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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 15, 2004

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 Bromelain supplements under the Rexall and/or Rexall Premium label(s):

- Bromelain is a natural digestive enzyme.
- Digestive enzymes are responsible for breaking down food into different nutrients.
- As a natural enzyme, Bromelain plays a role in protein digestion in the gastrointestinal tract.

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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