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October 15, 2002

Office of Nutritional Products, Labeling and Dietary Supplements (HFS-810) Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Pkwy College Park, MD 20740

OCT 23 2002

Re:

Notification for Statements on Dietary Supplement Labels

Dear Sir/Madam:

This firm represents Nature's Sunshine Products, Inc., Provo, Utah, a manufacturer and distributor of dietary supplement products (hereinafter "Nature's Sunshine"). Nature's Sunshine has requested that we notify your Agency on its behalf of the inclusion of statements of nutritional support on its dietary supplement product labels.

Pursuant to the requirements of Section 6 of the Dietary Supplement Health and Education Act of 1994, 21 U.S.C. §343(r)(6), and in accordance with the authorized provisions of 21 CFR §101.93(a), your Agency is hereby notified that Nature's Sunshine has made statements of "nutritional support", as described in 21 U.S.C. §343(r)(6)(A), for its dietary supplements as follows:

Product Name

Label Statement(s)

Hydrated Bentonite

Intestinal system support, dietary supplement, cleanses and detoxifies intestinal tract, absorbs impurities.

Milk Thistle Combination Liv-Guard

Digestive system support, powerful antioxidant for liver protection. A combination of herbs and vitamins designed to provide nutritional support for the liver.

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Perfect Eyes with Lutein

Vital nutritional support, for healthy eyes, supports macular region health, herbal combination supplement, contains herbs and nutrients for optimum ocular nutrition and antioxidants to help protect the body against the harmful effects of free radicals. Lutein specifically has been shown to support the health of the macular region of the eye.

Breast Enhance

Female glandular system support, helps maintain balance in female hormones, contains herbs that help promote breast size and firmness, may also promote fertility and reduce mild menstrual mood changes and cramping.

Cramp Relief

Female glandular system support, herbal combination supplement, may be helpful for cramping during menstruation.

Liquid Calcium with Magnesium, Zinc & Vitamin D, 16 Fl. Oz.

Structural system support, to support healthy bones, liposomes for enhanced bioactivity, maintain pH balance, strengthens bones and can also maintain pH balance, dietary supplement.

Liquid Calcium with Magnesium, Zinc & Vitamin D, 2 Fl. Oz.

Structural system support, to support healthy bones, liposome technology to enhance absorption.

Cellular Energy

Aids in production of ATP for energy, supports energy at the cellular level, vital nutrition support. Every cell in the body produces energy thbrough a series of reactions that take place in a part of the cell known as the mitochondria. These reactions are essential to maintaining optimal health as well as energy and vitality. Cellular Energy contains vitamins, minerals, and other co-factors involved in these vital processes that regulate normal energy production and cellular metabolism.

Magnesium Complex

Highly bioavailable, alkalizing, promotes musculoskeletal health, skeletal system support. Magnesium citrate is an alkalizing form while magnesium malate has been found especially beneficial for musculoskeletal health.

Liquid Vitamin B12 Complete Dulse Liquid

Promotes energy, boosts general well-being. Supports thyroid activity and function, glandular system support.

Urinary Maintenance

Key system urinary, provides kidney support, functions as an effective diuretic.

Lymphomax

Key system lymphatic, provides lymphatic support, supports detoxification and mobilization of lymphatic system.

Vitamin E

Vital nutritional support, powerful antioxidant formula, supports heart health, natural Vitamin E.

Liquid Herbs Lymphatic Drainage

Lymphatic system support, helps body perform natural lymphatic drainage function.

Liquid Herbs Kidney Drainage

Urinary system support, helps kidneys perform their normal daily function.

Thyroid Support

Glandular system support, helps support thyroid function, supports body's calorie burning efficiency. The thyroid gland regulates the body's metabolic activity level and is most commonly known as the "Master of Metabolism". The thyroid plays a major role in regulating functions such as body temperature, burning of fuel, production of gastric secretions and synthesis of fats, proteins, white blood cells, and sex hormones. Thyroid Support provides raw glandular extracts, amino acids, vitamins, minerals, enzymes, and phytonutrients to enhance performance and efficiency of these vital processes.

Maca

Nourishes male and female reproductive system, enhances mental and physical strength, promotes stamina/reduces fatigue, glandular system support.

Cellu-Smooth

Mobilizes fat stores, supports general circulation, protects against free-radical damage to structural skin proteins. Cellu-Smooth is specially

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formulated to reduce absorption of dietary fat, and protect against free radical damage to structural skin proteins.

Adrenal Support

Adrenal substance from New Zealand, helps support adrenal function, supports body's ability to regulate stress, immune system support, support and strengthen the adrenal glands.

The undersigned hereby certifies on behalf of Nature's Sunshine that the information contained in this correspondence is complete and accurate.

Sincerely yours,

GRONEK & ARMSTRONG

Robert E. Armstrong

CC: Nature's Sunshine Products, Inc.