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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 13, 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 Saw Palmetto Standardized Extract supplements under the Sundown label:

- Promotes Prostate and Urinary Health in Men.
- Saw Palmetto is an extract derived from the berry of the Saw Palmetto tree, and is the leading herb for men's health.

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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