

United States Senate
Washington, DC 20510-1304

April 3, 2012

The Honorable Margaret Hamburg
Commissioner
U.S. Food and Drug Administration
10903 Hampshire Avenue
Silver Spring, MD 20093

Dear Commissioner Hamburg:

I am calling on the U.S. Food and Drug Administration (FDA) to take regulatory action to address the rising health concerns around energy drinks.

Energy drinks with names like Monster Energy, Red Bull, Rockstar, Full Throttle, and AMP are now common fixtures in grocery stores, vending machines, and convenience stores. These products target young people claiming to increase attention, stamina, performance, and weight loss. The website for Monster Energy Drink claims to deliver “twice the buzz of a regular energy drink...and the big bad buzz you know and love.” Rockstar Energy Drink claims “to provide an incredible energy boost for those who lead active and exhausting lifestyles.” The glossy marketing tailored to youth has worked – 30 to 50 percent of adolescents report consuming energy drinks.

However, a recent report by the Substance Abuse and Mental Health Services Administration (SAMHSA) shows that energy drinks pose potentially serious health risks. The report found that between 2005 – 2009, the number of emergency room (ER) visits due to energy drinks increased ten-fold from 1,128 to 13,114 visits.

A major factor contributing to these hospitalizations is the exceptionally high levels of caffeine in energy drinks. According to the American Academy of Pediatrics, adolescents should not consume more than 100mg of caffeine daily. One 16oz can of Monster contains 160mg of caffeine, which is equivalent to almost 5 cans of soda. However, this caffeine level does not account for caffeine from additives, like guarana, or ingredients with stimulating properties, like taurine and ginseng.

Consuming large quantities of caffeine can have serious health consequences, including caffeine toxicity, stroke, anxiety, arrhythmia, and in some cases death. Young people are especially susceptible to suffering adverse effects because energy drinks market to youth, their bodies are not accustomed to caffeine, and energy drinks contain high levels of caffeine and stimulating additives that may interact when used in combination.

The FDA has the authority to regulate caffeine levels in soft drinks to .02 percent or less of the product – about 71mg in a 12oz soda. The agency also has the authority to regulate additives in beverages to ensure they are safe for their intended use and when used in combination with other ingredients.

Most energy drinks are currently marketed as dietary supplements, therefore they do not need to establish evidence of their products' safety or adhere to a limit on the level of caffeine. At the same time, many energy drinks come in single-use containers ranging from 8oz to 32oz and are marketed like beverages. Rockstar Energy Drink's website says, "enjoy this fully refreshing lightly carbonated beverage."

If the FDA makes a determination that energy drinks are beverages with high levels of caffeine and additives that raise safety concerns, the agency would have the authority to limit the level of caffeine and require the manufacturers to provide scientific evidence that ingredients such as guarana, taurine, and ginseng are safe for their intended use and in combination with caffeine and other energy drink ingredients.

The distinction between dietary supplements and foods with dietary ingredient additives is not always clear, leaving room for some food and beverage products to be marketed as dietary supplements in order to circumvent the safety standards required for food additives. I urge the FDA to clarify the definition of conventional foods and its authority to oversee the safety of foods, including energy drinks, containing dietary supplement ingredients.

I also ask the agency to investigate energy drinks like Monster Energy, Rockstar, and Full Throttle to ensure they are not in fact conventional foods, based on the FDA's 2009 "Guidance for Industry: Factors that Distinguish Liquid Supplements from Beverages." According to the draft guidance, beverages can be distinguished from liquid supplements based on factors such as the volume in which they are intended to be consumed, product or brand name, labeling, advertising, and packing as a single or multiple use beverage.

I also ask the FDA to enforce its regulatory authority over the caffeine levels in energy drinks, including Red Bull and AMP currently marketed as beverages, and to investigate caffeine levels in energy drinks marketed as supplements.

Finally, I urge the FDA to address the safety concerns posed by additives in energy drinks by requiring manufacturers to provide scientific evidence that ingredients, such as guarana, taurine, and ginseng, are safe for their intended use and when used in combination with other ingredients and caffeine.

Thank you for your attention to this important matter.

Sincerely,



Richard J. Durbin
United States Senator