

The Vitamin Shoppe Since 1977[®]

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VITAMIN SHOPPE INDUSTRIES INC.

September 15, 2000

Dr. Robert Moore
Branch Chief (HFS-811)
Dietary Supplements Branch
Food and Drug Administration
200 C Street S.W.
Washington D.C. 20204

Rec'd
SEP 26 2000

Re: FDCA 403(r)(6) Notification

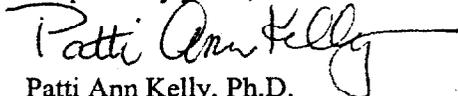
Dear Dr. Moore: . .

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.

975-0162

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<u>Product Names</u>	<u>VS#</u>	<u>Ingredients</u>	<u>Structure/Function Statements</u>
Bio-C-Complex 500	1006, 1007	Bioflavonoids	1) Bioflavonoids improve absorption of Vitamin C.
B Vitamins	Header Copy	B Vitamins	1) B vitamins are utilized in the metabolism of fat, converting carbohydrates into energy, and proper functioning of the nervous system.
Pantethine Complex	1057	Pantothenic Acid	1) Pantothenic acid is a major constituent of a cofactor called coenzyme A, which is essential in the metabolism of carbohydrates and fats.
Vitamin B-1 (Thiamin Mononitrate)	1142, 1143 1144, 1145	Vitamin B-1	1) Vitamin B-1 is essential for normal functioning of all body cells, especially nerves. 2) Vitamin B-1 is involved in the body processes that breakdown carbohydrates, protein and fat for energy.

<u>Product Names</u>	<u>VS#</u>	<u>Ingredients</u>	<u>Structure/Function Statements</u>
Vitamin B-2 (Riboflavin)	1146, 1147	Vitamin B-2	<ol style="list-style-type: none"> 1) Vitamin B-2 is involved in the body processes that breakdown carbohydrates, protein and fat into energy. 2) Vitamin B-2 is important for normal growth and development.
Pantothenic Acid	1150, 1151 1152, 1153 1154, 1155	Pantothenic acid	<ol style="list-style-type: none"> 1) Pantothenic acid is converted to coenzyme A in the body, an important catalyst in the breakdown of fats, carbohydrates and proteins in the body. 2) Pantothenic acid plays a role in energy production and the formation of adrenal hormones and red blood cells.
Vitamin B-12 (Cyanocobalamin)	1170, 1171	Vitamin B-12	<ol style="list-style-type: none"> 1) Vitamin B-12 is essential for formation of red blood cells and nerve tissue. 2) B-12 and other B Vitamins play a role in the functioning of nerve cells.
Biotin	1168, 1169	Biotin	<ol style="list-style-type: none"> 1) Biotin is an essential cofactor for enzymes involved in the metabolism of glucose, fats and amino acids.
Inositol	1158, 1159	Inositol	<ol style="list-style-type: none"> 1) Inositol plays a role in fat metabolism.

<u>Product Names</u>	<u>VS#</u>	<u>Ingredients</u>	<u>Structure/Function Statements</u>
No-Flush Niacin	1310, 1311	Hexaniacinate	1) Hexaniacinate is metabolized in the body to niacin and inositol.
Niacinamide Yeast Free	1532, 1533	Niacinamide	1) Niacinamide is a major form of niacin in the blood, participating in the metabolism of fats and supports the health of the nervous system.
→ Folic Acid <i>see docket 975-0163</i>	1148, 1149 1527	Folic Acid	1) Folic acid, along with Vitamin B-6 and B-12 promote a healthy cardiovascular system. 2) Folic acid is vital to the development of the nervous system in a growing fetus. 3) Deficiencies in folic acid have been linked to some forms of birth defects.
Co Enzyme Q10	1088, 1089 1090 1230 1276,1277 1260, 2134 2135	Coenzyme Q10	1) Coenzyme Q10 is a nutrient required by every cell in the body for energy support.

<u>Product Names</u>	<u>VS#</u>	<u>Ingredients</u>	<u>Structure/Function Statements</u>
Glucosamine Sulfate and Chondroitin Sulfate	1486, 1487 1488	Glucosamine sulfate	1) Glucosamine is needed by the body to produce glycosaminoglycan, a mucopolysaccharide found in cartilage.
		Chondroitin sulfate	2) Chondroitin sulfate is a type of glycosaminoglycan related to glucosamine, rich in sulfur and a major constituent of cartilage.
Vitamins A & D with Beta Carotene	1185,1186	Vitamin A	1) Vitamin A is essential for eye health as well as immune system function.
		Beta Carotene	1) As an antioxidant, beta carotene is an immune booster and protects the body from free radicals.
		Vitamin D	1) Vitamin D is required by the body for calcium and phosphorus absorption. 2) Vitamin D is important for the development of bones and teeth in children. 3) Vitamin D is essential for bone maintenance throughout life.

<u>Product Names</u>	<u>VS#</u>	<u>Ingredients</u>	<u>Structure/Function Statements</u>
Zinc	1450	Zinc	1) Zinc is involved in cellular growth and repair, collagen synthesis and carbohydrate metabolism.
Magnesium Citrate	1084, 1085	Magnesium	1) One of magnesium's most important roles is that of helping the muscles relax.
Potassium Citrate	1080,1081	Potassium	1) Potassium plays a major role with sodium to control water balance.
Chelated Iron	1202, 1203	Iron	1) As a constituent of hemoglobin, iron plays an essential role in the transport of oxygen from the lungs to the tissues.
Manganese	1445	Manganese	1) Manganese plays a role in the activation of enzymes that metabolize protein, fat, and carbohydrates.
Calcium Citrate plus Magnesium with Vitamin D	1086,1087 1123	Calcium, Magnesium Vitamin D	1) Calcium, magnesium and Vitamin D work together to maintain healthy bones.
Methylsulfonylmethane (MSM)	1500, 1501	Sulfur	1) Sulfur is one of the building blocks of glycosaminoglycans, structural components in cartilage.

<u>Product Names</u>	<u>VS#</u>	<u>Ingredients</u>	<u>Structure/Function Statements</u>
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Melatonin	1393,1333 1335,1336 1334	Melatonin	1) Melatonin is a natural hormone that regulates the human biological clock and promotes normal sleep patterns.
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