United States Senate
WASHINGTON, DC 20510

October 26, 2012

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

Dear Commissioner Hamburg:

We are writing regarding recent reports that the Food and Drug Administration (FDA) has received information on five fatalities that occurred after the consumption of Monster energy drinks. News of these reports has been followed by a new *Consumer Reports* study that measured the amount of caffeine in 27 top selling energy drinks, which found that five products had caffeine levels at least twenty percent above the listed amount and eleven drinks did not specify the amount of caffeine. In light of these deaths, the *Consumer Reports* study, and a November 2011 report by the Substance Abuse and Mental Health Services Administration (SAMHSA), which found a ten-fold increase in emergency room visits due to energy drinks between 2005-2009, we believe it is necessary for the FDA to take immediate action to address a serious public health issue.

On September 11, 2012, we sent the FDA a letter calling on the agency to take action to address rising public health concerns around energy drinks. That letter was a follow-up to an earlier letter setting out concerns with energy drinks and asking the FDA to take action to protect consumers. We have not received a response to this letter. Once again, we reiterate our request for the FDA to investigate the interactions between caffeine and stimulants in energy drinks, to assess the health risks associated with caffeine consumption by children and adolescents, and to finalize and issue guidance that clearly distinguishes liquid dietary supplements from beverages.

As stated in earlier letters, energy drinks contain not only high levels of caffeine, but additives with stimulant properties, such as guarana, taurine, and ginseng. We urge the FDA to assess potential safety concerns posed by multiple additives with stimulating properties in energy drinks when used in combination and with caffeine.

Additionally, it is apparent that the FDA needs to examine the impact of energy drink consumption on children and teens. Industry marketing to young people has resulted in heavy consumption of energy drinks by adolescents. Unfortunately, the FDA's assessment of safe levels of caffeine consumption does not appear to consider divergent consumption patterns for young people compared to adults or recognize differences in safe levels of caffeine consumption for adults compared to children. We urge the FDA to consider energy drink and caffeine

consumption habits of children and adolescents when assessing the health risks of high caffeine consumption. We also urge the FDA to take action to limit the amount of caffeine in beverages to safe levels.

Furthermore, we are deeply concerned that some industry actors exploit the FDA's limited authority to regulate dietary supplements by marketing their products as dietary supplements, in order to avoid FDA safety and regulatory requirements that apply to foods and beverages. This is particularly apparent in the energy drink industry, where many of the most popular products are classified as dietary supplements, despite being marketed, shelved, and consumed as beverages. This allows energy drink manufacturers to avoid FDA oversight and offer products containing additives whose safety has not been demonstrated. The FDA must issue final guidance on this matter and make clear which products may be considered dietary supplements and which products must be considered conventional foods and beverages.

Thank you for your consideration of these concerns. We look forward to your response.

Sincerely,

Richard J. Durbin
United States Senator

Richard Blumenthal
United States Senator