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Office of Nutritional Products  
Labeling & Dietary Supplements  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740-3835

December 7, 2004

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 our Lutein supplements under the Sundown label:

- Promotes Healthy Eye Function.
- Lutein helps maintain eye health and is an antioxidant.
- Lutein is one of the most abundant carotenoids in fruits, vegetables and plants and can be found in the macula of healthy eyes.

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

Sincerely,

Angelica S. Vrablic, Ph.D.  
Manager, Nutrition Research

ASV/mb

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