United States Senate
WASHINGTON, DC 20510

September 11, 2012

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

Dear Commissioner Hamburg:

We write in response to your August 10, 2012, letter regarding proposed actions the Food and Drug Administration (FDA) should take to address rising health concerns around energy drinks.

We were pleased to learn that the FDA intends to release final guidance distinguishing liquid dietary supplements from beverages. The current ambiguity between conventional foods and dietary supplements leaves room for some food and beverage products to circumvent safety standards, such as those required for foods additives. We encourage the agency to issue the final guidance in a timely manner. Final guidance could help FDA and industry properly characterize products as dietary supplements and beverages. Further, considering that most energy drinks are currently marketed as dietary supplements, the final guidance could help clarify which energy drinks are in fact beverages and subject to greater regulatory oversight.

Your letter did not address one of our greatest concerns, which include the potential interactions and cumulative effects of additives with stimulant properties in energy drinks with high levels of caffeine. While ginseng and other additives were not mentioned, your letter reviews taurine and guarana, which are generally regarded as safe (GRAS) food additives when used to add flavor.

We ask you to explain how the Agency determines that taurine and guarana when used at varying concentrations are added to energy drinks for flavoring uses as opposed to non-flavoring uses, such as providing a stimulating effect. The front of Red Bull cans feature taurine prominently on the label next to "vitalized body and mind." The placement and prominence of taurine on the label may suggest the additive is used for non-flavor purposes. We ask FDA to provide additional information on the safety of multiple additives with stimulating properties in energy drinks when used in combination and with caffeine.

A second area of concern that was not adequately addressed in FDA's review of health risks posed by caffeine is the failure to consider the unique health risks associated with consuming high levels of caffeine among young people. Your letter stated that an updated assessment by the FDA on caffeine consumption in the United States found that most caffeine is

consumed through caffeine naturally present in coffee and tea. Unfortunately, there was no assessment of the shifting consumption patterns among young people, who are major energy drink consumers. Further, the letter's review of safety concerns posed by caffeine appears to use healthy adults' ability to consume 400 milligrams (mg) of caffeine as the standard for measuring potential health risks.

Products with names like Monster Energy, Red Bull, Rockstar, Full Throttle, and AMP are marketed to young people, and the marketing has worked – 30 to 50 percent of adolescents report consuming energy drinks. Your letter notes that a healthy adult can consume up to 400 mg of caffeine a day, but the American Academy of Pediatrics recommends that adolescents consume no more than 100 mg of caffeine daily. Additionally, numerous studies cite that young people are especially susceptible to suffering adverse health effects due to consuming large quantities of caffeine.

While we recognize the FDA's efforts to assess caffeine consumption in the United States, young people are not small adults. Therefore determinations on the safety of caffeine should not be based solely on healthy adults. We ask the FDA to include adolescents and children in their assessment of the safety risks posed by consuming high levels of caffeine, such as those in energy drinks.

We also urge the FDA to assert its authority to regulate the level of caffeine in energy drinks marketed as beverages. FDA currently limits caffeine in soft drinks to .02 percent or less of the product – about 71 mg in a 12oz soda. Your letter stated that, "the Agency has not challenged the use of caffeine in other beverages at levels comparable to the prior-sanctioned use level of 200 ppm." A November 22, 2011, Drug Abuse Warning Network report by the Substance Abuse and Mental Health Service Administration (SAMHSA) cites levels of caffeine in energy drinks ranging from 80 to 500 mg per serving. These levels are well above the prior-sanctioned use limit of .02 percent in soda and the 50 mg of caffeine in many 12oz sodas. Many energy drinks are sold in single-use 8 to 32oz cans right next to soft drinks. The FDA currently regulates caffeine levels in soft drinks. We urge the agency to assert its regulatory authority over caffeine levels in energy drinks marketed as beverages.

Thank you for your attention to this important matter.

Sincerely,

Richard J. Durbin
United States Senator

Richard Blumenthal
United States Senator