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January 3, 2002

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Office of Nutritional Products Labeling
and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St. SW.,
Washington, D.C. 20204

BY:.....

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:

<u>Product Name</u>	<u>Label Statement(s)</u>
ALJ	Respiratory system support.
Antioxidant Arsenal	Immune system support. Antioxidant Arsenal combines nutrients scientifically documented as powerful antioxidants. Antioxidants help the body fight "free radicals," charged particles produced by chemical pollution and normal body processes. These unstable particles can set off a chain reaction of cellular destruction if not quickly subdued by antioxidants - the free-radical

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scavengers. Typically, the aging process and compromised cellular integrity are linked to free-radical damage. Antioxidants are known to be essential for the body to maintain good health. The most well-known antioxidants, such as proanthocyanidins, are included in these packets. They are combined with nutrients believed to keep body cells intact and to safeguard DNA, the cell's "master plan" for cellular function and reproduction. Unlike other antioxidants, proanthocyanidins cross the blood-brain barrier to help protect vital brain and nerve cells.

Antioxidants with Grapine

Specially formulated for children. This powerful antioxidant formula was created to help offset the harmful effects of free radicals on young, growing bodies. Free radicals are produced naturally in the body, even without exposure to pollutants. Age, higher levels of activity, and exercise increase the need for antioxidant supplements.

Blood Build

Liver and kidney detox. Build healthy red blood cells. Circulatory system support.

BP-X

Circulatory system support.

Burdock

Digestive system support.

Carotenoid Blend

Potent antioxidant activity. Cardiovascular benefits. Eye health. Immune enhancement. Vital nutrition support. The potent antioxidant activity of this carotenoid blend helps prevent free-radical damage. Support the health of: heart, vascular system, skin, and vision.

Catnip

Nervous system support.

CC-A Relief

Immune system support. This combination of vitamins and herbs was specifically chosen to support the immune system. CC-A and IGS II help support the immune system and ALJ helps support the respiratory system.

Chewable Vitamin C

Immune system support.

CoQ10 - 100	Heart health. Vital co-enzyme needed for cellular energy. Promotes healthy heart and circulatory system. Supports healthy gums. Circulatory system support. Co-enzyme Q10, a powerful antioxidant, is necessary for inducing chemical changes within cells. CoQ10 produces adenosine triphosphate (ATP), needed to produce energy in all cells.
Cornsilk	Urinary system support.
C-X	Glandular system support.
Dandelion	Urinary system support.
Defense-Shield	Defense-Shield may be used to support the immune system prior to, or after a cleanse, or any time your diet may be compromised. Each packet contains a total of six capsules containing essential nutrients for immune system function, plus Chinese herbs.
Dong Quai	Glandular system support.
Elderberry Plus	Historically, elderberries, reishi mushroom, and astragalus root are known to stimulate the immune system.
Energ-V Pack	This package contains 30 packets each containing four different supplement products: Vitamins, herbs, and enzymes specifically chosen to support the glandular, circulatory, and nervous systems. The Energ-V Pack provides nutritional support for the glandular, circulatory, and nervous systems. This unique combination of nourishing herbs, enzymes, vitamins and other nutritional elements helps to support vigor and vitality. B-Complex provides the essential water soluble B vitamins that constantly need to be replenished. Proactazyme provides the enzymes necessary to get the optimum nutrient values from the foods we eat. Energ-V provides a combination of herbs to support an active lifestyle. Adapta-Max provides

a number of adaptogen herbs and other nutritional factors that help the body to perform at its best.

Garlic	Immune system support.
Ginger	Digestive system support.
Gotu Kola	Nervous system support.
Herbal Trace Minerals	Minerals activate enzymes. Glandular system support.
Horsetail	Structural and circulatory system support.
HY-C	Supports normal range blood sugar level. Supports the liver and pancreas. Menopause support. Glandular system support.
Juniper Berries	Urinary system support.
Kidney Activator	Urinary system support. Kidney strengthening. Supports bladder and kidney health.
Lecithin	Nervous and circulatory system support.
Licorice Root Extract	Supports adrenal gland. Provides lymphatic energy. Glandular system support.
Licorice Root - Concentrated	Supports adrenal gland. Provides lymphatic energy. Supports proper sugar balance. Glandular system support.
Liquid Multiple Vitamins Plus Iron	Formulated to provide maximum nutritional support, including antioxidants to help fight the damaging effects of free radicals.
LIV-J	Digestive system support.
Lobelia	Respiratory system support.
Lobelia Essence	Respiratory system support.
Lung Support	Supports respiratory health. Respiratory system support.

Marshmallow and Fenugreek	Respiratory system support.
Master Gland Formula	Key system glandular.
Mega-Chel (180 Tablets)	Key system circulatory.
Mega-Chel (90 Tablets)	Key system circulatory.
Melatonin Extra	Glandular system support. Melatonin, a hormone produced by the pineal gland, controls sleep patterns and influences our biological clock, affecting the way we age. Melatonin levels drop as we age, which may explain why sleep patterns change. Melatonin Extra provides 3.0 mg of pure melatonin combined with herbs and natural Vitamin E, a powerful antioxidant for optimal benefits. This combination creates a "synergistic" effect enhancing total product performance.
Men's Formula	Male glandular system support. Nature's Sunshine advanced nutritional combination is specifically designed to support the prostate gland.
Natural Changes	Menopause and glandular system support. Each Natural Change packet contains a special selection of products to specifically provide nutritional support for women experiencing natural changes as they age. C-X provides nutrients that must be present for proper function of the reproductive glands of mature women, and provides plant sources of chromium, magnesium, and selenium. Wild Yam and Chaste Tree nutritionally supports the female glandular and reproductive systems. Flax Seed Oil provides nutritional support for the immune and circulatory systems, Omega-6 to support the glandular and structural systems, and Omega-9 to support the respiratory system. Omega-3 oils are known to play a role in cardiovascular or circulatory health. Skeletal Strength contains vitamins and minerals to nutritionally support the structural and nervous systems. Calcium is needed for muscle contraction. Phosphorus works synergistically

with B vitamins and helps maintain proper fluid balance in the body. Magnesium, often lacking in Western diets, and Vitamin D assist with calcium absorption. Nutri-Calm, a Key product, is designed to nutritionally support the nervous system, especially when under physical stress. Nutri-Calm contains C and B-Complex vitamins, combined with additional vitamins and herbs designed to provide soothing anti-stress nutritional support.

Nature's Prenatal

Multivitamin and mineral supplement for use during pregnancy and lactation. Vital nutritional support. Nature's Prenatal is a balanced combination of vitamins and minerals formulated to provide nutritional support for pregnant or lactating women. Essential nutrients needed for energy and metabolism during pregnancy and lactation. Antioxidants to help fight the damaging effects of free radicals. Ginger rhizome (*Zingiber Officinale*) for digestive comfort.

Nature's Three

Intestinal system support.

Nervous Fatigue Formula

Supports adrenal function. Provides energy/metabolism boost. Nurtures central nervous system/heart connection. Circulatory system support.

Olive Leaf Extract

Immune and circulatory system support. Olive leaf extract is a natural way to support the immune and circulatory systems. It specifically enhances the immune system with its powerful neutralizing constituents, without harming beneficial bacteria.

Oregon Grape

Digestive and circulatory system support.

Papaya Mint

Digestive system support.

Parsley

Urinary system support.

Passion Flower

Nervous system support.

PBS	Digestive and glandular system support.
PLS II	Intestinal system support.
PS II	Glandular system support.
Psyllium	Intestinal system support.
Psyllium Hulls (Bulk)	Intestinal system support.
Psyllium Hulls (100 Capsules)	Digestive system support.
P-X	Urinary and glandular system support.
Pyruvate	Promote weight loss. Enhance fat loss. This unique, natural blend of ingredients offers a powerful, natural alternative designed to help maintain muscle tissue during weight loss.
Red Beet Root Formula	European liver cleanse. Vital nutritional support.
Red Clover	Circulatory system support.
Red Raspberry	Glandular system support.
Safflowers	Digestive system support.
Sage	Immune system support.
Sarsaparilla	Glandular system support.
SF (100 Capsules)	Weight loss.
SF (50 Capsules)	Weight loss. These herbs supply nutritional support needed during weight loss.
Small Intestine Detox	A small intestine cleanse. Supports nutrient absorption. Digestive system support.
Stevia	The FOS material is a pre-biotic dietary supplement. This product has a 0 glycemic index.

Stress Pack

This combination of vitamins and herbs was specifically chosen to support the nervous system. The Stress Pack provides nutritional support for the nervous system and in the management of stress due to physical or emotional causes. Stress can increase the need for certain nutrients and Nutri-Calm provides B-Complex, Vitamin C (core anti-stress nutrients), plus other nutrients and herbs. SUMA (with adaptogen herbs), STR-J and Hops Concentrate provide herbal support to help nourish the body to better handle stress.

Synerpro Vitamin E with Selenium

Powerful antioxidant formula. Supports heart health. Vital nutritional support.

Thermo-Chi

Herbal thermogenic weight control program. Thermo-Chi weight management program uses thermogenesis, good eating habits, and exercise to help control weight. Thermogenesis is a scientific process known to increase metabolic fat burn. Thermo-Chi is designed for long-term weight management.

Tiao He Cleanse

Special Formula #1 - Cellular formula. LBS II - Intestinal support. Psyllium Hulls - Bulking agent. Burdock Root - Nourishes circulatory system. Black Walnut Hulls - Strengthens digestive system.

Ultimate Echinacea

Immune system support.

Uva Ursi

Urinary system support.

White Oak Bark

Immune system support.

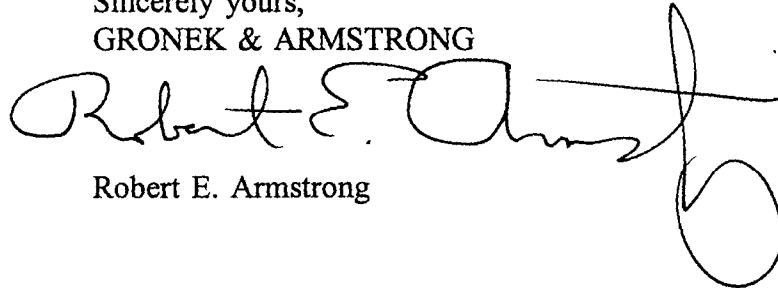
X-Action Pack

This vitamin, mineral, and herbal combination was prepared for men specifically to support the circulatory and nervous systems. The X-Action Pack provides nutritional support for the circulatory and nervous systems. The AM packet is specifically designed to provide an energy lift during the afternoon. The PM packet is designed to decrease feelings of fatigue, or physical and mental exhaustion. Use of X-Action will help

men to obtain a heightened state of sensitivity making them more receptive to outside stimuli. Yohimbe and muira puama herbs have historically been used to support the nervous system. Nature's Sunshine uses yohimbe bark that is rich in yohimbine, an alkaloid found in the plant. X-Action also contains arginine, an amino acid that helps to increase nitric oxide in the blood stream. This is believed to play a positive role in increasing male energy.

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

A handwritten signature in black ink, appearing to read "Robert E. Armstrong". The signature is fluid and cursive, with a large, stylized initial "R" and "A".

Robert E. Armstrong

REA:
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CC: Nature's Sunshine Products, Inc.