

# GRONEK & ARMSTRONG

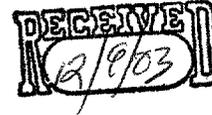
ATTORNEYS AT LAW  
98TH FLOOR - SEARS TOWER  
233 SOUTH WACKER DRIVE  
CHICAGO, ILLINOIS 60606

1657 '04 JAN -8 12:04

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

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

December 1, 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 Synergy Worldwide, Orem, Utah, a manufacturer and 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 supplements as follows:

<u>Product Name</u>	<u>Label Statement(s)</u>
Men's Formula	Sexual and prostate health, Men's Formula is a nutritional complex specifically formulated for men to invigorate energy levels, improve sexual activity and performance, and promote prostate health.

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

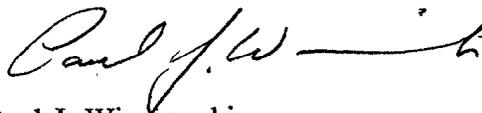
97S 0162

LET

13443

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

Sincerely yours,  
GRONEK & ARMSTRONG

A handwritten signature in black ink, appearing to read "Paul J. Wisniewski", with a long horizontal flourish extending to the right.

Paul J. Wisniewski

PJW:  
pr

Enclosures

CC: Synergy Worldwide