Congress of the United States
Washington, DC 20515

January 17, 2013

Scott Henderson, President
Living Essentials
38955 Hills Tech Dr
Farmington Hill, MI, 48331

Dear Mr. Henderson:

The Food and Drug Administration (FDA) is launching an investigation to strengthen its understanding of energy drinks and health risks posed by these products, particularly for vulnerable groups including young people and those with pre-existing cardiac conditions. This investigation follows recent adverse event reports of illness, injury and death allegedly linked to the consumption of products marketed as "energy drinks" or "energy shots," and mounting concerns regarding the safety of this rapidly growing class of products.

Although the term "energy drink" is not defined by the FDA, it generally represents a class of products in liquid form that typically contains high levels of caffeine. Currently, manufacturers have the discretion to decide whether an energy drink product will be marketed and labeled as a conventional food (beverage) or as a dietary supplement. While the FDA does have the authority to regulate both conventional foods and dietary supplements, the requirements for ingredients, manufacturing processes, reporting of adverse events and labeling, differ depending on whether the product is marketed as a beverage or as a supplement. In 2009, the FDA issued draft guidance to clarify when a liquid product should be classified as a supplement versus beverage, but the guidance, which is non-binding in nature, has yet to be finalized by the Agency.

The blurred distinction between supplements and conventional foods or beverages combined with recent published reports by the Substance Abuse and Mental Health Services Administration (SAMHSA) and FDA regarding consumption of energy drinks has led to significant consumer confusion and concern about the safety and use of these products. One of the major concerns surrounding energy drinks is the potential health risks for children who consume these products. Furthermore, questions have been raised about the combination of high levels of caffeine with other stimulant ingredients.

To better understand the scope of these issues, we respectfully request that you provide a written response to the following questions by no later than the close of business on February 1, 2013. The questions refer to your products marketed under the brand 5-hour ENERGY.

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1. Do you consider your products, marketed under the brand 5-hour ENERGY, to be a supplement, conventional food/beverage or neither? Please explain why. If you consider your product(s) to be neither a supplement nor a conventional food, please explain how you classify your product(s).

2. How does your company determine whether your product(s) should be marketed and labeled as a dietary supplement or as a conventional food?

3. Typically, dietary supplements contain a supplement facts panel as a part of the product label, while conventional foods contain a nutrition facts panel. How is the nutrition information presented on your product(s) (i.e., with a supplement facts or nutrient fact panel)? Please explain why. If you include neither a nutrition facts panel nor a supplement facts panel on your product(s), please explain why.

4. How much caffeine from all sources in milligrams does your product(s) contain in the entire package?

5. What is the recommended serving size and how many milligrams of caffeine from all sources is present in one serving size of your product(s)?

6. Does your company list the recommended serving size and the milligrams of caffeine per serving on your product(s) label? If yes, where and in what form? If no, why not?

7. In calculating the amount of caffeine included in your product(s), do you include the amount contributed by other stimulant ingredients such as guarana? If no, why not?

8. In addition to caffeine, does your product(s) include any other stimulants? If so, what are they and what are the amounts? Are these additional stimulants and their quantities listed on your product(s) label? If they are not listed, why not?

9. Does your company market energy products to children or teenagers? If so, what advertising tools do you use to target this demographic?

10. Please describe the advertising claims made by your product(s). Are these claims considered to be health claims, qualified health claims, structure/function claims, nutrition content claims, or other claims? Has your company substantiated structure/function claims? If so, please provide documentation (i.e., study results, summaries, analysis, etc.) that substantiates these claims. If not, why not?

11. What ingredients, aside from caffeine, impact the advertising and marketing claims made by your product(s)? Please list the ingredients that impact these claims and what each ingredient is responsible for in the overall product(s). Please provide data and documentation to support your answer.

12. Has your company performed any studies to determine whether your product(s) is safe for consumption by children and teens? If no, why not? If so, what was determined by these studies? Please provide documentation to support the conclusion drawn.

13. Has your company performed any studies to examine the potential for serious health consequences of using your product(s), including caffeine toxicity, stroke, anxiety, arrhythmia, and in some cases death? If so, please provide these studies. If no, why not?

Thank you for your assistance and cooperation in responding to this request. Should you have any questions, please have your staff contact Dr. Avenel Joseph in Rep. Markey's office at 202-225-2836, Dr. Binta Beard in Sen. Durbin's office at 202-224-2152, or Mr. Alex Chasick in Sen. Blumenthal's office at 202-224-2823.

Sincerely,

Edward J. Markey

Edward J. Markey

Dick Durbin

Richard J. Durbin

Richard Blumenthal

Richard Blumenthal