

Source Naturals, Inc.  
Scotts Valley, CA 95066

December 5, 2000

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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

JAN - 8 2001

RE: Notification of Nutritional Support Statements

Dear Sir or Madam:

I hereby notify the Food and Drug Administration (FDA) of the use of statements of nutritional support in the labeling of Genistein (regular label) a dietary supplement. Source Naturals® is the manufacturer of Genistein (regular label).

Statements being made in the labeling of Genistein (regular label):

- (1) Genistein, an isoflavone phytonutrient derived from soybeans, has been the focus of scientific research since 1966. Studies have shown that genistein can bind to the same receptor sites as estrogen. Soybeans are the only significant dietary source of genistein; however, the amount of soy foods necessary to meet the body's needs can be difficult to incorporate in today's diet. In Asia, where soy is a staple, the daily intake can be up to 20 times that of a Western diet.
- (2) Source Naturals Genistein is made from isoflavone rice soybean powder that yields a consistent standardized isoflavone content. The unique chemical-free process requires approximately 400 pounds of soybeans to yield just one pound of finished powder.

To the best of my knowledge, and based upon information and belief present 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, Inc.

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