

United States Senate

WASHINGTON, DC 20510

April 26, 2016

Dr. Robert Califf
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Califf:

We are writing to urge the U.S. Food and Drug Administration (FDA) to take meaningful action on pure and highly-concentrated bulk powdered caffeine products. We first shared our concerns about these products with the agency over a year ago, and the FDA has yet to ban the retail sale and marketing of pure and highly-concentrated bulk powdered caffeine products sold outside of pharmaceutical and food production purposes. Given the mounting evidence, it is clear that regulation and enforcement of these products is long overdue.

Data collected by the American Association of Poison Control Centers indicates that, since 2014, there have been 60 incidents involving powdered caffeine cases in at least 25 states. The vast majority of these cases involved individuals under 18 years of age. This is unacceptable.

In September 2015, the FDA sent warning letters to five dietary supplement companies, alerting them that their labels violate FDA regulations and do not adequately address the risks associated with consumption. These companies responded by voluntarily removing these products from their websites. Despite this fact, bulk pure, powdered caffeine and other dangerous forms of highly-concentrated caffeine remain widely available and easy to buy over the internet.

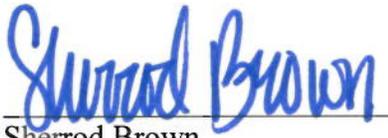
While we appreciate the FDA's attention to these five companies, we remain concerned that, according to the Center for Science in the Public Interest (CSPI), nearly 20 other retailers – domestic and international – continue to market and sell powdered caffeine in multiple forms. Moreover, these products do not provide a way to measure a safe dosage per FDA recommendations, and are sold in quantities that could easily kill hundreds of individuals if ingested incorrectly.

It is disturbing that despite several unintended and untimely deaths associated with powdered caffeine, the FDA has done little to regulate these products or adequately enforce the standards in place to protect Americans from the substantial risk associated with ingesting powdered caffeine in any form. Unfortunately, in the absence of strong regulatory action, companies are continuing to develop new delivery mechanisms and creative advertising ploys to attract new powdered caffeine users and are doing so without relaying the serious health consequences of improper use.

We request that the FDA use its authority to scrutinize the powdered caffeine market, enforce the safety mechanisms in place, and ultimately ban pure and highly-concentrated bulk powdered caffeine products in all of its forms.

Thank you for expediently attending to this matter.

Sincerely,



Sherrod Brown
United States Senator



Richard J. Durbin
United States Senator



Richard Blumenthal
United States Senator



Edward J. Markey
United States Senator



Charles E. Schumer
United States Senator