From the Chief Legal Officers of:

The State of Connecticut

The State of Utah

The Territory of Guam

September 25, 2009

Via Certified Mail, Return Receipt Requested

Dr. Margaret A. Hamburg, Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Re: Alcoholic Energy Drinks

Dear Dr. Hamburg:

We are the co-chairs of the National Association of Attorneys General Youth Access to Alcohol Committee. We write to express our grave concerns about the health and safety hazards posed by alcoholic energy drinks (AEDs), also known as caffeinated alcoholic beverages. AEDs are a class of alcoholic beverages to which are added caffeine and other stimulants, such as guarana, that are metabolized as caffeine. Although a relative newcomer to the marketplace, AEDs are a fast growing segment with surging sales and market growth, particularly among youth.[1]

As set forth in published studies, scientific research demonstrates that there is no common understanding or consensus among qualified scientific experts supporting the safety of adding

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[1] New products are being introduced with ever increasing levels of caffeine and alcohol and in larger can sizes, including in 23.5 ounce cans containing up to 12% alcohol by volume. For example, as recently as July 31, 2009, TTB approved the label for United Brands Company Inc.'s "Max Vibe," an AED with 12% alcohol by volume (https://www.ttbonline.gov/colasonline/viewColaDetails.do?action=publicDisplaySearchBasic&ttbid=09205000000005.) They are promoted to a young audience for consumption in multiple servings, via images and text depicting or describing simultaneous or consecutive consumption of multiple cans, and in association with extreme sports or other high risk activities such as snowboarding, skateboarding, and motocross biking. This rapid pace of growth and its attendant increase in the population exposed to this health hazard underscore the need for immediate action.

caffeine to alcoholic beverages. On the contrary, as evidenced by the attached letter from scientists and medical professionals, there is a strong, emerging consensus of scientific opinion that the combination of caffeine and alcohol in AEDs has not been demonstrated to be safe, but rather poses a serious public health risk. For these reasons, we believe the use of caffeine (and other stimulants that are metabolized as caffeine) as an additive to alcohol is not Generally Recognized As Safe (GRAS) under the Food and Drug Administration's ("FDA") regulations. We therefore urge the FDA to exercise its authority under the Federal Food, Drug and Cosmetic Act ("FDCA") to protect consumers by taking all necessary steps that will result in the immediate removal of AEDs from the marketplace.

The GRAS Standard

A food additive is presumed "unsafe" unless its particular use has been approved by federal regulation or is Generally Recognized As Safe (GRAS) under the conditions of its intended use.[2] Under the GRAS guidelines, the burden is on the manufacturer to prove that (1) an additive is safe for its intended use based on published scientific literature, and (2) there is a consensus of scientific opinion regarding the safety of the use of the substance. 21 CFR §§ 170.3, 170.30. The FDA has approved caffeine as GRAS only for use in non-alcoholic cola-type beverages in concentrations no greater than 200 parts per million. 21 C.F.R. § 182.1180. The FDA has not approved caffeine for use at any level in alcoholic beverages. For the reasons set forth below, we believe the use of caffeine in alcoholic beverages does not meet the requirements of the GRAS standard because it is neither safe based on scientific evidence, nor is there common knowledge or expert consensus regarding its safety.

Published Scientific Literature Does Not Demonstrate that Caffeine is a Safe Additive for Alcoholic Beverages

Several recent scientific studies published in peer reviewed journals demonstrate the dangers of mixing caffeine with alcohol. As these studies show, stimulants such as caffeine appear to mask the intoxicating effects of alcohol, which may lead to increased risk-taking and other serious alcohol-related problems such as traffic accidents, violence, sexual assault, and suicide. See, e.g., Ferriera, 2006, Marczinski and Fillmore, 2006.

There is no Consensus of Opinion that the Use of Caffeine in Alcoholic Beverages is Safe

In addition to published scientific studies, the GRAS standard requires there be a consensus about the safety of the substance for its intended use among qualified experts based on generally available scientific data. In the case of AEDs, there is no consensus that the use of

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[2] See generally, CFSAN/Office of Food Additive Safety, "Guidance for Industry Frequently Asked Questions About GRAS" (December 2004).

caffeine in alcohol is safe. On the contrary, experts in the field agree that the use of caffeine added to alcohol poses a significant public health threat and that it has never been shown or demonstrated that any quantity or level of caffeine is safe for use in alcohol. This view is shared by state law enforcement agencies, state alcohol regulators, and public health groups.[3]

For the foregoing reasons, the combination of alcohol and caffeine or other substances which metabolize as caffeine in AEDs render those beverages inherently unsafe. We ask the FDA to use its authority under the FDCA to cause the immediate removal of AEDs from the marketplace.

Very truly yours,

Richard Blumenthal
Connecticut Attorney General
Committee Co-Chair

Mark Shurtleff
Utah Attorney General
Committee Co-Chair

Alicia G. Limtiaco
Guam Attorney General
Committee Co-Chair

Enclosures

cc via email:

Joshua M. Sharfstein, M.D., Principal Deputy Commissioner, Food and Drug Administration

Susan W. Berndt, Assistant Director, Market Compliance Office, Alcohol and Tobacco Tax and Trade Bureau

[3] Pursuant to separate settlement agreements between Attorneys General and the San Francisco City Attorney and Anheuser-Busch and MillerCoors, those companies have agreed to stop manufacturing and distributing all alcoholic energy drinks. The National Alcohol Beverage Control Association (NABCA) recently passed a resolution expressing serious concern about the manufacture, marketing, and consumption of these products.

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