



0217 10 2004

DEC 22

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 SAM-e and Double Strength SAM-e supplements under the CVS label:

Ingredient: S-adenosylmethionine

- Joints & Well-being
- Shown to support:
 - Joint health & flexibility
 - Mood and emotional well-being.
 - Healthy liver function
- Sam-e is responsible for the proper functioning of many biochemical reactions and is critical in the manufacture of joint cartilage and the maintenance of neural cell membrane function.
- SAM-e also supports liver health.
- It is very important to sustain proper amounts of SAM-e in the body because significant amounts of SAM-e are not readily available in the everyday diet.
- Supplementing with SAM-e helps maintain joint health, mood and emotional well-being.
- SAM-e helps maintain healthy cartilage, promotes a positive mood and well-being and supports liver health.
- SAM-e is involved in over 35 biochemical reactions involving enzymatic transmethylation.
- The methylation process is the mechanism by which the body gets rid of potentially damaging compounds, synthesizes neurotransmitters, makes components of cartilage, regulates enzyme activity within the cell and maintains the flexibility of cell membranes.

97S 0162

LET

15197

90444