DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

JUL 25 2001

Mr. Martin J. Hahn, Esq.
Hogan & Hartson L.L.P.
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004-1109

Dear Mr. Hahn:

This is in response to your letter of June 20, 2001 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission, on behalf of Snapple Beverage Group, states that Snapple beverage Group is marketing the product "Venom High Potency Energy with Instant Bite Energy Supplement" and is making the following claim for it:

"High Potency Energy with Instant Bite Energy Supplement."

This statement is, in part, a nutrient content claim subject to 21 U.S.C. 343(r)(1)(A). FDA has authorized a nutrient content claim for "high potency" (see 21 CFR 101.54(f)). A dietary supplement that meets the requirements in the regulation may use the term "high potency" to describe individual vitamins or minerals that are present at 100 percent or more of the RDI per reference amount of the food customarily consumed. However, the claim that is the subject of your submission does not appear to be a claim that may use the term "high potency" and, as such, the claim is an unauthorized nutrient content claim that misbrands the product.

Please contact us if you require further assistance.

Sincerely,

John B. Foret
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling,
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

975-0163

LET528

Copy:
Snapple Beverage Group
709 Westchester Avenue
White Plains, New York 10604

Copies:
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200
FDA, New York District Compliance, HFR-NE140

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June 20, 2001

Office of Nutritional Products Labeling
and Dietary Supplements (HFS 450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street SW
Washington DC 20204

Re: Dietary Supplement Section 403(r)(6) Notification

Dear Sir or Madam:

On behalf of our client, Snapple Beverage Group (Snapple), we submit this notification pursuant to Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA). As required by 21 C.F.R. § 101.93(a)(2), we provide the following information.

1. **Name and Address of Manufacturer:** Snapple Beverage Group, 709 Westchester Avenue, White Plains, NY 10604.

2. **Text of Statement:** "High Potency Energy with Instant Bite Energy Supplement".

3. **Dietary Ingredients in the Product:** Taurine, ascorbic acid, bee pollen, potassium citrate, Maté Extract, Siberian Ginseng Extract, Guarana Extract, niacinamide, calcium pantothenate, pyridoxine hydrochloride, riboflavin, cyanocobalamin.

4. **Name of Dietary Supplement:** Venom™ High Potency Energy with Instant Bite Energy supplement.

We certify that the information in this notice is complete and accurate and that the company has data to substantiate that the claims made for this product are truthful and not misleading.

Sincerely,

Martin J. Hahn

HahnMJ/hahnmj