

# GRONEK & ARMSTRONG

ATTORNEYS AT LAW

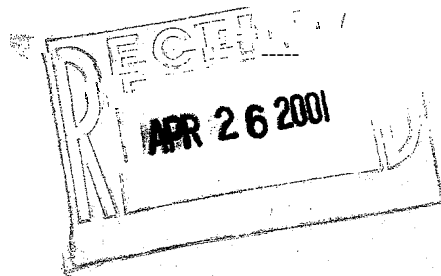
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April 24, 2001

Office of Nutritional Products, Labeling  
And Dietary Supplements (HFS-8 10)  
Center for Food Safety and applied Nutrition  
U.S. FOOD AND DRUG ADMINISTRATION  
200 C. Street S.W.  
Washington, D.C. 20204



Re: Notification for Statements on Dietary Supplement Labels

Dear Sir or Madam:

This firm represents Nature's Sunshine Products, Inc., of Provo, Utah, a manufacturer and distributor of dietary supplement products (hereafter "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</u>  |
|--------------------------|---|
| EW                       | Nervous System Support.   |
| Nature's Chi             | Vital Nutritional Support. Chinese Energy Formula. Boosts energy. Herbs release trapped vitality or "Chi".  |
| Nature's Noni (capsules) | Nervous and Structural System Support. Optimizes benefits for nervous and structural systems. Supports joint health. Overall tonic formula. Historically, many parts of the plant were used to target the Digestive, Intestinal, Respiratory, and Immune Systems. It is particularly useful today in maintaining healthy skin and creating a feeling of well-being. Select parts from two morinda species are utilized to ensure maximum health benefits. |
| Nerve Control            | Nervous System Support. Relaxes irritable nerves and muscle tension. Supports the central nervous system.   |
| Nature's Noni Juice      | Structural, Immune and Digestive System Support. Antioxidant Protection. Supports Joint Health. Historically, many parts of the plant were used to target the Digestive, Intestinal, Respiratory, and Immune Systems. It is particularly useful today in maintaining healthy skin and creating a feeling of well-being. Select parts from two morinda species are utilized to ensure maximum health benefits.   |

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|                   |   |
|-------------------|---|
| Nutri-Calm        | Key System – Nervous. Nervous System Support. <b>Nutri-Calm</b> tablets contain C and B-Complex vitamins combined with additional vitamins and herbs designed to provide you with the most soothing anti-stress product available.  |
| Niacin            | Circulatory and Nervous System Support.   |
| Omega 3 EPA       | Circulatory System Support.   |
| Pau D'Arco        | Immune System Support. Strengthens immune system. Assists detoxification process. Nourishes blood and supports the circulatory system. Helps build blood & maintain a healthy circulatory system.   |
| PDA               | Key System – Digestive Enzymes. Digestive System Support. Adds hydrochloric acid to supplement normal body acids. Contains pepsin for natural protein digestion. Helps supply enzymes lacking in diet. One capsule provides 325 mg of betaine HCl, a dilute hydrochloric acid to supplement normal body acids, and 20 mg of pepsin for natural protein digestion.   |
| Pregnenolone      | Nervous, Structural and Glandular System Support. Helps support memory, mood, and joint health. Supports female glandular balance. Anti-aging. Pregnenolone is derived from Wild Yam root and supports brain health, memory, mood and energy production, hormonal balance, and joint health.  |
| Sam-e             | Nervous and Structural System Support. Mood, emotional well-being, energy. Joint mobility & liver health. Sam-e helps the body with mood, emotional well-being, energy, liver health, joint health, and mobility. It is a natural compound found in every living cell and is involved in important biochemical reactions throughout the body, especially in the manufacture of neurotransmitters <b>in the</b> brain and maintenance of cartilage.  |
| Saw Palmetto      | Glandular System Support. Supports prostate gland health.   |
| St. John's wort   | Nervous System Support. Supports emotional balance and feeling of well-being. Helps maintain positive outlook and healthy motivation. St. John's Wort helps support a person's emotional state in response to the stresses of everyday life. Studies show the ingredient called 'hyperforin' is the key to effectiveness and mood enhancing effects.  |
| Stress-J          | Nervous System Support. Natural herbal <b>calming</b> . For occasional stress relief.   |
| Stress Relief     | Nervous System Support. Natural <b>calming</b> formula. Supports the nervous system. For occasional stress relief.  |
| Suma              | Immune System Support. Provides energy and emotional support. Supports immune system.   |
| Super Antioxidant | Immune System Support. Super Antioxidant provides tocotrienols, rose hips, lycopene (carotenoid), silymarin, and <b>curcumin</b> for super antioxidant protection at the cellular level. Studies show tocotrienols have greater antioxidant activity in certain fatty cell membranes and in areas of the brain and heart. Alpha lipoic acid is fat and water soluble, allowing movement in and out of cell structures, and interacts with vitamin C and E to enhance free radical scavenging. Lycopene is the carotenoid most often linked with |

prostate health, and is also a powerful antioxidant.

THIM-J

Thymus Immune Formula. Immune System Support. Supports thymus gland function and response. Contains antioxidants to neutralize free radicals. Activates T-cells. Supports immune function.

Trace Mineral Maintenance

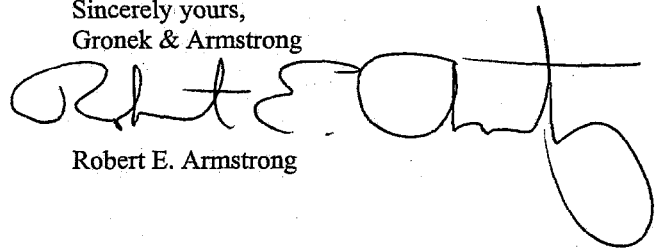
Vital Nutritional Support. Minerals activate enzymes.

TS-II

Thyroid Balancing Formula. Glandular System Support. Supports proper thyroid function. Balances the thyroid.

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", written in a cursive style. The signature is positioned to the right of the typed name.

Robert E. Armstrong

CC: Nature's Sunshine Products, Inc.