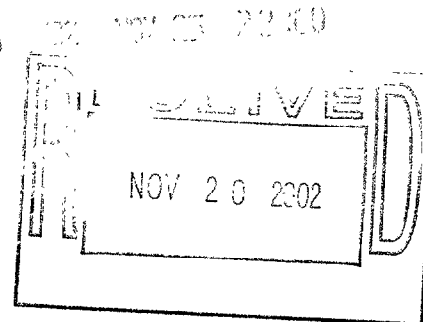


4700 Westside Avenue  
North Bergen, NJ 07047



Telephone: 201-866-7711  
www.vitaminshoppe.com

Vitamin Shoppe Industries Inc.



November 14, 2002

Dr. Robert Moore  
Branch Chief (HFS-811)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
Harvey W. Wiley Federal Building  
5100 Paint Branch Parkway  
College Park, MD 20740-3835

Re: FDCA 403(r)(6) Notification

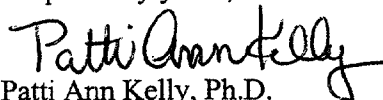
Dear Dr. Moore:

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)), Vitamin Shoppe Industries Inc. submits this notification that statements are included in labeling its dietary supplements, as attached.

Vitamin Shoppe Industries Inc. at 4700 Westside Avenue, North Bergen, New Jersey is the distributor of the dietary supplements.

The undersigned certifies that the information contained in this notice is complete and accurate, and that the notifying firm has substantiation that each statement is truthful and not misleading.

Respectfully yours,

  
Patti Ann Kelly, Ph.D.  
Director of Scientific and Regulatory Affairs  
Vitamin Shoppe Industries Inc.

97S 0162

LET

11239

82623

Also see docket 97S-0163

Item #	Name	Basis for Structure/Function Statement	Structure/Function Statement	Structure/Function Category
vsu-6018	Echinacea Goldenseal Complex	Echinacea purpurea (herb)	Promotes immune health	
vs-1028 vs-1029	E-400 with Selenium 50 mcg	Vitamin E (as d-alpha, gamma, beta, delta tocopherols) Selenium (as l-selenomethionine)	Selenium, an antioxidant, enhances the antioxidant activity of vitamin E.	
vs-1032 vs-1033	Phosphatidyl Choline 385 mg	Phosphatidyl Choline(from soy lecithin)	Essential for healthy liver function.	
vs-1036 vs-1037	Selenium 50mcg	Selenium (from yeast)	An essential mineral that supports the antioxidant activity of vitamin E . Antioxidant protection against free radicals.	
vs-1072 vs-1073 vsu-6001	Beta Carotene 25,000 IU Vitamin A activity	Vitamin A (as 100% beta-carotene)	Beta-carotene protects the body against free radicals. Supports immune and eye health.	
vs-1082 vs-1083	Zinc 100 mg	Zinc (as zinc citrate)	Zinc supports immune system function . Supports immune health.	
vs-1084 vs-1085	Magnesium Citrate Complex	Magnesium (as magnesium citrate, oxide)	Magnesium maintains healthy bones and teeth. Magnesium is necessary for protein synthesis. It is very important for proper functioning of the nervous system as well as cell and heart functions.	
vs-1091 vs-1092	TMG	Trimethylglycine (TMG) (as betaine) (from sugar beets)		Cardiovascular
vs-1117 vs-1118 vs-1174 vsu-6010	Chelated Cal-Mag	Calcium (as carbonate, amino acid chelate) Magnesium (as oxide, amino acid chelate)	Maintains healthy bones and teeth .	
vs-1136 vs-1137	C-500 with Acerola	Vitamin C (as sodium ascorbate)	An antioxidant to support immune function, vascular and joint health.	
vs-1166 vs-1167	Choline	Choline (from 650 mg choline bitartrate)	Involved in absorption and transport of fat.	
vs-1179 vs-1180 vsu-6019	Zinc Lozenges Plus	Zinc (as gluconate, oxide)	Supports immune health. Zinc supports immune system function.	
vs-1183 vs-1184 vs-1658	Deodorized Garlic 500	Garlic(Pure-Gar®) (Allium sativum) (bulb)	Promotes cardiovascular health. Garlic helps maintain healthy cardiovascular and immune function. It also helps maintain cholesterol levels that are already within the normal range.	Cardiovascular
vs-1224 vs-1225	Calcium Magnesium Complex	Calcium (as carbonate, caseinate) Magnesium (as oxide)	Maintains healthy bones and teeth.	
vs-1252 vs-1253	Marine Carotene 25,000 IU Vitamin A Activity	Vitamin A (Betatene®) (as beta-carotene from Dunaliella salina)	Supports immune and eye health.	Antioxidants
vs-1258 vs-1259	C-2000 Complex Buffered Powder	Vitamin C (as calcium ascorbate)	An antioxidant to support immune, vascular and joint health.	

Item #	Name	Basis for Structure/Function Statement	Structure/Function Statement	Structure/Function Category
vs-1261 vs-1262	Non-Oily Dry A 10,000 IU	Vitamin A (as retinyl acetate)	Supports eye health and immune function. Dry A- Vitamin A is essential for eye health as well as immune function.	
vs-1271 vs-1293	Carotenoid Complex	Vitamin A (as beta-carotene) Lycopene (Lyc-O-Mato™) (from tomato) Lutein (FloraGlo®) (from marigolds) Alpha-Carotene Zeaxanthin Gamma-Carotene Cryptoxanthin	Antioxidants that protect against free radicals. Carotenoid Complex contains 7 carotenoids that can be beneficial to the human body.	Antioxidants
vs-1299 vs-1308	Boron 3 mg	Boron (as amino acid chelate)	Supports bone health. Boron promotes bone health.	
vs-1310 vs-1311	No-Flush Niacin 500 mg	Niacin (as inositol hexaniacinate) Inositol (as inositol hexaniacinate)	Supports normal cholesterol. Niacin helps maintain cholesterol levels that are already within the normal range.	
vs-1332	Garlic Odor Free	Garlic (Pure-Gar®) ( <i>Allium sativum</i> ) (clove)	Promotes cardiovascular health. Garlic helps maintain healthy cardiovascular and immune function. It also helps maintain cholesterol levels that are already within the normal range.	Cardiovascular
vs-1400	Woman's Magnesium Complex AM	Magnesium (as magnesium citrate, oxide, hydroxyapatite)	Promotes healthy bones and teeth.	
vs-1402	Life Changes	Vitamin E (as d-alpha tocopheryl succinate) Vitamin B6 (as pyridoxine HCl) Chromium (ChromeMate®) (as chromium polynicotinate) Black Cohosh ( <i>Cimicifuga racemosa</i> )(root) Chasteberry ( <i>Vitex agnus-castus</i> ) (fruit)	Menopause support. Life Changes is a formula that contains vitamins, minerals, and herbs such as Black Cohosh, Chasteberry which promote well-being during a woman's life transition (menopause).	
vs-1406 vs-1407 vs-1408	Nutritional Support for Joints	Glucosamine Sulfate 2KCl Chondroitin Sulfate Boswellin® ( <i>Boswellia serrata</i> )	Promotes healthy flexible joints.	Joint Solutions
vs-1414	Alpha Lipoic Acid 100 mg	Alpha-Lipoic Acid	Protects against free radicals. Alpha lipoic acid is a coenzyme of energy producing reactions at the cellular level. Known as the "universal antioxidant" as it is both fat and water soluble. It helps maintain healthy blood glucose levels. Alpha lipoic acid supports glucose uptake and utilization. Preliminary research suggests it may protect the heart, nervous system and cognitive function as we age.	Antioxidants

Item #	Name	Basis for Structure/Function Statement	Structure/Function Statement	Structure/Function Category
vs-1451	Gugulipids Extract	Gugulipids Extract (Commiphora mukul) (resin)	Supports normal cholesterol levels. Gugulipids supports cholesterol levels already within the normal range.	
vs-1455 vs-1473	Allicin 4000 Garlic	Garlic (Pure-Gar®) (Allium sativum) (clove)	Promotes cardiovascular health. Garlic helps maintain healthy cardiovascular and immune function. It also helps maintain cholesterol levels that are already within the normal range.	Cardiovascular
vs-1458 vs-1459	HMB™ Patented Protein Breakdown Suppressor	HMB™	Recovery agent. HMB supplementation with a strength training program can be beneficial for body composition and can support development of lean body mass.	Protein breakdown suppressor.
vs-1516 vs-1517	Calcium Lactate	Calcium (Puracal ®) (as calcium lactate trihydrate)	Maintains healthy bones and teeth.	
vs-1521	Calcium Gluconate	Calcium (as calcium gluconate)	Maintains healthy bones and teeth.	
vs-1523	Homocysteine Blocker	Vitamin B6 (as pyridoxine HCl) Folic Acid Vitamin B12 (as cyanocobalamin)	Elevated levels of homocysteine, an amino acid metabolite, can be a risk factor for cardiovascular and heart health. Recent research has shown that folic acid, and vitamins B12 and B6 promote normal levels of homocysteine and enhance cardiovascular health.	
vs-1524	Lactase Enzyme	Lactase Enzyme	For natural lactose digestion. Lactase is an enzyme that breaks down lactose. It helps individuals with an inability to fully digest lactose to consume products containing lactose, such as dairy products.	Digestive health
vs-1550 vs-1551 vs 1552	E-200 IU; E-600 IU	Vitamin E (as d-alpha, gamma, beta, delta tocopherols)	An antioxidant to promote cardiovascular and joint health.	
vs-1570 vs-1613	Ginkgo Neuro-Mind	Vitamin B6 (as pyridoxine HCl); Vitamin B12 (as cyanocobalamin) Ginkgo biloba Extract (leaf) Phosphatidylserine (Leci-PS™) DHA	Ginkgo Neuro-Mind	Memory Booster
vs-1573	Ginkgo Energizer	Ginkgo biloba (leaf) Coenzyme Q10	Promotes energy and circulation	Energy Booster
vs-1579	Immune Complete	Vitamin A (as 100% beta carotene) Vitamin C (as ascorbic acid) Zinc (as zinc gluconate) Echinacea purpurea Extract Elderberry Extract (Sambucus Nigra) Astragalus membranaceous (root)	Immune complete	Immune Booster

Item #	Name	Basis for Structure/Function Statement	Structure/Function Statement	Structure/Function Category
vs-1638	Aged Garlic Extract™	Aged Garlic Extract™ Powder (bulb)	Promotes cardiovascular health. Garlic helps to maintain healthy cardiovascular and immune function. It also helps maintain cholesterol levels that are already within the normal range.	Cardiovascular
vs-1654	Psyllium Husks Powder	Psyllium Seed Husk Powder	Supports Healthy Regularity Psyllium husks helps support healthy colon movement, and help to maintain regularity.	Intestinal health and colon care.
vs-1668 vs-1739	Horse Chestnut Extract	Horse Chestnut Extract (Aesculus hippocasranum) Horse Chestnut (Aesculus hippocastanum)	Supports leg vein circulation	
vs-1699 vs-1701 vs-1706	Spiru-Soy	Supro ® soy protein isolate	Soy Protein Promotes Cardiovascular and Bone Health.	
vs-1705	Astaxanthin	Astaxanthin (BioAstin ®) (from marine-algae) (Haematococcus pluvialis)	Protects against free radicals. A powerful antioxidant. Asthaxanthin is a natural carotenoid derived from microalgae and a powerful antioxidant.	Antioxidants
vs-1721	Chlorophyll	Chlorophyllin Copper Complex	Chlorophyll Concentrate works to help reduce odors originating in the digestive tract.	
vs-1724 vs-1725	Maximum Strength Milk Thistle Extract 175 mg	Milk Thistle Extract (Silybum marianum) (seed/fruit)	Milk Thistle helps maintain healthy liver function.	
vs-1731	Allicin 6000 Garlic	Garlic (Pure-Gar ®) (Allium sativum) (clove)	Promotes cardiovascular health	Cardiovascular
vs-1734	Tonalin CLA Liquid	Tonalin ® Proprietary Blend (from safflower seeds)	Supports reduction of body fat. CLA has been shown to play a vital role in reducing body fat and enhancing/preserving lean muscle mass according to human clinical studies and laboratory testing. This product may support a weight management or diet program that includes regular exercise and a calorie restricted diet.	Weight Management
vs-1745	Carb Shredder	Chromium (Chromax ®)(as chromium picolinate) White Kidney Bean Extract (Phaseolamin 2250™)(Phaseolus vulgaris)(dried bean) Korean Ginseng Extract (Panax ginseng) (root) Green Tea Extract (Camellia var. sinesis)(leaf)	With Phaseolamin™, an amylase inhibitor. Amylase is an enzyme responsible for breaking down starch into glucose. Chromium plays a role in glucose utilization, enhances glucose uptake and may enhance body composition. Green tea enhances metabolic rate. Ginseng supports normal blood glucose levels. Chromium picolinate supplementation may support a decrease in body fat and preservation of lean body mass.	Weight Management

Item #	Name	Basis for Structure/Function Statement	Structure/Function Statement	Structure/Function Category
vs-1763 vs-1764	Ipriflavone	Ipriflavone (Ostivone™) (7-Isopropoxy Isoflavone)	Maintains Healthy Bone Density. Used for years in Europe and Japan. Ostivone™ has been shown clinically to promote bone strength and health.	Bone Solutions
vs-1765	Occu-Plus with Lutein	Vitamin A (as 100% beta-carotene) Lutein (FloraGLO®)(from marigolds) Zeaxanthin (from marigolds) Bilberry (Vaccinium myrtillus)(leaf) standardized to 25% Anthocyanidins	Advanced supplement for normal vision. Designed to help support healthy vision. Supports eye health.	Eye Health
vs-1770 vs-1771	Salmon Oil	Salmon Oil - providing: . 12% EPA (Eicosapentaenoic Acid) & . 18% DHA (Docosahexaenoic Acid)	Omega-3 Fatty Acids for Cardiovascular and Joint Health. These fatty acids play important roles, including support of cardiovascular and joint function, as well as healthy brain development.	
vs-1812	Relora	Proprietary Blend: Magnolia officinalis Phellodendron amurense (bark)	May support mood and promote relaxation	
vs-1824 vs-1825	Easy to swallow Calcium 1000	Vitamin D (as cholecalciferol) Calcium (as calcium carbonate)	Maintains healthy bones. Calcium and vitamin D help maintain healthy bones.	
vs-1826	L-Theanine	L-Theanine(Suntheanine ®)	L-Theanine helps to support relaxation and a calm mood.	Mood Support
vs-1828 vs-1829	Easy to swallow C-1000	Vitamin C (as ascorbic acid)	An antioxidant to support immune function, vascular and joint health. Vitamin C is an antioxidant that protects against free radical damage.	
vs-1844	E-200 IU plus C-500	Vitamin C (as ascorbic acid) Vitamin E (as d-alpha, gamma, beta, delta tocopherols)	Antioxidants to promote immune and cardiovascular health	
vs-1846	Ultra Sugar Aid with Diachrome™	Biotin (as Diachrome™) Magnesium (as magnesium oxide) Zinc(OptiZinc ®) Chromium (Chromax ®) (as chromium picolinate) Gymnema sylvestre (leaf) Fenugreek (trigonella foenum-graceum) (seed) Alpha Lipoic Acid Inositol	Ultra Sugar Aid supports glucose uptake and normal blood glucose levels. Chromium and Biotin work together to support normal blood glucose levels. Chromium and Biotin play a role in glucose utilization.	
vs-1854	UC II	Undenatured Type II collagen (from chicken sternum cartilage)	Promotes healthy flexible joints.Promotes healthy joints, and enhances joint mobility and flexibility.	Joint Solutions
vs-1868	Biotin	Biotin	Biotin, a member of the B-vitamin family, is involved in the synthesis of fatty acids and glucose, and the metabolism of the branched chain amino acids. Studies have shown that biotin may support glucose utilization, as well as provide nutritional support for healthy hair and nails.	

Item #	Name	Basis for Structure/Function Statement	Structure/Function Statement	Structure/Function Category
vs-1876	Ascorbyl Palmitate	Vitamin C (as ascorbyl palmitate)	Ascorbyl palmitate is known for skin care due to the antioxidant properties of Vitamin C, and the role of Vitamin C in collagen synthesis.	
vs-1879	Glucosamine & Chondroitin Sulfate with ESTER C ®	Vitamin C (Ester C ®) (as calcium ascorbate) Glucosamine Sulfate 2KCl Chondroitin Sulfate A	Maintains healthy flexible joints. Glucosamine and Chondroitin Sulfate support cartilage function and maintain healthy joints. Vitamin C supports joint health. Enhances joint mobility and flexibility.	Joint solutions
vs-1884	Boswellia Serrata Standardized Extract 250 mg	Boswellia serrata Extract (Boswellin ®) (resin)	Supports joint health.	
vs-1901	Easy to Swallow Kava Kava Extract	Kava Kava Extract (Piper methysticum) (root)	Promotes calm and relaxation.	
vs-1905	Phaseolamin 2250™	White Kidney Bean Extract (Phaseolamin 2250™)(Phaseolus vulgaris)(dried bean)	An amylase inhibitor. Amylase is an enzyme responsible for breaking down starch into glucose.	
vs-1910 vs-1911	Beta-sitosterol	Phytosterol Concentrate (Beta Sitosterol, Campesterol, Sigmasterol)	Supports Normal Cholesterol. Supports cholesterol levels that are already within the normal range supports cardiovascular health.	Cholesterol Solutions
vs-1922 vs-1923	Tonalin CLA 1000 mg	Tonalin ® Proprietary Blend containing: Conjugated Linoleic Acid	Supports reduction of body fat. CLA has been shown to play a vital role in reducing body fat and enhancing/preserving lean muscle mass according to human clinical studies and laboratory testing. This product may support a weight management or diet program that includes regular exercise and calorie restricted diet.	Weight Management
vs-1943	Ashwagandha	Ashwagandha Extract (Withania somnifera)(root) (standardized to 1.5% Withanolides)	Traditionally used as an adaptogen - an herb with multiple, nonspecific actions that counteract the effects of stress and generally promote wellness.	
vs-1946	Artichoke Extract	Artichoke Extract (Cynara scolymus)(leaf) (standardized to 13-18% Caffeoylquinic acids calculated as chlorogenic acid)	Supports normal cholesterol Supports cholesterol levels that are already within the normal range. Digestive aid.	

Item #	Name	Basis for Structure/Function Statement	Structure/Function Statement	Structure/Function Category
vs-1952	Estromensil	Plant Estrogens (Isoflavones)(as red clover extract)	Maintains bone health. Promotes emotional well-being. Scientific evidence suggests isoflavones may support a woman's estrogen level as she ages. Estromensil also supports bone health and emotional well-being, important factors for living healthy during mid-life. Estromensil is the ideal daily supplement to support a woman's estrogen levels before and during mid-life. Estromensil has been shown to maintain bone health and promote emotional well-being.	
vs-1955	Vinpocetine	Vinpocetine	Supports brain and memory function Research has shown that Vinpocetine works by increasing oxygen and blood flow to the brain.	Memory Booster
vs-1970	Fennel Seed 480 mg	Fennel ( <i>Foeniculum vulgare</i> ) (seed)	Digestive support.	
vs-1973	Calcium Citrate	Calcium (as calcium citrate)	Maintains healthy bones and teeth. It is essential for building and maintaining strong teeth and bones.	
vs-1976	Magnesium Citrate	Magnesium (as magnesium citrate)	Maintains healthy bones and teeth. Magnesium is necessary for protein synthesis and for the proper functioning of the nervous, cardiovascular, and muscular skeleton systems .	
vs-2025 vs-2026 vs-2027	Echinacea 400 mg	Echinacea purpurea (herb)	Promotes immune health. Echinacea supports the body's immune system.	
vs-2028 vs-2029	Echinacea Goldenseal Complex	Echinacea purpurea (herb) Echinacea angustifolia (herb)	Promotes immune health. Echinacea supports the body's immune system.	
vs-2078	Tonalin CLA Liquid	Tonalin ® Proprietary Blend (from safflower seeds) providing: Conjugated Linoleic Acid 740 mg-820 mg	Weight and diet management. CLA has been shown to play a vital role in reducing body fat and enhancing/preserving lean muscle mass according to human clinical trials and laboratory testing. This product may support a weight management or diet program that includes regular exercise and a calorie restricted diet.	
vs-2079 vs-2102 vs-2159	Milk Thistle Extract 70 mg	Milk Thistle Extract ( <i>Silybum marianum</i> )(seed/fruit)	Maintains liver health.	



Item #	Name	Basis for Structure/Function Statement	Structure/Function Statement	Structure/Function Category
vs-2151	NutraFlora ® FOS	NutraFlora ® FOS (Fructo-oligosaccharides)	A probiotic enhancer.	Intestinal health and colon care.
vs-2153 vs-2154	Citrimax plus Chromium Picolinate	Chromium (Chromax ®)(as chromium picolinate)	Chromium supports glucose uptake and fat metabolism. Chromium plays a role in glucose utilization, may enhance body composition.	Weight Management
vs-2191 vs-2193	AHCC	AHCC ® Proprietary Blend (Acetylated Alpha and Beta Glucan). Rice Bran, Mycelia Extract from 5 Basidiomycetes mushrooms including Shitake	Patented Immune Enhancing Complex. Research suggests that AHCC may play a role in increasing Natural Killer Cells (NK), Killer T-Cells, macrophages, and interleukin-12 (IL-12, a powerful cytokine that is instrumental in maintaining cell health, all of which support a body's natural defense mechanism.	Immune Booster
vsu- 6008	B-Complex 100 - Kosher	Thiamin (vitamin B1) (as thiamin mononitrate) Riboflavin (vitamin B2) Niacin (as niacinamide) Vitamin B6 (as pyridoxine HCl) Folic Acid Vitamin B12 (as cyanocobalamin) Biotin Pantothenic Acid (as d-calcium pantothenate) Choline (as choline bitartrate) Inositol PABA(para-aminobenzoic acid)	Promotes energy, mental and heart health.	
vsu-6012	C-500 with Rose Hips	Vitamin C (as ascorbic acid) Rose Hips (Rosa canina)(fruit)	An antioxidant to support immune, vascular and joint health.	
vsu-6013	C-500 Complex	Vitamin C (as ascorbic acid)	An antioxidant to support immune, vascular and joint health.	
vsu-6014	Magnesium Citrate	Magnesium (as magnesium citrate)	Maintains healthy bones and teeth.	