

October 7, 2008

Dockets Management Branch  
U.S. Food and Drug Administration  
5630 Fishers Lane  
Rockville, MD 20852

Re: Docket 97P-0498/CPI or FDA-1997-P-0033

Dear Sir or Madam:

Enclosed is a copy of a recent peer-reviewed publication entitled “Caffeinated energy drinks - A growing problem.” The review analyzes several problems related to the use and marketing of energy drinks, with information and suggestions we hope will be helpful for the development of FDA regulatory policy regarding this relatively new and rapidly growing segment of consumer products.

Briefly, the energy drink market has grown exponentially in recent years, with increasing numbers of children and adolescents exposed to the aggressive marketing of literally hundreds of different brands. There are increasing reports of caffeine intoxication from energy drinks. The combined use of energy drinks and alcohol (including caffeinated alcoholic beverages, such as MillerCoors’ Sparks) has increased sharply, and studies suggest that such combined use may increase the rate of alcohol-related injury. Also of concern are data indicating that the use of energy drinks may serve as a transition to the non-medical use of prescription stimulants.

The new report found products that contain caffeine in amounts equivalent to more than 14 12-oz cans of Coca-Cola Classic or five 6-oz. cups of coffee. Many energy drinks exceed the 0.02% caffeine limit specified by FDA for soft-drinks and cola-type beverages.

We encourage FDA to consider regulating the labeling and composition of energy drinks in light of the reality of the marketplace:

1. Companies should be required to label the caffeine content of caffeinated energy drinks (and other caffeine-containing products). That practice has received wide support, including from the American Medical Association, and is voluntarily employed by a growing number of major manufacturers. This issue relates to a petition filed in 1997 that requested labeling of caffeine content [Petition for Amendment of Food-Labeling Regulations to Require Quantitative Labeling of Caffeine Content and Request Review of Health Effects of Caffeine, Docket No. 97P-0498/CPI]. The case for caffeine labeling is now more urgent because of the new and growing category of highly caffeinated energy drinks.

2. Because of the harmful effects of excess caffeine intake and in light of the current marketplace, the FDA should replace the current, unenforced 0.02% caffeine limit with a higher limit that is actually enforced.
3. The FDA should require warning labels, similar to those mandated for OTC caffeine products, on foods, beverages, and dietary supplements containing more than a specified level of caffeine. When appropriate, the warning should indicate the risk of combining these products with alcohol.

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