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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

August 13, 2003

SEP 11 2003

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 Black Cohosh supplements under the CVS label:

- Menopausal Balance
- Nutritional Support for Menopause
- Black Cohosh contains natural plant-estrogens, which help promote a positive outlook and alleviate mood changes and the occasional sleeplessness associated with menopause.

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

Sincerely,

Joanne DeCandia, MS, RD  
Director of Nutrition Communications

JD/eg

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