



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

07-22-07 11:00:00 AM

DEC 22 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

October 22, 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 RE-FEM supplements under the CVS label:

**Ingredients:** Black Cohosh

- Menopause support
- Helps alleviate the common symptoms of menopause including:
  - hot flashes
  - mood changes
  - irritability
  - night sweats
  - occasional sleeplessness
- RE-FEM contains natural, herb-based phyto-estrogens, which help promote a positive outlook and alleviate the mood changes, hot flashes, night sweats, and 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,

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

ASV/mb

97S 0162 LET

15205

90444