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MAY 16 2001

Ms. Karla LaSasso
Manager, Documentation
Solgar Vitamin & Herb
500 Willow Tree Road
Leonia, New Jersey 07506

Dear Ms. LaSasso:

This is in response to your letter of April 19, 2001, on behalf of Naturvite Natural Vitamins, Lyndhurst, New Jersey, to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Naturvite Natural Vitamins is making the following claim, among others, for the folic acid contained in the products **Folic Acid, 400 mg** and **Women's Multiple**:

“...reduce the risk of having a child born with neural tube defects.”

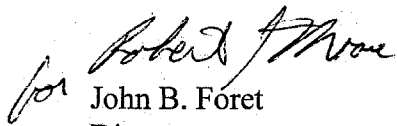
This statement is not a statement of nutritional support subject to 21 U.S.C. 343(r)(6), but is a health claim subject to 21 U.S.C. 343(r)(1)(B). FDA has authorized a health claim on the relationship between folate and neural tube defects (see 21 CFR 101.79). A dietary supplement that meets the eligibility and message requirements set forth in this regulation may bear a claim for the relationship between folate and neural tube defects. A health claim for folate and neural tube defects on the label or in the labeling of a food or dietary supplement that is not in accordance with the requirements in 21 CFR 101.79 would misbrand the food or dietary supplement under 21 U.S.C. 343(r)(1)(B). Moreover, making a claim that is not in accordance with the requirements in 21 CFR 101.79 subjects a product to regulation as a drug under 21 U.S.C. 321(g)(1)(B) because the product is intended to treat, cure, prevent, or mitigate a disease, neural tube defects.

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Please contact us if we may be of further assistance.

Sincerely,



John B. Foret
Director

Division of Compliance and Enforcement
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

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, New Jersey District Office, Office of Compliance, HFR-MA340

Copy:

Naturvite Natural Vitamins

1170 Valleybrook Avenue

Lyndhurst, New Jersey 07071

NATURVITE®
NATURAL VITAMINS

APR 24 2001

April 19, 2001

Office of Nutritional Products
Labeling and Dietary Supplements (HFS-810)
FOOD AND DRUG ADMINISTRATION
200 C Street, S.W.
Washington, D.C. 20204

75605

RE: Notification for Statement on Dietary Supplement

Dear Sir/Madam:

In compliance with the Dietary Supplement Health and Education Act of 1994, **Naturvite Natural Vitamins** hereby makes its official notification under Section 101.93 that it has included a statement listed in Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act on its label. Accordingly, enclosed please find two (2) copies of this Notification. The following information is being provided:

The dietary supplement is being distributed by:

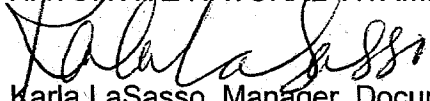
NATURVITE NATURAL VITAMINS
1170 Valleybrook Avenue
Lyndhurst, NJ 07071 USA

The name of the dietary supplement, the name of the dietary ingredients contained in the product which are the subject of this Notice, the text of the statement and structure/function claims are listed on the attached sheet.

I hereby certify that the information presented and contained in this notice is complete and accurate, and my files contain substantiation that the statements made are truthful and not misleading.

Thank you for your time and attention to this matter. If you have any questions, please do not hesitate to contact the undersigned.

Very truly yours,
NATURVITE NATURAL VITAMINS


Karla LaSasso, Manager, Documentation
SOLGAR VITAMIN & HERB
500 Willow Tree Road
Leonia, New Jersey 07506 USA

Certified Mail – Return Receipt Requested
#70000600002417979699

1170 VALLEYBROOK AVENUE
LYNDHURST, NJ 07071 USA

PHONE 888.235.6606
FAX 201.635.4514

NATURVITE Product Name	Ingredient	Statement	Structure/Function Claim
L Carnitine	L Carnitine	Energy Support	Carnitine is made up of two essential amino acids, lysine and methionine. It is required for fat metabolism in cells, including heart and muscle cells. In the heart, fats are the preferred source of energy, filling 90% of metabolic needs. Naturvite provides the natural form of Carnitine (L-Carnitine) which is effectively used by the body.
Evening Primrose Oil	Evening Primrose Oil	None.	Evening Primrose Oil is a source of linoleic acid and gamma-linolenic acid, both omega-6 essential fatty acids that serve as building blocks for important cell membrane components.
Selenium 200 mcg	Selenium	Antioxidant	Selenium is an essential component of the body's antioxidant system. It also supports the functioning of other antioxidants, such as vitamin E and glutathione.
CoQ 10 60 mg	Coenzyme Q 10	Cardio Support	CoQ10 is found in the mitochondria of living cells. CoQ10 is a powerful antioxidant that plays a critical role in the production of energy in every cell of the body.
Calcium Citrate	Calcium	Bone Support	Calcium plays an important role in the maintenance of bones and teeth. Calcium Citrate is highly soluble, which helps facilitate its absorption. This may be particularly beneficial to women as they age.
Men's Multiple	Vitamin B6, B12, Folic Acid, Zinc and Lycopene	None.	Naturvite Men's Multiple includes Zinc and Lycopene which may help support the prostate; B6, B12 and Folic Acid, vitamins which may help maintain normal homocystein levels in the blood, (which may help cardiovascular function); and standardized herbs such as Korean, American and Siberian Ginseng, Saw Palmetto and Pygeum Africanum.
Advanced Acidophilus	Acidophilus	Digestive Support	Acidophilus is "friendly bacteria" that aids in the digestive process by helping to maintain intestinal microflora. Naturvite Acidophilus offers stability without refrigeration and survivability through the digestive tract.

NATURVITE Product Name	Ingredient	Statement	Structure/Function Claim
MSM	MSM	Joint and Collagen Support	MSM is a sulfur compound found in many foods and the human body. Sulfur is a critical nutrient for connective tissue.
Vitamin K	Vitamin K	Bone Support	Vitamin K is necessary for proper clotting and for building strong bones. Since nutritional intake of Vitamin K is not always adequate in post-menopausal women, supplementation with Vitamin K is important.
SAMe	SAMe	Amino Acid Support	SAMe is naturally found in the body and plays a critical role in many biological reactions, including several in the brain. It also plays a role in the biosynthesis of two amino acids, cysteine and methionine.
Glucosamine Chondroitin	Glucosamine and Chondroitin	Joint Support	Glucosamine and Chondroitin are natural components of joint tissue. Glucosamine and Chondroitin may help support the maintenance of joint and cartilage tissue and normal joint flexibility.
B complex Stress	Vitamin B1, B2, B3 and B6	Energy Support	B-Complex Stress Formula is a high potency B-Complex vitamin that helps to support the body in times of physical stress. B vitamins have a wide variety of important functions including assisting in the release of energy from food's and in the maintenance of skin, eyes, and nervous system function. This complex also contains Vitamin C, a potent antioxidant.
Flaxseed oil	Flaxseed Oil	None.	Flaxseed Oil is a source of linoleic and gamma linolenic acid, both Omega 6 essential fatty acids, that serve as building blocks for important cell membrane components.
Chromium Picolinate	Chromium Picolinate	Metabolism Support	Chromium Picolinate supplies Chromium, an element necessary for proper metabolism.

NATURVITE Product Name	Ingredient	Statement	Structure/Function Claim
B Complex 100	Vitamin B1, B2, B3 and B6	Energy Support	Naturvite B-Complex "100" is a high potency B-complex vitamin tablet. B vitamins have a wide variety of important functions including assisting in the release of energy from foods, and in the maintenance of skin, eyes and nervous system function.
Essential Amino Complex	Histidine, Isoleucine, Leucine, Lysine, Methionine, Phenylalanine, Threonine, Valine	None.	Amino acids are the building blocks of protein, which is the most abundant substance in the body after water. Though our body can produce most of the amino acids it needs, there are a few that it can't. This complex provides 8 of these needed amino acids in a balanced formula.
Lecithin 1200	Lecithin	Cell Support	Lecithin is a type of lipid that is needed by every living cell in the human body. Lecithin may enable fats to be dispersed in water and removed from the body.
Eye Support Complex	Lutein	Vision Support	Eye Support Complex provides antioxidants specifically beneficial for the eyes. These ingredients may help scavenge free radicals and help maintain eyesight for later years.
Chelated Zinc	Chelated Zinc	Immune Support	Zinc is an essential element that is a component of over 200 enzymes in the body. It is selectively concentrated in the prostate and may help support prostate function. Zinc is also the most abundant trace element in the eye, where it supports antioxidant activity and may be important for eye function. Our Zinc formula is chelated, providing high bioavailability.
Vitamin C 500 mg	Vitamin C	None.	Vitamin C is a powerful antioxidant that plays a role in many body functions. In addition to helping maintain bones, teeth, gums and collagen. Vitamin C is important in the absorption of iron.
Saw Palmetto	Saw Palmetto	Prostate Support	Saw Palmetto is a small palm tree with red berries which has been traditionally used by Native Americans. The berries supply a variety of fatty acids and plant sterols that may help promote prostate function and may help maintain normal urine flow.

NATURVITE Product Name	Ingredient	Statement	Structure/Function Claim
Glucosamine Sulfate 1000 mg	Glucosamine Sulfate	Joint Support	Glucosamine is a natural component of joint tissue. Glucosamine Sulfate may help support the maintenance of joint and cartilage tissue and normal joint flexibility.
Ginkgo Biloba	Ginkgo Biloba	Memory Support	Ginkgo biloba, a tall, hardy deciduous tree, has been used in Chinese medicine for thousands of years. Research suggests that ginkgo may help maintain normal mental alertness, concentration, and memory. Additionally, it may help improve blood flow throughout the body and maintain the tone and elasticity of blood vessels.
Cranberry Extract	Cranberry	Urinary Tract Support	Naturvite Cranberry has naturally occurring proanthocyanidins, which may help support the urinary tract.
Gentle Iron	Iron Bisglycinate	Stomach Friendly Iron	Iron is a key mineral that transports oxygen throughout the body. Gentle Iron is formulated for women who need iron in a form that is gentle on the stomach.
Calcium Magnesium Citrate	Calcium Citrate, Magnesium Citrate	Bone Support	Calcium and Magnesium are both important in helping to maintain bones and teeth. Calcium Magnesium Citrate is highly soluble, which helps facilitate its absorption. This may be particularly beneficial to women as they age.
St. John's Wort	St. John's Wort	Mood Support	None.
Vitamin E 400 iu	Vitamin E	None.	Vitamin E is an extremely effective lipid soluble antioxidant that may help the body protect against free radical damage.

NATURVITE Product Name	Ingredient	Statement	Structure/Function Claim
Cod Liver Oil	Cod Liver Oil	None.	Cod Liver Oil is an excellent source of Vitamin A, which plays an important role in eye function and is a potent antioxidant.
L-Arginine L-Ornithine	L-Arginine/L-Ornithine	Muscle Support	Arginine is essential in muscle metabolism because it provides a vehicle for transporting, storing and excreting waste products. It is also an important factor in tissue generation and regeneration, and is involved in creatine synthesis. Ornithine is an intermediate involved in the synthesis of Arginine. Naturvite provides the natural form of Arginine/Ornithine which is effectively used by the body.
L-Lysine	L-Lysine	None.	Though our body can produce most of the amino acids it needs, there are a few that it can't, including Lysine. Lysine is necessary for growth and tissue formation. Naturvite provides the natural form of Lysine which is effectively used by the body.
Folic Acid 400 mcg	Folic Acid	None.	Folic Acid is an important B vitamin during a woman's childbearing years. Folic Acid may reduce the risk of having a child born with neural tube birth defects. It may also help maintain normal homocysteine levels in the blood, which may help support cardiovascular function.
Soy Isoflavones	Genestein, Daidzein	Phytoestrogen	Super Concentrated Soy Isoflavones (non-GMO) offer important phytoestrogens, genistein and daidzein, which have received attention in the scientific community for their beneficial properties.
Women's Multiple	Vitamins B6, B12 and Folic Acid	None.	Naturvite's Women's Multiple includes B6, B12 and Folic Acid, vitamins which may help maintain normal homocysteine levels in the blood (which may help support cardiovascular function); Folic Acid which may help to reduce the risk of having a child with neural tube birth defects; and standardized herbs, such as Black Cohosh and Dong Quai, which may help support a woman's general wellness.