

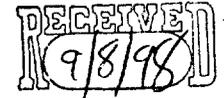


6/05/98

September 4, 1998

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Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C St. S.W.  
Washington D.C. 20204

RE: *Notification of marketing a dietary supplement that bears on its label or its labeling a statement provided for in section 403 (r) (6) of the Federal Food, Drug and Cosmetic Act.*

Dear FDA Consumer Safety Officer:

USANA, Inc. submits this notification for its dietary supplement products that bear statements of nutritional support in accordance with section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act.

**Manufacturer of Dietary Supplement:** USANA, Inc.  
3838 West Parkway Blvd.  
Salt Lake City, Utah 84120-6336

**Name of Dietary Supplements:  
(including brand name)** "Chelated Mineral", "Mega Antioxidant",  
"CoQuinone", "Proflavanol", "Poly C",  
"CalMag Plus", "Melatonin KL",  
"Procosamine", "OptOmega",  
"Kid's Choo-ables", "LEAN Formula."

**Text of Statements Being Made for "Chelated Mineral":**

"Chromium acts to maintain healthy sugar metabolism which is critical to achieve proper blood levels of glucose."

also see docket 97S-0163

LET 2076

“Zinc, for example, plays a vital role in the activities of over 200 enzymes. It is essential in the manufacturing of proteins and nucleic acids (the genetic material of cells) and is involved in the action of insulin in the utilization of carbohydrates.”

“Selenium works with vitamin E to preserve the elasticity of tissues, thus helping you retain your youthful-looking skin.”

“Magnesium is essential for the formation and maintenance of healthy bones and teeth (where 70 percent of the body’s magnesium is found). It is involved in the metabolism of carbohydrates and amino acids and also plays an important role in neuromuscular contractions. It also is an activator of hundreds of enzymes which are essential to life. ”

“Iodine is a crucial component of the thyroid hormones, which regulate metabolism, growth, reproduction, and the synthesis of protein.”

“To help you enjoy a healthier life, the USANA Essentials, consisting of both the Mega Antioxidant and the Chelated Mineral, have been designed to provide an optimal supply of nutrients. Together, they can help your body maintain nutritional balance throughout the day, protect against environmental damage with a broad spectrum of antioxidant activity, and promote repairing and healing from the daily stress caused by today’s hurried lifestyle.”

**Text of Statements Being Made for “Mega Antioxidant”:**

“Vitamin E plays an important role in the human body. It is one of the most important of all antioxidants because it helps maintain strong cell membranes.”

“Vitamin E protects LDL cholesterol from oxidation and has been shown to cross the blood brain barrier to prevent free radical damage to the walls of cells in the brain and other central nervous system tissue.”

“One of the many health enhancing functions of vitamin C is its ability to combat the cellular damage caused by free radicals.”

“Vitamin A inhibits the signs of premature skin aging and it is a vital constituent of photo-pigments necessary for vision.”

“Beta-carotene has been shown to be a key ingredient in the basic ability of the immune system to function properly.”

“Carotenoids are antioxidant molecules that are involved in the protection of the human body from free radical damage.”

“Coenzyme Q<sub>10</sub> acts as an energy coenzyme, an essential component of the mitochondrial electron transport chain, which is the fundamental unit for energy production in our cells.”

“Alpha Lipoic Acid offers protection against a wide variety of free radicals both inside and outside the cell.”

“Mega Antioxidant also includes glutathione and N-acetyl L-cysteine, both of which are critical components of an important cellular antioxidant system. N-acetyl L-cysteine is a building block for glutathione. Together, they help in the body to regenerate other antioxidants.”

“Another important ingredient is cruciferous extract from cabbage, made up of sulfur containing molecules that help neutralize specific species of free radicals that attack the membranes of the cell.”

“B-complex vitamins are fundamental to cellular health, metabolism and growth.”

“Folic acid, one of the B vitamins, has been shown, together with vitamin B12 and vitamin B6, to facilitate the conversion of homocysteine to methionine. This conversion has the effect of reducing blood levels of homocysteine to maintain a healthy cardiovascular environment.”

#### **Text of Statements Being Made for “CoQuinone”:**

“One substance that is crucial to energy production in every cell and organ in the body is coenzyme Q<sub>10</sub>. (CoQ<sub>10</sub>)”

“There have been more than ten human clinical studies performed to evaluate the efficacy of CoQ<sub>10</sub> supplementation. The most consistent and significant finding of these studies has been an improvement in cardiac energetics.”

“Thirty years of scientific research in the United States, Europe and Japan has revealed the vital role CoQ<sub>10</sub> plays in relation to cellular energy production, modulating the immune system, and reenergizing the heart and other muscles.”

“CoQ<sub>10</sub> helps your body convert the food you eat into energy. More specifically, it plays an essential role in the production of adenosine triphosphate, the energy molecules your cells use.”

“CoQ<sub>10</sub> also functions in your body as an antioxidant. It helps to quench free radicals and maintain the structural integrity and stability of cell membranes. It further serves to reduce oxidation of low density lipoprotein (LDL) cholesterol and aids in the regeneration of vitamin E.”

“CoQ<sub>10</sub> supplementation has been shown to improve total energy output and increase the production of ATP which is the major energy molecule in the body. Some studies have shown that it helps increase maximum oxygen consumption, maximum heart rate, tolerance to blood lactic acid levels, and overall performance.”

“Alpha lipoic acid, also known as thiocytic acid, is a vitamin-like antioxidant that is easily absorbed through the gut and transported across cell membranes, offering protection against a wide variety of free radicals both inside and outside the cell.”

“Once inside the body’s tissues, alpha lipoic acid can be converted to dihydrolipoic acid (DHLA), an equally potent free radical scavenger.”

“The alpha lipoic acid and DHLA can act as metal chelators, binding up excess copper, iron, mercury, and cadmium, thus limiting the negative impacts of these heavy metals on the body.”

**Text of Statements Being Made for “Proflavanol”:**

“Free radicals have become a devastating enemy to our health. Antioxidants are the weapons that provide the electrons which neutralize these free radicals.”

“Proanthocyanidins (flavanols) appear to be some of the most powerful free-radical scavengers yet discovered.”

“Proanthocyanidins are completely safe, and they are one of the few antioxidants that cross the blood-brain barrier to protect neural tissue.”

“Not only do they neutralize free radicals themselves, but they also conserve and regenerate vitamins C and E. Vitamin E is a powerful free-radical scavenger and flavanols and vitamin C regenerate vitamin E so that it may continue its protective role.”

“Scientifically observed documented benefits of the use of proanthocyanidins include . . . enhanced capillary strength and vascular function.”

“Scientifically observed documented benefits of the use of proanthocyanidins include . . . Enhanced immune resistance.”

“Scientifically observed documented benefits of the use of proanthocyanidins include . . . Increased peripheral circulation, improving vision.”

“Scientifically observed documented benefits of the use of proanthocyanidins include . . . Reduction in premature skin aging and loss of elasticity.”

**Text of Statements Being Made for “Poly C”:**

“Vitamin C helps to combat free radicals and is important in the synthesis of collagen.”

“ A recent study has found that adults who took supplemental vitamin C had a significantly lower death rate from heart attack and stroke compared to those who didn’t take supplemental vitamin C.”

**Text of Statements Being Made for “CalMag Plus”:**

“CalMag Plus was carefully formulated to enable the following ingredients (calcium, magnesium, boron, silicon, vitamin D) to give you strong and healthy bones.”

“Calcium is also critical to nerve conduction, contraction of muscles, blood clotting, neural function, cell division and electrical conduction in the heart.”

“Calcium helps to regulate blood pressure and is essential for the production and activity of enzymes and hormones that regulate digestion, energy, and fat metabolism.”

“Calcium is acquired only through diet and must be provided in adequate amounts to help improve bone density.”

“CalMag Plus contains high amounts of calcium citrate, accompanied by necessary trace minerals and vitamin D to optimize bone mineralization.”

“Along with Calcium, Magnesium is an important component of strong, healthy bones.”

“Magnesium is involved in the metabolism of carbohydrates and amino acids.”

“Magnesium also plays an important role in neuromuscular contractions and helps regulate the alkaline balance in the body.”

“Magnesium is an activator of hundreds of enzymes which are essential to life.”

“This all-important mineral (magnesium) aids in the mobilization of the ATP enzyme system, which is essential for much of the energy used by the body.”

“New research shows that magnesium is also helpful in neutralizing free radicals.”

“Boron has been shown to reduce calcium excretion and deposition of calcium in the bone.”

“Silicon, present in the connective tissues of the body, is essential for proper calcium utilization. This is key to the calcium mineralization of the bone.”

“Vitamin D must be present to enhance the absorption of calcium in the small intestine and for the utilization of calcium in bone formation. It regulates calcium levels in the blood, which allows calcium to perform its various tasks.”

“Supplementation of calcium, magnesium, vitamin D, boron, and silicon are necessary for the bone formation and to improve bone density for life long bone health.”

**Text of Statements Being Made for “Melatonin KL”:**

“While researchers are giving melatonin credit for helping to curb the effects of the normal aging process, melatonin has been shown to be a natural, highly effective, non-addictive aid to healthy sleep. Put simply, melatonin is nature's way of giving us a good night's rest.”

“Melatonin KL stimulates natural sleeping processes by supplementing you with small amounts of melatonin.”

“Melatonin KL not only helps you sleep but it helps you sleep the way your body was meant to sleep.”

“Melatonin helps to support your body's natural sleeping cycles – REM and all!”

“The active ingredients in kava, six potent compounds called kavalactones, have been shown in clinical trials to promote muscle relaxation and an overall calm feeling.”

“The kava in Melatonin KL prepares your mind and body for sleep and allows the melatonin to provide a natural, healthy, restorative night's sleep.”

“Melatonin, when taken before normal bedtime in the new time zone, is a natural way to help your body adapt more quickly and completely as well as to reset your internal clock.”

“USANA's Melatonin KL is designed to help restore the body's natural sleeping rhythms.”

**Text of Statements Being Made for “Procosamine”:**

“To help maintain healthy joints, USANA has created Procosamine, a product with an optimal blend of glucosamine, manganese, vitamin C, and silicon.”

“Glucosamine, an aminosugar, is an important precursor in the biosynthesis of cartilage. Specifically, it is a building block of proteoglycans – or protein molecules with a high content of bound carbohydrate – which, with collagen, compose the cartilage matrix. Proteoglycans are essential for healthy cartilage because they bind the water that lubricates and cushions the joint.”

“In addition to its role as a biochemical precursor, glucosamine is believed to play a regulatory role in cartilage formation, normalizing cartilage metabolism by encouraging higher production of collagen and proteoglycans and by inhibiting synthesis of enzymes that break down cartilage.”

“Double-blind clinical studies have demonstrated the efficacy of glucosamine supplements in maintaining healthy cartilage, robust joints, and full range of motion.”

“Manganese is required for enzymes involved in the biosynthesis of proteoglycans.”

“Vitamin C is essential for the reactions central to collagen formation.”

“Silicon is required for maximum activity affecting collagen formation and ultimately cartilage composition.”

“Procosamine is designed to promote optimal joint health and full joint mobility.”

**Text of Statements Being Made for “OptOmega”:**

“There are two essential fatty acids, both of which are especially important to cardiovascular health: alpha-linolenic acid (an Omega-3 fatty acid) and linoleic acid (an Omega-6 fatty acid).”

“EFAs: Major Factors for Heart Health.”

“Essential fatty acids can help you maintain normal blood pressure and healthy levels of triglycerides (serum cholesterol).”

“EFAs help maintain optimal blood pressure by contributing to the elasticity of arterial walls.”

“Diets that are high in EFA’s incorporate the EFA into the membrane of every cell. Just as in artery walls, this helps to maintain the membrane in a soft, fluid, flexible state. These flexible membranes incorporate cholesterol to regain structural rigidity. This process helps to maintain healthy serum cholesterol levels.”

“Diets rich in Omega 3 fatty acids have been shown to lower serum triglyceride levels by more than 50%”

“The fatty acids linoleic acid and alpha-linoleic acid are also essential precursors in the biosynthesis of prostaglandins.”

“The prostaglandins are important hormone like substances that mediate several important functions, including platelet aggregation, sodium removal, relaxing blood vessels, and improving circulation. The balance of Omega-6 to Omega-3 essential fatty acids is critical to maintaining optimal prostaglandin biosynthesis.”

“Vitamin E and B-carotene can help to prevent lipoproteins from oxidizing.”

“Researchers believe that the same attributes of tumeric that preserve the freshness of the food we eat may also protect living cells from damage caused by free radicals.”

**Text of Statements Being Made for “Kid’s choo-ables”:**

“The Kid’s choo-ables contains an extra boost of vitamins E and C, two of the most powerful antioxidants needed by the human body.”

“Vitamin E is one of the most important antioxidants because it helps maintain strong cell membranes and plays a critical role in helping the body protect itself.”

Vitamin C is a key player in combating cellular damage caused by free radicals.”

**Text of Statements Being Made for “L·E·A·N Formula”:**

“USANA’s L·E·A·N Team Formula uses HCA (Hydroxy-Citric Acid) to reduce the production and storage of fat.”

“This natural plant compound inhibits the enzyme ATP lyase, one of the central enzymes in the production of fat (lipogenesis).”

“HCA is able to reduce fat production without the adverse side effects caused by some common weight-loss drugs.”

“USANA’s L·E·A·N Team Formula uses several natural ingredients to work with your body to increase thermogenesis so that you burn more stored fat throughout the entire day.”

“Sida cordifolia is an herb containing a low level of compounds that help stimulate the thermogenesis process.”

“Kola nut contains compounds that stimulate the body to enhance the effectiveness of other thermogenic activators.”

“Salicin combined with Sida cordifolia and kola nut increases the effectiveness of thermogenesis.”

“Potassium iodide helps the body maintain an increased metabolic rate when total caloric intake is reduced.”

“Cayenne stimulates the production of ATP, which increases body heat and uses more energy, thus metabolizing more fat.”

“N-Acetyl L-Carnitine (NAC) is used by the body to transport fats into the mitochondria, where they can be metabolized to produce energy in the cells.”

“USANA uses the amino acids L-tyrosine and L-phenylalanine, along with the herbs valerian officinalis and hypericum perforatum (St. John’s Wort) to elevate emotions.”

“L-Tyrosine is a precursor to the important brain neurotransmitters epinephrine, norepinephrine, and dopamine which transmit nerve impulses and are essential to normal moods and a sense of well-being.”

“L-Phenylalaine is used by the brain to manufacture norepinephrine, which promotes mental alertness and memory, promotes a positive mood, and suppresses appetite very effectively.”

“Valerian officinalis, promotes relaxation and is recognized world wide for its calming effect on the body.”

“Valerian is not addictive and has been used to promote muscle relaxation and sleep.”

“Hypericum perforatum (St. John’s Wort) has been used to promote calmness, maintain mood, and to promote restful sleep.”

“Reports have shown that Hypericum perforatum can increase the level of neurotransmitters that are critical to stabilizing mood and sense of well-being.”

“Hypericum has been shown to prevent the destruction and/or re-uptake of critically important neurotransmitters. Proper levels of these chemicals are critical to maintaining a stable mental state.”

“Gymnema sylvestre, dubbed as the “sugar destroyer”, reduces the metabolic effects of sugar by reducing its digestion in the intestines, thus reducing blood-sugar levels.”

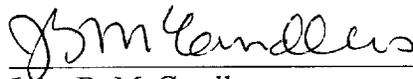
John B. McCandless declares:

1. That he is Vice President and Chief Operating Officer of Usana, Inc. (hereinafter "applicant") and is authorized to make this declaration;
2. That information contained in this statement is complete and accurate, and that USANA, Inc. has substantiation that the statement is truthful and not misleading.

DATED this 4<sup>th</sup> day of September, 1998.

USANA, INC.

By:



John B. McCandless

Vice President and Chief Operating Officer