

GRONEK & ARMSTRONG

ATTORNEYS AT LAW

98TH FLOOR - SEARS TOWER
233 SOUTH WACKER DRIVE
CHICAGO, ILLINOIS 60606

FDALAW@GRONEKANDARMSTRONG.COM

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

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

November 15, 2004

NOV 30 2004

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 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 a dietary supplement product label.

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 dietary supplement as follows:

Name

Label Statement(s)

Perfect Shape Liquid 1 Pint

Weight management and structural support, Perfect Shape Liquid is designed to support weight management by utilizing protein and important amino acids contained in our premier source of collagen. Perfect Shape Liquid helps the body obtain a favorable ratio of the fat-storing hormone insulin and the fat-burning hormone glucagons, while supporting the body's production of human growth hormone, which helps burn fat and strengthens and supports muscle tissue. Collagen is also important for healthy skin and strong joints.

97S 0162

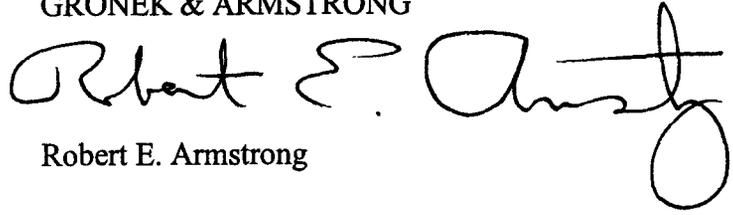
LET

15045

Two copies of this notification are enclosed with this original document.

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

REA:
pr

Enclosures

CC: Synergy Worldwide