## GRONEK & ARMSTRONG

April 6, 2001

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

APR 1 1 TEH: (312) 655-1800

BY:

Office of Special Nutritionals (HFS-450) 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:

## **Product Name**

## **Label Statement**

Anti-Gas (Formerly AG-C)	Digestive / Intestinal System Support. Alleviates gas. Relieves occasional indigestion.
Bowel Detox (Formerly Bowel B u i l d )	Key System – Intestinal. Cleanses and nourishes the colon. Builds intestinal muscle strength. Absorbs toxins.
Chickweed	Urinary and <b>Glandular</b> System Support. Promotes fat digestion. Inhibits appetite.
Co Q10 Plus	Circulatory System Support.
Co Q10 – 100	Circulatory System Support. Heart health. 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.
Co Q10 30	Circulatory System Support. Co-enzyme Q10, a vitamin-like nutrient, is necessary for the essential enzyme function of inducing chemical changes within cells. Co Q10 produces adenosine triphosphate (ATP), needed to produce energy in all cells, and all cells, and also acts as a powerful antioxidant.

Cordyceps Glandular, Circulatory, Respiratory, and Immune System Support.

Cordyceps is a unique dietary supplement purported to have more pronounced benefits than ginseng in energizing the body's systems. This supplement helps the body when experiencing symptoms of fatigue,

promoting stamina and healthy lung function.

Evening Primrose Oil Circulatory and Glandular System Support.

Flash-Ease Female Glandular System Support.

Flax Seed Oil Omega-3 oil supports the Immune and Circulatory Systems; Omega-6 oil

supports the Glandular and Structural Systems; Omega-9 oil supports the

Respiratory System. Immune stimulator.

FV Immune System Support.

Folic Acid Plus Glandular System Support. Folic acid is essential for human health,

especially for the developing fetus.

Food Enzymes (tablets) Key System Digestive. One tablet will digest a minimum of: 30 grams of

protein, 30 grams of carbohydrates, and 20 grams of fats.

Garlic Oil (capsules) Immune System Support.

Garcinia Combination Glandular System Support for Weight Management. Suppress appetite.

Increase energy. Part of Nature's Sunshine Weight Loss Program. Many exciting studies using garcinia have produced very encouraging results in the

area of weight management.

Germanium Combination Immune System Support.

GLD-F Glandular System Support.

Ginkgo / Gotu Kola Circulatory System Support.

Ginkgo Biloba Extract Nervous and Circulatory System Support. Improves brain function, memory,

& concentration. Promotes optimal circulation to the brain. Gingko biloba promotes optimal blood circulation to the brain and supports memory and

concentration functions.

Gotu Kola Nervous System Support.

Synerpro Grapine with Protectors Vital Nutritional Support. Grape skin extract provides anthocyanidins, an

antioxidant that may play a role in supporting the Circulatory System.

Hawthorn Berries (liquid herb) Circulatory System Support.

Guggul Lipid

Circulatory System Support. Numerous studies using **guggul** lipid have shown this herb to have significant nutritional attributes. Consider using Guggul Lipid with LOCLO High Dietary Fiber Supplement as part of a diet plan designed to substantially lower fat and cholesterol intake while increasing dietary fiber.

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.