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BY:

Office of Nutritional Products  
Labeling & Dietary Supplements  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C Street, SW (HFS-810)  
Washington, D.C. 20204

November 13, 2001

Dear Sir or Madam:

This letter will serve as a 30 day notification pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994 that NBTY Inc. is using the following statements on the Time Release L-Lysine 1000 mg supplement under the Major brand name.

- Plays an important role in supporting immune system function
- Lysine is an essential amino acid (not made by the body).
- Amino acids perform a variety of functions and form the basis for protein.
- Lysine assists in the production of antibodies, hormones and enzymes and aids in the repair of collagen and tissue.

The above statements are accompanied by the required disclaimer pursuant to Section 6 of the Dietary Supplement Health and Education Act.

Sincerely,

Ona Scandurra, MS, RD  
Director of Nutrition Communications

OS/am

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