

A Weekly FAX from the Center for Substance Abuse Research

University of Maryland, College Park

FDA to Evaluate Safety and Legality of Alcoholic Beverages Containing Caffeine

"The increasing popularity of consumption of caffeinated alcoholic beverages by college students and reports of potential health and safety issues necessitates that we look seriously at the scientific evidence as soon as possible."

--Dr. Joshua Sharfstein, Principal Deputy Commissioner of Food and Drugs, FDA

What are caffeinated alcoholic beverages? Caffeinated alcoholic beverages are alcoholic beverages to which the manufacturer has intentionally added caffeine and/or other stimulants that are metabolized as caffeine (e.g., guarana). An increasing number of companies are producing these beverages, with young people as the apparent marketing target. The reported prevalence of combined caffeine and alcohol use among U.S. college students is high as 28%.

What are the potential health concerns with caffeinated alcoholic beverages? Studies have shown that people who drink caffeinated alcoholic beverages drink larger quantities of alcohol. Caffeine can mask the negative effects of alcohol intoxication, increasing the chance that users will engage in potentially risky behaviors, such as drinking and driving, because they don't feel that they are intoxicated. Users of caffeinated alcoholic beverages are also more likely to experience alcohol-related consequences, such as being taken advantage of or taking advantage of someone else sexually. Consuming these beverages may also be associated with adverse effects on heart rhythm, most likely in individuals with pre-existing cardiovascular conditions.

Is caffeine approved by the FDA for use in alcoholic beverages? A food additive is presumed by the FDA to be 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. The FDA has approved caffeine as GRAS for use only in non-alcoholic cola-type beverages at concentrations of no greater 0.02 percent. The FDA has not approved caffeine for use at any level in alcoholic beverages.

What is the FDA doing about this? On November 13, 2009, the FDA issued a mandate to nearly 30 manufacturers* of caffeinated alcoholic beverages to produce within 30 days their rationale and supporting data concluding that their use of caffeine in an alcoholic beverage is either GRAS or prior sanctioned.** To be GRAS, the burden is on the manufacturers to show that 1) the use of caffeine is safe for use in alcoholic beverages based on publicly available scientific evidence and 2) there is a consensus among qualified experts regarding the safety of caffeine for this use. In their letter to manufacturers of caffeinated alcoholic beverages, the FDA states that, "If FDA determines that the use of caffeine in your alcoholic beverage is not GRAS or subject to a prior sanction, FDA will take appropriate action to ensure that this product is removed from the marketplace."

*In the past year, Anheuser-Busch and Miller agreed to discontinue their caffeinated alcoholic beverages and agreed to not produce any caffeinated alcoholic beverages in the future.

**A substance is considered prior-sanctioned if its specific use in food was authorized by the FDA or the Department of Agriculture prior to September 6, 1958.

SOURCES: Adapted by CESAR from the following documents available on the FDA website at <http://www.fda.gov/Food/FoodIngredientsPackaging/ucm190366.htm>: "FDA to Look Into Safety of Caffeinated Alcoholic Beverages; Agency Sends Letters to Nearly 30 Manufacturers," *FDA Press Release*, 11/13/09; *FDA, Questions & Answers on Caffeine in Alcoholic Beverages*, 2009; *CAB Letter to FDA from Attorneys General*, 9/25/09; *CAB Letter to FDA from Scientists*, 9/21/09.

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