency and cardiovascular disease and myocardial infarction (**Food Multi Hi-Potency Vegetarian Formula, Magnesium complex, Ultrahers**), wound healing (**Ultrahis, Ultrahers, Food Multi Hi-Potency Vegetarian Formula**), diarrhea, cardiac rhythm disorders, and cardiovascular disease (**Folic acid - 800 mcg, Stress B w/herbs, Ultrahers, and Ultrahis**), claudication (**Super C, E and carotene**

plus selenium and bioflavonoids), prostate disease (**Saw palmetto berry extract**), osteoporosis (**Ultrahers**), or that represent a product as an antifungal and antibacterial (**Anti-Yeast**) or antiviral and antimutagenic (**Cat's claw 250 mg**) suggests that a product is intended to treat, cure, prevent, or mitigate disease.

Section 403(r)(6) of the act makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for your products (identified above) suggest that they are intended to treat, prevent, or mitigate diseases. These claims do not meet the requirements of section 403(r)(6) of the act. These claims suggest that these products are intended for use as drugs within the meaning of section 201(g)(1)(B) of the act, and that they are subject to regulation under the drug provisions of the act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Your submission also indicates that you are making claims of a relationship between calcium and osteoporosis (**Calcium citrate (1000 mg) (Greenline)** and **Cal-Mag Chew w/vitamin D (Greenline)**).

These statements are not statements of nutritional support subject to section 403(r)(6) of the act, but are health claims subject to section 403(r)(1)(B) of the act. FDA has authorized a health claim on the relationship between calcium and osteoporosis (see 21 CFR 101.72). A dietary supplement that meets the eligibility and message requirements set forth in this regulation may bear a claim for the relationship between calcium and osteoporosis. A health claim on the label or in the labeling of a food or dietary supplement that is not in accordance with the requirements in 21 CFR 101.72 would misbrand the food or dietary supplement under section 403(r)(1)(B) of the act. Moreover, failure to make a claim in accordance with the requirements in 21 CFR 101.72 subjects the product to regulation as a drug under section 201(g)(1)(B) of the act because the product is intended to treat, cure, prevent, or mitigate a disease, osteoporosis.

Please contact us if we may be of further assistance.

Sincerely yours,

James T. Tanner, Ph.D.
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

Page 4 - Mr. Eric Baker

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, Los Angeles District Office, Compliance Branch, HFR-PA240

cc:

HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO, JGordon)
HFS-456 (file)
HFS-450 (r/f, file, OSN#56511)
HFD-310 (BWilliams)
HFD-314 (Aronson)
HFS-600 (Reynolds)
HFS-605 (Bowers)
GCF-1 (Nickerson, Dorsey)
r/d:HFS-456:RMoore:1/20/98
Revised per GCF-1:DDorsey:1/27/98
f/t:rjm:HFS-456:1/28/98:56511.adv:disc25

Hi-Pot FOS - 800 mg
GREENLINE

DATE: **DEC 18 1997**
Responsible for the text:


Egan Badart

FRONT LABEL: helps to stabilize the probiotic microflora in the human body; has a protective action against the overgrowth of harmful bacteria.*

BACK LABEL: Fructo-oligo-saccharides, (FOS), are preferential foods for bifidobacteria and lactobacilli which produce lactic acid, lower pH and protect the internal environment of the body from the overgrowth of pathogenic bacteria.*

*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to treat, diagnose, cure or prevent any disease.

References:

1. Fernandes, C.F., Shahani, K.M. & Amer, M.A. (1987) Therapeutic role of dietary lactabacilli and lactobacillic fermented dairy products., FEMS Microbiol. Rev., 46, 343-356.
2. Gilliland, S.E. (1990) Health and nutritional benefits from lactic acid bacteria., FEMS Microbiol. Rev., 46, 337-342.
3. Gurr, M.I. (1987) Nutritional aspects of fermented milk products., FEMS Microbiol. Rev., 46, 337-342.
4. Rasic, J.L. and Kurmann, J.A. (1978). Yoghurt, Scientific Grounds, Technology, Manufacture, and Preparations, vol.1, Technical Dairy Publ. House, p.362.

NATURAL PREMIUM E 400 I.U.
GREENLINE

DATE: **DEC 18 1997**
Responsible for the text.



Egan Badart

FRONT LABEL: An essential nutrient, promotes natural growth, development and provides, as a lipid-soluble antioxidant, protection in intermediary metabolism. *

BACK LABEL: prevents formation of free radicals in body², reduces clotting tendencies of the blood³, promotes normal red blood-cell formation⁶, possesses antihistaminic properties^{4,5} ;and normalizes abnormal hormone levels^{7*}

* This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

References:

1. Sokol, R.J. (1996) Vitamin E in Present Knowledge in Nutr., 7th ed., Ziegler, E.E., & Filer, L.J., ILSI Press, Washington D.C., p.130-136.
2. Chow, C.K. (1979) Nutritional influences on cellular antioxidant defense systems. Am. J. Clin. Nutr. 32:1066-1081.
3. Haeger, K. (1974) Long-time treatment of intermittent claudication with Vitamin E. Am. J. Clin. Nutr. 27(10):1179-81.
4. Hermann, W.J. (1979) The effect of tocopherol on high- density lipoprotein cholesterol: A clinical observation. Am. J. Clin. Path. 72:848-852.
5. Kanimura, M. (1972) Antiinflammatory activity of Vitamin E. J. Vitaminol, 18(4):204-209.
6. Leonard, P.J. and Losowsky, M.S. (1971) Effect of alpha-tocopherol administration on red cell survival in vitamin E-deficient human subjects. Am. J. Nutr. 24:388-93.
7. Sundaram, G.S. (1981) Serum hormones and lipoproteins in benign breast disease. Cancer Res. 41:3814-16.

GLUCOSAMINE SULFATE - 750 mg
GREENLINE

DATE: **DEC 18 1997**

Responsible for text:


Egan Badart

FRONT LABEL: Normalizes connective tissue metabolism including cartilage and joints. *

BACK LABEL: Glucosamine sulfate is a component of proteoglycans of connective tissue and participates in the maintenance of this tissue. Disturbances of the metabolism of the matrix of the connective tissue can cause articular pain, joint tenderness, joint swelling, and restriction of active and passive movements. ^{1,2,3,4,5,6*}

*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

REFERENCES:

1. Crolle, G. & D'Este, E. (1980) Glucosamine sulphate for the management of arthrosis: a controlled clinical investigation. *Curr. Med. Res. Opin.* 7(2): 104-109.
2. Drovanti, A., Bignamini, A., Rovati, A. (1980) Therapeutic activity of oral glucosamine sulfate in osteoarthritis: a placebo-controlled double-blind investigation. *Clin. Ther.* 4(4): 260-272.
3. Reichelt, A. et al. (1994) Efficacy and Safety of Intramuscular Glucosamine Sulfate in Osteoarthritis of the Knee A randomised, placebo-controlled, double-blind study. *Drug Res.* 44(1): 75-80.
4. Setnikar, I., Cereda, R., Pacini, M.A., & Revel, L. (1991) Antireactive properties of glucosamine sulfate. *Arzeimittelforschung.* 41(2): 157-161.
5. Tapadinhas, M.J., Rivera, I.C., & Bignamini, A.A. (1982) Oral glucosamine sulphate in the management of arthrosis: report on a multi-centre open investigation in Portugal. *Pharmatherapeutica.* 3(3): 157-168)
6. Vaz, A.L. (1982) Double-blind clinical evaluation of the relative efficacy of ibuprofen and glucosamine sulphate in the management of osteoarthritis of the knee in out-patients. *Curr. Med. Res. Opin.* 8(3): 145-14

ULTRAMUNE
GREENLINE

DATE: **DEC 18 1997**
Responsible for text:



Egan Badart

FRONT LABEL: supports, by improving diets, the activity of the human immune system.*

BACK LABEL: Echinacea helps maintain the integrity of the immune functions in the body^{2,7}; Astragalus is an adaptogen - has a balancing effect on bodily functions¹¹; Vitamin C strengthens the immune system, strength of the blood vessels and helps the body fight infection¹⁰; Garlic helps to maintain the fluidity of the blood and the function of the cardiovascular system^{1,5,6,8}; Pycnogenols are antioxidants and coenzyme Q10, also an anti-oxidant, helps the body's cells use oxygen and generate energy.^{3,4,9*}

* This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

References:

1. Abdulla, T.H., Kandil, O., Elkadi, A. and Carter, J. (1988) Garlic revisited: therapeutic or the major diseases of our times? J. Natl. Med. Assoc. 80(4):439-445.
2. Bauer, R. and Wagner, H. (1991) Echinacea species as potential immunostimulatory drugs. Econ Med Plant Res 5:253-321.
3. Fujioka, T. (1983) Clinical study of cardiac arrhythmias using a 24-hour continuous electrocardiographic recorder (5th report): Antiarrhythmic action of coenzyme Q10 in diabetics. Tohoku J. Exp. Med. 141 (suppl.):453-63.
4. Kamikawa, T. (1985) Effects of coenzyme Q10 on exercise tolerance in chronic stable angina pectoris. Am. J. Cardiol. 56:247.
5. Lau, B.H.S. (1989) Detoxifying, radioprotective and phagocyte-enhancing effects of garlic. Int. Clin. Nutr. Rev. 9:27-31.
6. Lau, B.H.S, Tadi, P.P., and Tosk, M.J. (1990) Allium sativum (garlic) and cancer prevention. Nutr. Res. 10:937-948.
7. Sumiyoshi, H. and Wargovich, M.J. (1989) Garlic (allium sativum): a review of its relationship to cancer. Asian Pacific J. Pharmacol. 4: 133-140.
8. Vanfraechem, J.H.P., Folkers, K.J. (1981) Coenzyme Q10 and physical performance, in: " Biomed. & Clin. Aspects of Coenzyme Q", 3:235-41. Eds.: Folkers,K. and Yamamura,Y.
9. Vilkas, M. (1994) Vitamines, Mecanismes d'action chimique. Hermann Ed. Paris p. 107-126.

DRY E 400 I.U.
GREENLINE

DATE: **DEC 18 1997**
Responsible for the text:



Egan Badart

FRONT LABEL: An essential nutrient, promotes natural growth, development and provides, as a lipid-soluble antioxidant, protection in intermediary metabolism. *

BACK LABEL: prevents formation of free radicals in body², reduces clotting tendencies of the blood³, promotes normal red blood-cell formation⁶, possesses antihistaminic properties^{4,5} ;and normalizes abnormal hormone levels^{7*}

* This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

References:

1. Sokol, R.J. (1996) Vitamin E in Present Knowledge in Nutr., 7th ed., Ziegler, E.E., & Filer, L.J., ILSI Press, Washington D.C., p.130-136.
2. Chow, C.K. (1979) Nutritional influences on cellular antioxidant defense systems. Am. J. Clin. Nutr. 32:1066-1081.
3. Haeger, K. (1974) Long-time treatment of intermittent claudication with Vitamin E. Am. J. Clin. Nutr. 27(10):1179-81.
4. Hermann, W.J. (1979) The effect of tocopherol on high- density lipoprotein cholesterol: A clinical observation. Am. J. Clin. Path. 72:848-852.
5. Kanimura, M. (1972) Antiinflammatory activity of Vitamin E. J. Vitaminol, 18(4):204-209.
6. Leonard, P.J. and Losowsky, M.S. (1971) Effect of alpha-tocopherol administration on red cell survival in vitamin E-deficient human subjects. Am. J. Nutr. 24:388-93.
7. Sundaram, G.S. (1981) Serum hormones and lipoproteins in benign breast disease. Cancer Res. 41:3814-16.

COQ10 (30 mg, 50 mg, and 100 mg)
GREENLINE

DATE: **DEC 18 1997**
Responsible for the text:


Egan Badart

FRONT LABEL: participates in the efficient production of food energy and, specifically, in maintaining cardiac functions.*

BACK LABEL: improves cardiac function², stabilizes the heart rhythmic action¹, and supports energy supply from foods³. *

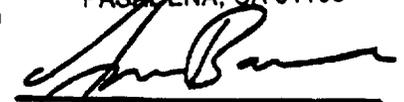
* This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

References:

1. Fujioka, T. (1983) Clinical study of cardiac arrhythmias using a 24-hour continuous electrocardiographic recorder (5th report): Antiarrhythmic action of coenzyme Q10 in diabetics. Tohoku J. Exp. Med. 141 (suppl.):453-63.
2. Kamikawa, T. (1985) Effects of coenzyme Q10 on exercise tolerance in chronic stable angina pectoris. Am. J. Cardiol. 56:247.
3. Vanfraechem, J.H.P., Folkers, K.J. (1981) Coenzyme Q10 and physical performance in Biomed. & Clin. Aspects of Coenzyme Q. Vol. 3: 235-241 Elsevier/North Holland Biomedical Press.

DATE: **DEC 18 1997**
Responsible for the text:

NATURAL E D-ALPHA TOCOPHEROL 400 I.U.
GREENLINE



Egan Badart

FRONT LABEL: An essential nutrient, promotes natural growth, development and provides, as a lipid-soluble antioxidant, protection in intermediary metabolism. *

BACK LABEL: prevents formation of free radicals in body², reduces clotting tendencies of the blood³, promotes normal red blood-cell formation⁶, possesses antihistaminic properties^{4,5} ;and normalizes abnormal hormone levels^{7*}

* This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

References:

1. Sokol, R.J. (1996) Vitamin E in Present Knowledge in Nutr., 7th ed., Ziegler, E.E., & Filer, L.J., ILSI Press, Washington D.C., p.130-136.
2. Chow, C.K. (1979) Nutritional influences on cellular antioxidant defense systems. Am. J. Clin. Nutr. 32:1066-1081.
3. Haeger, K. (1974) Long-time treatment of intermittent claudication with Vitamin E. Am. J. Clin. Nutr. 27(10):1179-81.
4. Hermann, W.J. (1979) The effect of tocopherol on high- density lipoprotein cholesterol: A clinical observation. Am. J. Clin. Path. 72:848-852.
5. Kanimura, M. (1972) Antiinflammatory activity of Vitamin E. J. Vitaminol, 18(4):204-209.
6. Leonard, P.J. and Losowsky, M.S. (1971) Effect of alpha-tocopherol administration on red cell survival in vitamin E-deficient human subjects. Am. J. Nutr. 24:388-93.
7. Sundaram, G.S. (1981) Serum hormones and lipoproteins in benign breast disease. Cancer Res. 41:3814-16.

Hi-Pot. Acidophilus w/FOS
GREENLINE

DATE: **DEC 18 1997**
Responsible for the text:



Egan Badart

FRONT LABEL: helps to stabilize the probiotic microflora of the living organism; has a protective action against the overgrowth of harmful bacteria.*

BACK LABEL: Fructo-oligo-saccharides, (FOS), are preferential foods for bifidobacteria and lactobacilli which produce lactic acid, lower pH and decrease the susceptibility of the body to invasion of pathogenic bacteria. Lactobacillus acidophilus in conjunction with Bifidobacteria help to prevent the overgrowth of harmful organisms in the intestine following antibiotic therapy. L. acidophilus, Bifidobacteria and L. bulgaricus contribute to stabilizing the intestinal flora.^{1-7*}

*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to treat, diagnose, cure or prevent any disease.

References:

1. Fernandes, C.F., Shahani, K.M. & Amer, M.A. (1987) Therapeutic role of dietary lactobacilli and lactobacillic fermented dairy products., FEMS Microbiol. Rev., 46, 343-356.
2. Gilliland, S.E. (1990) Health and nutritional benefits from lactic acid bacteria., FEMS Microbiol. Rev., 46, 337-342.
3. Gurr, M.I. (1987) Nutritional aspects of fermented milk products., FEMS Microbiol. Rev., 46, 337-342.
4. Martini, M. et al. (1991) Strains and species of lactic acid bacteria and fermented milk products (yogurt): effect on in vivo lactose digestion. Am. J. Clin. Nutr., 54:1041-1046.
5. Radulovic, D. (1970) Effect of lactobacillus bifidus on Escherichia coli 0111B4., Mikrobiologija 6(2), 225-233.
6. Radulovic, D. (1971) Sensitivity of Candida albicans to lactobacillus bifidus and its active factor. Mikrobiologija 892, 179-187.
7. Rasic, J.L. and Kurmann, J.A. (1978) Yoghurt, Scientific Grounds, Technology, Manufacture and Preparations. ,Vol. 1, Technical Dairy Publishing House, p.362.

DATE: DEC 18 1997

Responsible for text:

PHOSPHATIDYLSERINE - GINGKO biloba complex
GREENLINE


Egan Badart

FRONT LABEL: Contains natural ingredients (sterols, flavonoids, diterpenes) that regulate the following physiological functions: cardiovascular activity, glucose and oxygen uptake by the brain cortex, and blood supply to the brain*

BACK LABEL: Phosphatidylserine and Gingko biloba work synergistically to maintain brain functions. Both are sources of ingredients that improve mental alertness², cognitive status², short term memory⁵ and motor reaction. Gingko biloba also increases blood supply to the brain^{1,4*}

* This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

References:

1. Auguet, M. et al. (1986) Bases pharmacologiques de l'impact vasculaire de l'extrait de gingko biloba. Press Med., 15(31): 1524-1528.
2. Crook, T.H. et al. (1991) Effects of phosphatidylserine in age-associated memory impairment. Neurol. 41: 644-649.
3. Etienne, A., Hecquet, F. et al. (1986) Mecanismes d'action de l'extrait de gingko biloba sur l'oedeme cerebral experimental. Press Med., 15 (31): 150610
4. Le Ponchin-Lafitte, M. et al. (1982) Ischermie cerebrale apres ligature non simultanee de arteres carotide chez le rat: effet de l'extrait de gingko biloba. Sem. Hop Paris, 58: 403.
5. Palmieri, G. et al. (1987) Double-blind controlled trial of phosphatidylserine in subjects with senile mental deterioration. Clin. Trials, 1,24: 73-83.
6. Ransmayr, G. et al. (1987) Double-blind placebo-controlled trial of phosphatidylserine in elderly subjects with arteriosclerotic encephalopathy. Clin. Trials J. 24: 62-72.
7. Willard, T. (1991) The Wild Rose Scientific Herbal. Wild Rose College of Natural Healing. Calgary, Alberta, Canada, p.143.
8. Bruneton, J. (1995) Pharmacognosy. Phytochemistry. Medicinal Plants., Lavoisier Publishing, New York, p. 282.

CALCIUM CITRATE (1000 mg)
GREENLINE

DATE: **DEC 18 1997**
Responsible for the text:



Egan Badart

FRONT LABEL: Calcium is an essential element needed for mineralization of bones and teeth and for functions of muscle and nervous systems. *

BACK LABEL: maintains calcium balance in the body¹ and, specifically, prevents bone demineralization². *

* This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

References:

1. Heaney R.P. (1978) Menopausal changes in calcium balance performance. J. Lab & Clin. Med. 92 (6):953-63.
2. Spencer, H. (1964) Absorption of calcium in osteoporosis. Am. J. Med. 37:223.
3. Squire, J.M., ed. (1990) Molecular mechanism of muscle contraction. Macmillan, London.
4. Kater, S.B., Mattson, M.P., Cohen, C., and Connor, J. (1988). Calcium regulation of the neural growth cone. Trends in Neurological Science, II, 315-321.

ULTRAVIT ENTERPRISES INC.
116 WEST DEL MAR
PASADENA, CA 91106

DATE: **DEC 18 1997**
Responsible for the text:


Egan Badart

CAL - MAG CHEW w/ VITAMIN D
GREENLINE

FRONT LABEL: maintains normal mineralization of bones and teeth and supports the muscle functions. *

BACK LABEL: maintains calcium balance in the body² and specifically, prevents bone demineralization⁵ ; magnesium stimulates incorporation of calcium in bones¹ and regulates neuromuscular activity³; Vitamin D also promotes calcium absorption⁴ *

* This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

References:

1. Hahn, T.J. (1986) Parathyroid hormone, calcitonin, Vitamin D, mineral and bone: Metabolism and disorders, in Mazzaferri EL, Textbook of Endocrinology. Third edition, New York, Elsevier Science Publishing Co., p. 467.
2. Heaney R.P. (1978) Menopausal changes in calcium balance performance. J. Lab & Clin. Med. 92 (6):953-63.
3. Iseri, L.T., French, J.H. (July 1984) Magnesium: Nature's calcium blocker. Am. Heart J. p.188.
4. Passmore, R., Eastwood, M.A. (1986) Davidson and Passmore: Human Nutrition and Dietetics. Eighth edition. London, Churchill Livingstone, p. 139.
5. Spencer, H. (1964) Absorption of calcium in osteoporosis. Am. J. Med. 37:223.

ULTRABONES
GREENLINE

DATE: **DEC 18 1997**
Responsible for the text:



Egan Badart

FRONT LABEL: supports the system of connective tissue of the body. *

BACK LABEL: Combination of essential minerals, trace elements, vitamins, and important components of the connective tissue system supports the diet not only in maintaining the extracellular ground substance and the insoluble protein fibers that are embedded in this ground substance but also in the state of mineralization of bones and teeth. Well functioning connective tissues are able to cope with mechanical stresses and to maintain the shape of your body.¹⁻¹⁶ *

*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

References:

1. Arnaud, C. & Sanchez, S. (1996) Calcium and Phosphorus. In Chap. 24 of Present Knowledge in Nutrition, Ziegler, E.E. & Filer, L.J., ILSI, Washington D.C., p.245.
2. Bernat, I. (1983) Iron deficiency, in Iron Metabolism. New York, Plenum Press p. 215-74.
3. Gallagher, J.C. (1979) Intestinal calcium absorption and serum Vitamin D metabolites in normal subjects and osteoporotic patients. J. Clin. Inves. 64: 729.
4. Hahn, T.J. (1986) Parathyroid hormone, calcitonin, Vitamin D, mineral and bone: Metabolism and disorders, in Mazzaferri El, Textbook of Endocrinology. Third edition, New York, Elsevier Science Publishing Co., p. 467.
5. Harper, A.E. (1983) Dispensable and Indispensable Amino Acid Interrelationships. Amino Acids Metabolism and Medical Applications Chap 7, John Wright, PSG Inc., Boston, p. 105-119.
6. Hiebert, C.A. (1977) Gastroesophageal reflux and ascorbic acid deficiency. Ann. Thorac. Surg. 24(2): 108-12.
7. Khmelevski,i, Iu V. (July - August 1985) Effect of Vitamins A, E, and K on the indices of the glutathione antiperoxidase system in gingival tissues in periodontosis. Vopr. Pitan. (4):54-56.
8. Linder, M.C. (1991) Nutritional Biochemistry and Metabolism with Clinical Applications., Elsevier, New York, p.247.
9. Monsen, E.R. (1982) Ascorbic acid: An enhancing factor in iron absorption, in Nutritional Bioavailability of Iron. American Chemical Society, 1982, pp. 85-95.
10. Neilsen, F.H. (1996) Other Trace Elements. In Chap. 35 of Present Knowledge in Nutrition. ILSI, Washington D.C., p.353.

11. Simonoff, M. (1984) Low plasma chromium in patients with coronary artery and heart diseases. *Biological Trace Elements Res.* 6:431.
12. Spencer, H. (1964) Absorption of calcium in osteoporosis. *Am. J. Med.* 37:223.
13. Vaz, A.L. (1982) Double-blind clinical evaluation of the relative efficacy of ibuprofen and glucosamine sulphate in the management of osteoarthritis of the knee in outpatients. *Curr.Med.Res.Opin.* 8(3): 145-149.
14. Willis, G.C. (July 15, 1957) The reversibility of atherosclerosis. *Canad. Med. Assoc. J.* p. 106-09.
15. Wolfe, S.N. (1980) Ascorbic acid and periodontal disease: A review of literature. *Periodt. Abstr.* 28 (2): 44-56.
16. Wolfe, S.N. (1984) Relationship of ascorbic acid levels of blood and gingival tissue with response to periodontal therapy. *J. Clin. Periodontal.* 11(3): 159-65.

ULTRAGEVITY
GREENLINE

DATE: **DEC 18 1997**
Responsible for the text:



Egan Badart

FRONT LABEL: contains antioxidants and other dietary components that help maintain a state of well-being of the body. *

BACK LABEL: Lecithin supports the integrity of biomembranes; it is also a source of choline, a nutrient necessary for the healthy functioning of cells, nerves and the brain^{3,6,13}. Zinc is essential for enzyme catalytic, structural, and regulatory functions in the body,¹. Chromium works with insulin to promote the metabolism of fats and carbohydrates^{5,9}; Selenium is a powerful antioxidant which works synergistically with Vitamins A, C, & E^{4,10}. Garlic helps to maintain the fluidity of the blood and the functions of the cardiovascular system^{2,7,12} *.

* This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

References:

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BETA-CAROTENE (25,000 I.U.)
GREENLINE

DATE: **DEC 18 1997**
Responsible for the text:



Egan Badart

FRONT LABEL: Beta - Carotene is a precursor of Vitamin A. It is an antioxidant. Diets containing beta-carotene present in fruits and vegetables have been associated with many health maintaining properties. *

BACK LABEL: beta-carotene is used in its natural form from algae Dunaliella salina. In addition to beta carotene, the Dunaliella isolate contains other carotenoids: alpha - carotene, zeaxanthin, cryptoxanthin and lutein.^{1-4*}

*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease

References:

1. Block, G. (1994) Nutrient sources of provitamin A carotenoids in the American diet. Am. J. Epidemiol., 139:290-293.
2. Blumberg, J. (1995) Considerations of the scientific substantiation for antioxidant vitamins and carotene in disease prevention. Am. J. Clin. Nutr. 62(Suppl): 1521S-1526S.
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DATE: **DEC 18 1997**

Deluxe Anti-Oxidant/Ultra Anti-Oxidant
GREENLINE Responsible for the text:


Egan Badart

FRONT LABEL: provides a mixture of lipid- and water- soluble, natural, occurring in plants, antioxidants acting synergistically. *

BACK LABEL: Contains vitamin antioxidants, C and A. Also contains a mixture of phyto-antioxidants (plant-derived ones) :polyphenols from green tea leaves, lycopene, pycnogenols, and antioxidants from grape seeds, turmeric, rosemary, and bilberry. The antioxidants are free radical scavengers, especially oxygen containing free radicals that reorganize metabolism of the tissues. ^{1-15*}

* This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

References:

1. Ascherio, A., Rimm, E.B., Stampfer, M.J., Colditz, G.A., and Willet, W.C. (1995) Intake of carotenoids and retinol in relation to risk of prostate cancer. J. Natl. Cancer. Inst. (1995) 7(23): 1767-1769.
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Ultra Eyes
GREENLINE

DATE: **DEC 18 1997**
Responsible for the text:



Egan Badart

FRONT LABEL: supports the replenishment of nutrients important for maintaining the function of the eye.*

BACK LABEL: Taurine with bilberry extract help to maintain retinal functions of the photoreceptor cells responsible for adaptation to light, dark, and for the enlargement of the visual field. Selenium in combination with Vitamins A, C, & E helps to protect the eye tissues from oxidative damage. Vitamin A along with the other carotenoids helps the formation of visual purple¹⁻¹⁸.*

*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

References:

1. Atkinson, D. (1952) Malnutrition as an etiological factor in senile cataract. *Eye, Ear, Nose & Throat Monthly*, 31: 79-83.
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DATE: **DEC 18 1997**

Responsible for the text:

FOOD MULTI HI-POTENCY VEGETARIAN FORMULA / Ultra Source
GREENLINE



Egan Badart

FRONT LABEL: a dietary supplement that improves vegetarian diet, supports removal of wastes from the body, and supports the vascular system.*

BACK LABEL: The combination of vitamins and minerals supply the diet with materials essential to maintain normal functions of the nervous system, respiratory system, cardiovascular system and gastrointestinal tract. The blend of herbs and fibers, specifically apple pectin, oat bran, and barley juice, have emollient and tonic properties^{1-35*}

* This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

References:

1. Bauer, U. (1984) 6-month double blind randomized clinical trial of ginkgo biloba extract versus placebo in 2 parallel groups in patients suffering from peripheral arterial insufficiency., *Arzn.-Forsch.* 34: 716-21.
2. Bender, D.A. (1992) Vitamin A: retinol and -carotene, in *Nutritional Biochemistry of the Vitamins*, Cambridge University Press, Cambridge, 19-26.
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7. Davis, W.H. (1984) Monotherapy with magnesium increases abnormally low high density lipoprotein cholesterol: A clinical essay. *Curr. Ther. Res.* 36: 341.
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MAGNESIUM COMPLEX 500 mg
GREENLINE

DATE: **DEC 18 1997**
Responsible for the text:



Egan Badart

FRONT LABEL: Magnesium participates in the synthesis of body proteins and specifically maintains the heart and muscles functions.*

BACK LABEL: maintains cardiovascular functions^{1,3,6,7,9}; inhibits platelet aggregation^{2,5}; assists in the correction of muscle potassium deficiencies¹⁰, bone growth⁴, and aids function of nerves and muscles^{4,8*}

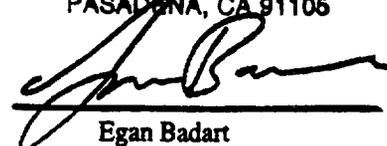
* This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

References:

1. Burch, G.E. and Giles, T.D. (November 1977) The importance of magnesium deficiency in cardiovascular disease. *Am. Heart J.* 94(5):649-657.
2. Davis, W.H. (1984) Monotherapy with magnesium increases abnormally low high density lipoprotein cholesterol: A clinical essay. *Curr. Ther. Res.* 36:34.
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10. Shils, M.E. (1996) Magnesium. In Chap. 25 of *Present Knowledge in Nutrition*, 7th ed., Ziegler, E.E. & Filer, L.J., ILSI Press, Washington D.C., p.256.

ULTRA HERS
GREENLINE

DATE: **DEC 18 1997**
Responsible for the text:



Egan Badart

FRONT LABEL: a dietary supplement that supports the metabolic and physiological functions of the female body.*

BACK LABEL: The combination of vitamins and minerals along with the combination of herbs helps maintain body homeostasis, maintain the vascular system, general resistance, and proper mineralization.^{1-36*}

* This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

References:

1. Ayres, S. and Miahn, R. (1978) Is Vitamin E involved in the autoimmune mechanism *Cutis* 21:321 - 25.
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18. Henkin, R.I. (1974) Zinc in wound healing. Editorial. *N. Engl. J. Med.* 291 913): 675-76.
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35. Willis, G.C. (July 15, 1957) The reversibility of atherosclerosis. *Canad. Med. Assoc. J.* pp. 106-09.
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FOLIC ACID (800 mcg)
GREENLINE

DATE: DEC 18 1997
Responsible for the text:



Egan Badart

FRONT LABEL: An essential nutrient, helps general metabolism, specifically transmethylations, and the development and maintenance of the nervous system particularly during early pregnancy. *

BACK LABEL: promotes normal red-blood-cell formation^{4,5} maintains nervous system^{3,4}; intestinal tract^{1,2}; sex organs⁵ white blood cells⁵ normal patterns of growth⁵ regulates embryonic development of nerve cells⁶ and promotes normal growth and development^{5*}

* This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

References:

1. Butterworth, C.E. Jr., & Bendich, A. (1996) Folic Acid and The Prevention of Birth Defects. *Ann. Rev. Nutr.*, 16: 73-97.
2. Carruthers, L.B. (1946) Chronic diarrhea treated with folic acid. *Lancet* 1:849.
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STRESS B w/ HERBS
GREENLINE

DATE: DEC 18 1997
Responsible for the text:



Egan Badart

FRONT LABEL: helps in the maintenance and adjustments of metabolism facing changes of the internal or external environments.*

BACK LABEL: Water soluble vitamins, methyl group donors (choline) and an adaptogen, Siberian Ginseng (*Eleuterococcus senticosus*,²⁵) participate in the maintenance of homeostasis of the organism that is exposed to various internal and external changes and disturbances¹⁻²⁵. *

*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

References:

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SAW PALMETTO BERRY EXTRACT -160 mg
GREENLINE

DATE: **DEC 18 1997**

Responsible for the text:


Egan Badart

FRONT LABEL: contains lipid and sterol substances (phytosterols: sitosterol free and esterified, campesterol, cycloartenol; polyprenols) which have mild tonic and nutritive properties^{1-4*}

BACK LABEL: Saw palmetto supplies components that help to maintain the prostate metabolism^{2,3} and exhibits both stimulatory and stabilizing effects on the body^{1-4*}

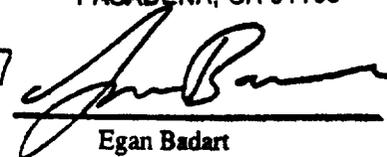
*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

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ULTRAHIS
GREENLINE

DATE: DEC 18 1997
Responsible for the text:


Egan Badart

FRONT LABEL: equips the male body with dietary supplementation that supports the diet in promoting human metabolic and physiological functions.*

BACK LABEL: The combination of antioxidants and minerals that, working synergistically increase energy yield, promote growth, development and recuperation. The combination of cayenne and saw palmetto aids in digestion and helps maintain the prostate metabolism^{1-25*}

* This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

References:

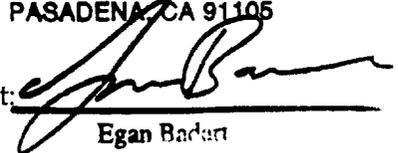
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DATE: **DEC 18 1997**

CAT'S CLAW - 250 mg
GREENLINE

Responsible for the text:


Egan Badart

FRONT LABEL: secures functioning of the cardiovascular system and connective tissue².*

BACK LABEL: Cat's Claw (*Uncaria tomentosa*), a traditional Peruvian herb, supports the general cellular metabolism, especially the digestive processes^{1,2,3,4}. *

* This statement has not been evaluated by the Food and Drug Administration. This product is not to be intended to diagnose, treat, cure or prevent any disease.

References:

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DATE: **DEC 18 1997**
Responsible for the text:



Egan Badart

Super C, E & Carotene + Selenium & Bioflavonoids
GREENLINE

FRONT LABEL: A natural antioxidant formula; supports the regular action of oxidation-reduction systems of the body metabolism *

BACK LABEL: Vitamin C strengthens the immune system; Citrus Bioflavonoids have antioxidant properties that act synergistically with Vitamin C ; Vitamins E and A are lipid soluble antioxidants ; Selenium supports the functions of all the antioxidant vitamins present
1-10 *

*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

References:

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Anti - Yeast
GREENLINE

DATE: **DEC 18 1997**
Responsible for the text:



Egan Badart

FRONT LABEL: participates in regulating metabolic functions of the body including body's resistance.*

BACK LABEL: components of this product : vitamins, plant extracts and Lactobacillus acidophilus support the diet by improving diets regulatory properties.^{1-8*}

* This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

References:

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