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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

July 26, 2002

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 the 5-HTP supplements under the PhysioLogics brand name:

<u>Ingredients</u>: Niacin, Vitamin B-6, Magnesium, 5-HTP (*Griffonia simplicifolia*), Valerian Root.

- 5-HTP is a precursor to serotonin, a neurotransmitter involved in sending messages through the nervous system, which contributes to a person's mood and well-being.
- Our product incorporates Vitamin B-6 to assist in the formation of serotonin, niacin and magnesium, which play important roles in the key functioning of the nervous system and Valerian root to help promote relaxation.
- Combined, these ingredients help provide your body with the natural ingredients needed to support proper mental function.

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

Sincerely,

Ona Scandurra, MS, RD

Director of Nutrition Communications

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