



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

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

January 4, 2005

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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 Branched Chain Amino Acids supplements under the PhysioLogics brand name:

**Ingredients:** Vitamin E (as d-Alpha Tocopherol), L-Leucine, L-Isoleucine, L-Valine

- [Exogenous] Muscle Nitrogen Source
- Biochemically Essential
- Branched Chain Amino Acids (BCAA's), which constitute Leucine, Isoleucine, and Valine, are considered biologically essential as they cannot be endogenously synthesized by hepatic enzymes.
- BCAA's are also biochemically unique as they are the only known amino acids metabolized and deaminated directly in the muscle cell, providing a direct source of nitrogen.
- BCAA's are implicated for individuals engaged in both recreational and strenuous exercise programs, as they are protein building blocks.

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

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