

June 25, 2014

The Honorable Margaret A. Hamburg, M.D. Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hamburg:

We write to express our concern about the potential harms resulting from the consumption of energy drinks. We understand from its public statements that the FDA is concerned about the risks of energy drinks. The agency last released adverse event reports in October 2012 concerning deaths and injuries linked to consumption of energy drinks. Energy drinks are the fastest-growing segment of the beverage industry and are contain a variety of chemicals, herbal ingredients, caffeine, and caloric or non-caloric sweeteners. We write to follow up on additional relevant information obtained since that time and urge several actions by the FDA to protect the public while new medical and scientific investigations are conducted.

From our recent Freedom of Information Act (FOIA) request for data from the Adverse Event Reporting (AER) System, we understand that FDA received reports of 17 deaths since October 2012. Overall, the AERs indicate that the FDA received 276 reports of adverse events involving energy drinks between January 1, 2004, and March 10, 2014. Excluding a suicide, thirty-four of the incidents involved death, often as a result of heart failure. Fifteen resulted in disability and one in miscarriage. Of the fatalities, 22 were linked to 5-Hour Energy, 11 to Monster and one to Rockstar brand beverages. The miscarriage was linked to a 5-Hour Energy drink.

We understand that the FDA is investigating these incidents to determine whether the deaths were caused in some way by consumption of energy drinks. We recognize that the AERs cannot determine with any certainty that energy drinks were or were not the cause of death.

Among the reports of non-fatal problems since 2004, 42 involved life-threatening injuries and 82 involved injuries that were characterized as "serious," while 37 involved injuries that were listed as "non-serious." One hundred and fifteen incidents resulted in hospitalization.

Adolescents and teenagers can be particularly vulnerable to the potential harms of energy drinks. Anais Fournier, a 14-year-old girl, died from a cardiac arrhythmia due to caffeine toxicity¹ after consuming a Monster energy drink while she was at the mall with her friends. In addition, the death of a 19-year-old in California and the brain damage of an Oklahoma 16-year-old have been linked to the consumption of Monster beverages.² Government records also show that two 15-year-old boys and an 18-year-old male died in Canada, possibly caused by their consumption of either Monster or Red Bull beverages.³ Further, a case report indicates that a 28-year-old man drank 3 cans of an energy drink 5 hours before playing basketball, and after playing in the game for 30 minutes, he lost consciousness and was hospitalized. Three days later, he died after

sudden cardiac arrest.⁴ While energy drinks have not been proven to be deadly, these reports demonstrate that some harms may result from energy drink consumption.

The popularity of energy drinks has risen in recent years, demonstrated by the 240% increase in sales from 2004 to 2009.⁵ In 2011, energy drinks were the fastest-growing beverage segment in the United States⁶ and sales reached a record-high \$9 billion that year, a 16 % increase from the previous year.⁷ Teens and young adults constitute the largest percentage of sales of energy drinks, accounting for nearly \$2.3 billion in sales.⁸

Energy drinks appear to be marketed heavily to children and teens. Approximately 30 to 50% of children, adolescents and young adults self-report consuming more than one energy drink per month. A Senate report published last year found that despite the insistence of energy drink manufacturers that they do not target their marketing to children and adolescents, "the use of unconventional market practices combined with product design and placement on store shelves assists in creating product images that appeal to children and teens." Testimony in a recent Maryland legislative hearing from industry representatives indicated that the companies define "minors" as those under 12 years of age, contradicting state laws that define minors as those below 18 years of age. A lawsuit by the San Francisco City Attorney against the Monster Beverage Company documents online participants in viral marketing on Facebook and other venues who are as young as six years old. Energy drink companies stage an active presence on social media and other online outlets and sponsor high school athletic events, concerts, and other areas in which teens gather. Further, poison control centers indicate that children less than 6 years old constitute the largest proportion of energy drink-related calls, suggesting that the packaging or other aspects of the drinks appeal to children.

Energy drinks are purchased and consumed like soft drinks. Energy drinks are located next to sodas in grocery stores, vending machines, and convenience stores. ¹⁵ In contrast to coffee (which, as a hot beverage, is sipped slowly), ¹⁶ energy drinks are consumed cold and often quickly "chugged," similar to soda.

Further, the FDA's issuance of the January 2014 Guidance Document entitled "Distinguishing Liquid Dietary Supplements from Beverages," demonstrates there may be confusion among consumers when distinguishing between beverages that are conventional foods and dietary supplements.¹⁷ In addition, recent surveys show that consumers – including teens – are unclear about the differences between energy drinks and sports drinks, with a recent survey finding that adolescents do not differentiate between sports and energy drinks, citing the same benefits for both beverages despite their vastly different ingredient compositions.¹⁸

Further, many of the ingredients commonly found in energy drinks may have potentially harmful effects. These substances, including caffeine, guarana, taurine, glucuronolactone, and ginseng, among others, potentially have no nutritional value and may, individually or collectively, pose the apparent health risks from consuming energy drinks. ¹⁹ As far as we can tell, the FDA has not examined some of those ingredients for safety, effectiveness, purity, or interactions with other energy-drink ingredients. ²⁰

To cite one example of a health concern, when combined with caffeine, taurine, a non-essential amino acid²¹ may also be dangerous. Although taurine is an amino acid naturally found in the body, "the use of amino acids in energy drinks in place of traditional dietary sources is not supported by the scientific literature and, therefore, is discouraged in children and adolescents."²² Taurine is part of a group of substances – called inotropes – known to increase contractility in the heart.²³ Although there is not yet evidence of adverse effects resulting specifically from taurine, deaths in European athletes have been linked to energy drinks containing taurine and caffeine (along with other ingredients). Therefore, many European countries have banned or limited the sales of energy drinks.²⁴ Additional research is essential to determining the safety of taurine and other unconventional ingredients commonly found in energy drinks, and those ingredients should be tested for safety in combination as well as separately.

FDA should address promptly and fully the potential threat to public health posed by energy drinks. We urge the agency to:

- Issue a public health warning to discourage people, especially those under 18, from consuming energy drinks and suggest to state and localities that they bar the sale of energy drinks to people under 18.
- Initiate a rulemaking to require that all beverages consumed in a soda-like manner, including energy drinks, comply with the same regulations that limit caffeine in "colatype beverages" (0.02%, or 71 milligrams per 12 ounces, see 21 C.F.R. § 182.1180).
- Initiate a rulemaking to require warning labels on energy drinks to alert consumers of the possible risk of heart attack, convulsion, and other adverse reactions.
- Initiate a thorough and independent study of the safety of these ingredients, both alone and in combination with each other in formulations typical of energy drinks.

Thank you for considering these concerns. We look forward to your reply.

Sincerely,

Laura MacCleery

Chief Attorney for Regulatory Affairs

Michael F. Jacobson, Ph.D.

Executive Director

Notes

¹ Autopsy Report of Anais Fournier, Age 14, Hagerstown Maryland Resident Who Died After Consuming Monster Energy Drink.

² Mulcahy and Adams. "Monster Beverage Company—A Case Study of Vertical Distribution Landmines." http://mulcahyllp.com/firmnews/practicenews/monsterbeveragecompanyacasestudyofverticaldistributionlandmines.

³ "Energy drinks suspected to have caused deaths of 3 Canadians." *Toronto Star*. November 18, 2012. http://www.thestar.com/news/canada/2012/11/18/energy_drinks_suspected_to_have_caused_deaths_of_3_canadians_html.

⁴ Avci, Sarikaya, and Buyukcam. "Death of a Young Man after Overuse of Energy Drink," *American Journal of Emergency Medicine* 31 (2013).

⁵ Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. (November 22, 2011). *The DAWN Report: Emergency Department Visits Involving Energy Drinks*. Rockville, MD.

⁶ Seifert, Schaechter, Hershorin, and Lipshultz. "Health Effects of Energy Drinks on Children, Adolescents, and Young Adults," *Pediatrics* (2011). http://pediatrics.aappublications.org/content/127/3/511.full.html

⁷ Meier, Barry. (2012, October 23). More Than a Case of the Jitters. *New York Times*, p. B1. Retrieved from http://www.nytimes.com/2012/10/24/business/safety-becomes-a-concern-with-energy-drinks.html

⁸ Rath, Mandy, BSN. "Energy drinks: What is all the hype? The dangers of energy drink consumption," *Journal of the American Academy of Nurse Practitioners* 24, 70-76 (2012).

⁹ Seifert, Seifert, Schaechter, Bronstein, Benson, Hershorin, Arheart, Franco and Lipshultz. "An analysis of energy-drink toxicity in the National Poison Data System," *Clinical Toxicology* 51, 566-574 (2013).

¹⁰ Congressman Markey, with Senators Durbin and Blumenthal. "What's all the Buzz About? A Survey of Popular Energy Drinks Finds Inconsistent Labeling, Questionable Ingredients, and Targeted Marketing to Adolescents." April 10, 2013.

¹¹ Stuart Pape, on Behalf of the American Beverage Association. Testimony in Opposition to House Bill 1273, Maryland House of Delegates, Economic Matters Committee. March 7, 2014.

¹² Dorsey, Matt. "Herrera blasts Monster Energy's lawsuit over unlawful marketing to youth, product safety," *City Attorney Dennis Herrera Statement*. April 30, 2013.

¹³ Blankson, Thompson, Ahrendt, and Patrick. "Energy Drinks: What Teenagers (and Their Doctors) Should Know," *Pediatrics in Review* 34, No. 2 (2013).

¹⁴ Seifert, Seifert, Schaechter, Bronstein, Benson, Hershorin, Arheart, Franco and Lipshultz. "An analysis of energy-drink toxicity in the National Poison Data System," *Clinical Toxicology* 51, 566-574 (2013).

¹⁵ Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. (January 10, 2013). *The DAWN Report: Update on Emergency Department Visits Involving Energy Drinks: A Continuing Public Health Concern.* Rockville, MD.

¹⁶ Arria and O'Brien. "The 'High' Risk of Energy Drinks," *Journal of the American Medical Association* 305, No. 6 (2011).

¹⁷ Congressman Markey, with Senators Durbin and Blumenthal. "What's all the Buzz About? A Survey of Popular Energy Drinks Finds Inconsistent Labeling, Questionable Ingredients, and Targeted Marketing to Adolescents." April 10, 2013.

¹⁸ Committee on Nutrition and the Council on Sports Medicine and Fitness. "Clinical Report—Sports Drinks and Energy Drinks for Children and Adolescents: Are They Appropriate?" Pediatrics 127, No. 6 (2011).

¹⁹ Committee on Nutrition and the Council on Sports Medicine and Fitness. "Clinical Report—Sports Drinks and Energy Drinks for Children and Adolescents: Are They Appropriate?" Pediatrics 127, No. 6 (2011).

²⁰ Blankson, Thompson, Ahrendt, and Patrick. "Energy Drinks: What Teenagers (and Their Doctors) Should Know," *Pediatrics in Review* 34, No. 2 (2013).

²¹ Bichler, Swenson & Harris. "A combination of caffeine and taurine has no effect on short-term memory but induces changes in heart rate and mean arterial blood pressure," *Amino Acids* 31, pp. 471-476 (2006).

²² Committee on Nutrition and the Council on Sports Medicine and Fitness. "Clinical Report—Sports Drinks and Energy Drinks for Children and Adolescents: Are They Appropriate?" Pediatrics 127, No. 6 (2011).

²³ Committee on Nutrition and the Council on Sports Medicine and Fitness. "Clinical Report—Sports Drinks and Energy Drinks for Children and Adolescents: Are They Appropriate?" Pediatrics 127, No. 6 (2011).

²⁴ Rath, Mandy. "Energy drinks: What is all the hype? The dangers of energy drink consumption," *Journal of the American Academy of Nurse Practitioners* 24, 70-76 (2012).