## GRONEK & ARMSTRONG

ATTORNEYS AT LAW

98TH FLOOR - SEARS TOWERS 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 MAR 0 5 2003

Re:

Notification for Statement on Dietary Supplement Labels

Dear Sir/Madam:

This firm represents Synergy Worldwide, Orem, Utah, a distributor of dietary supplement products (hereafter "Synergy"). Synergy 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 Synergy 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)

CALCIUM PLUS

Calcium Plus is a synergistic blend of vitamins, chelated calcium, trace minerals, and other potent ingredients which help maintain proper bone structure and function. It combines the optimal blend of nutrients that years of research have shown to be most important for bone health.

**DETOX PLUS** 

Clean out your body naturally and the easy way with this all-herbal formula that "hauls out trash and leaves everything internally looking spotless."

978 0162 LET 11582

83836

**BODY GUARD** 

Body Guard is formulated from the finest deep sea shark liver oil to provide maximum protection against oxidative stress, boost the immune system, and promote cardiovascular health.

PARADISE NONI GUAVA

A traditional tonic drink from the South Pacific that enhances energy and invigorates the body.

**BREAKDOWN** 

Breakdown fat complexer uses the pH chemistry of the digestive system to break down fats. Breakdown will complex 34 times its weight in fat. it also allows for better absorption of fatsoluble vitamins, allowing for a better balanced diet.

CARBOSMART

Thermogenic Diet Formula. CarboSmart naturally and safely prevents the digestion of carbohydrates and reduces the available calories your body may otherwise convert to fat. CarboSmart is 100% stimulant free.

PERFECT SHAPE

The best of science and nature in a complete and easy-to-use weight management supplement.

see Young again docket 1975-0163

Young Again features the latest in anti-aging hormone technology, including an exclusive blend of powerful human growth hormone releasers, DHEA, Pregnenolone and natural Progesterone. These hormones are some of the most powerful anti-aging compounds known to man.

**METAPLEX** 

MetaPlex provides the nutrients that allow for increased muscular size and strength. It is rich in a host of nutrients that interact with the major metabolic pathways, cycles, systems and functions of the body to enhance the formation of lean muscle.

**THERAPLEX** 

TheraPlex Recovery Enhancer provides nutrients necessary for the synthesis of connective tissues, bones, muscle, ligaments and tendons. It enhances recovery from workouts.

**CYBERPLEX** 

Cyber Plex Strength Enhancer provides the nutrients athletes need in order to build strength while at the same time supplying essential elements necessary for lean muscle gain.

The undersigned hereby certifies on behalf of Synergy that the information contained in this correspondence is complete and accurate.

Sincerely yours,

**GRONEK & ARMSTRONG** 

Robert E. Armstrong

PJW:REA:

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CC: Synergy Worldwide