GRONEK & ARMSTRONG

1737 03 ATTORNES AT LAW PA :28
98TH FLOOR - SEARS TOWER
233 SOUTH WACKER DRIVE
CHICAGO, ILLINOIS 60606

TEL: (312) 655-1800 FAX: (312) 655-1808

DENNIS M. GRONEK ROBERT E. ARMSTRONG PAUL J. WISNIEWSKI DEBORAH L. RUSS JACQUELINE P. KULER

February 26, 2003

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

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)

**ASTRAGALUS** 

Immune system support. Helps stimulate immune response. Adaptogenic herb - Helps the body cope with daily stress. Astragalus is a powerful adaptogenic herb that heightens immune system responses.

S.O.D.

Immune system support. Systemic enzyme and antioxidant. Protected from stomach acid., Anti-aging benefits. SOD superoxide dismutase functions as a antioxidant and is used by every cell in the body. Decreased production of SOD contributes to aging and

978 0162 LET 11584

possible development of degenerative concerns. This formula contains an SOD/Gliadin complex to ensure maximal amounts of SOD are delivered intact to the intestinal tract.

PS II

Glandular system support. Helps the body support a healthy prostate gland. Provides nutrition for the male glandular system.

SUPER ALGAE

Immune system support. Stimulates immune defense system. Maximizes protein, amino acid, chlorophyll and beta-carotene content of each specific algae. Algae has long been recognized as an ideal food providing protein and other essential nutrients. Nature's Sunshine combined Spirulina, Klamath Lake blue-green and chlorella to create a synergistic Super Algae formula. These three popular species were scientifically blended to maximize the unique nutritional benefits of each algae.

**ELEUTHERO** 

Glandular system support. Adaptogenic herb. Helps to balance the body. Supports energy.

**NERVE EIGHT** 

Nervous system support. Natural calming formula. Supports the nervous systems. For occasional stress relief.

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.