1740 '03 APR -4 P4:29

February 27, 2003

Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 C St. SW., Washington, D.C. 20204 MAR 1 4 2303

RE: Notification of Nutritional Support Statements

Dear Sir or Ma'am:

I hereby notify the Food and Drug Administration (FDA) of the use of statements of nutritional support in the labeling of AHCC<sup>®</sup> a dietary supplement. Source Naturals<sup>®</sup> is the manufacturer of AHCC<sup>®</sup>.

## Statements being made in the labeling of AHCC®:

- (1) AHCC® (Active Hexose Correlated Compound) is a proprietary compound produced by cultivation and enzymatic modification of several species of mushroom mycelia, including shiitake, grown in rice bran extract.
- (2) Considered a superfood supplement in Japan, AHCC has been researched extensively for its immune enhancement properties.
- (3) According to human and animal research, AHCC may significantly increase Natural Killer (NK) Cell activity.
- (4) AHCC may also increase macrophage activity, enhance cytokine production, and support the healthy functioning of the liver as well as act as an antioxidant.

To the best of my knowledge and belief, and based upon information available at the time of the execution of this notice, I certify that the above information is accurate and complete. Source Naturals possesses substantiation that the statements are truthful and not misleading.

Ira L. Goldberg

President, Source Naturals®

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