GRONEK & ARMSTRONG

ATTORNEYS AT LAW

98TH FLOOR ASEARS TOWERY 10 P3 29

233 SOUTH WACKER DRIVE

CHICAGO, ILLINOIS 60606

TEL: (312) 655-1800 APR 2 5 200 PAX: (312) 655-1808

April 23, 2001

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

> Office of Nutritional Products, Labeling and Dietary Supplements (HFS-810) Center for Food Safety and Applied Nutrition U.S. FOOD AND DRUG ADMINISTRATION 200 C. Street S.W. Washington, D.C. 20204

15651

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

Herbal Sleep

Nervous System Support. Supports restful sleep. Calms irritable nerves. Supports proper nervous system function. Formulated for its soothing and calming proporties.

calming properties.

Anamu

Immune and Structural System Support.

LB Extract

Intestinal System Support.

High Potency Grapine

Immune System Support. Grapine's proanthocyanidins readily cross the blood brain barrier to help protect vital brain and nerve tissue from oxidative damage and are among the most powerful antioxidants found in nature. Antioxidants help to neutralize "free radicals," highly active molecules that cause cell damage.

Hi-Lipase

Digestive System Support. Fat Digesting Formula. Enzymes to break down dietary fat. Assists proper digestion. Hi-Lipase is designed to provide more complete digestion of high fat foods, including nuts. **This** enzyme combination targets fats (**lipase**), proteins (protease), carbohydrates (amylase), and cellulose (**cellulase**). Hi-Lipase is protected with an exclusive herbal blend to: Relax and soothe the stomach. Activate the enzymes. Buffer and stabilize the enzymes from stomach acids.

Product Name

Label Statement

Nervous System Support. Anxiety Relief Formula. Naturally calming. Helps Concentrated Kava Kava with troubled sleep. Kava kava root, used for centuries in the South Pacific Islands for its natural calming and relaxing properties, contains kavalactones, phytonutrients considered to be the key to kava's unique benefits. Kelp Glandular System Support. Kelp is an algae . . . promoting proper glandular function and metabolism. Nervous System Support. The Chinese have used kudzu for its nutritional Kudzu / St. Johns Wort benefits for centuries. St. John's Wort contains hypericin, which has been shown in scientific studies to help support the Nervous System. The combination helps to support the emotional well-being of a person under stress. Intestinal and Circulatory System Support. Digestive tract detoxifier; Liquid Chlorophyll supports intestinal health, supports circulatory health. Digestive and Nervous System Support. Supports Liver Health, Relieves Liver Balance Stress; For Occasional Irritability. Tiao He (Wood Reducing) Vital Nutritional Support. High fiber diets are recommended for good health. SynerPro LOCLO Respiratory System Support. Marshmallow & Fenugreek Glandular System Support. Vitamin, mineral and herbal supplement Monthly Maintenance

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

providing maximum nutrition for women.

Sincerely yours, GRONEK & ARMSTRONG

Robert E. Armstrong

CC: Nature's Sunshine Products, Inc.