



90 Orville Drive, Bohemia, NY 11716-2510 ■ Phone: (631) 244-2000 ■ Fax: (631) 218-7480

DEC 22 2004

December 7, 2004

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

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 Pycnogenol® supplements under the Sundown label:

**Ingredients:** Vitamin A, Calcium, Selenium, Pycnogenol, Coenzyme Q-10, Grape Seed Extract, Whole Food Phytonutrient Proprietary Blend; Contains: Broccoli, Carrot, Spinach, Tomato.

- Antioxidant Support
- Our bodies need a variety of antioxidants to help fight against the cell-damaging effects of free radicals in the body.
- Pycnogenol® is a concentrated source of naturally occurring proanthocyanidins, organic acids and other biologically active components, that help to fight against excess free radicals in your body.
- Free radicals can contribute to oxidative stress, which in turn may contribute to the premature aging of cells.

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

975 0162

LET

ASV/mb

15092

90444