



We Make Quality Affordable

August 25, 2005

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Food and Drug Administration  
 Center for Food Safety and Applied Nutrition  
 Office of Nutritional Products, Labeling, and Dietary Supplements  
 Division of Nutritional Programs and Labeling  
 200 C Street SW  
 Washington, DC 20204

SEP - 7 2005

Re: 21 U.S.C. Section 343(r)(6), Notification of Statements on Dietary Supplements

Dear Sir/Madam:

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. This notification is a change to a previously submitted structure/function claim dated June 30, 2005. This claim supercedes the previous claim.

Statements being made in the labeling of AHCC<sup>®</sup>:

(1) AHCC<sup>®</sup> (Activate Hexose Correlated Compound) is a proprietary extract produced from specially cultivated and hybridized mushrooms. According to extensive research in humans, as well as numerous non-clinical studies, AHCC<sup>®</sup> supports immune system function through its effects on macrophages and NK (Natural Killer) Cells. NK cells and the intercellular mediators they produce are critical for the maintenance of healthy cell cycle function. AHCC<sup>®</sup> has also been shown possess antioxidant properties, and supports healthy liver function.

To the best of my knowledge, and based upon information and belief present at the time of the executing of this notice, I certify that the above information is accurate and complete. NOW Foods possesses substantiation that the statements are truthful and not misleading.

Michael Lelah, Ph.D.  
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 NOW Foods  
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2005-7120  
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*Michael Lelah*

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