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

RE: Notification of Nutritional Support Statements

1318 '03 MAR 19 P2:29



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 Mushroom Immune Defense a dietary supplement. Source Naturals[®] is the manufacturer of Mushroom Immune Defense.

Statements being made in the labeling of Mushroom Immune Defense:

- (1) Contains mycelia biomass (mycelium—a network of fibrous filaments—plus the medium it lives on and uses for fuel) from the best-studied species of immune-supportive mushrooms, featuring shiitake, reishi, and maitake.
- (2) Also fortified with six immuno-potentiating myco-extracts to ensure high potency.
- (3) Mushroom compounds, including beta-glucans, glycoproteins and polysaccharides, support a wide range of immune defenses: natural killer cell, T-cell and macrophage activity, and cytokine production.
- (4) A biochemically diverse, high-potency formula that provides optimum immune assistance.

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®

Leethey

975 0162 LET 11496

83737