UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Petition to Ban the Retail Distribution Of Pure and Highly Concentrated Caffeine Sold in Powder Form as a Dietary Supplement.

Submitted by

CENTER FOR SCIENCE IN THE PUBLIC INTEREST

December 9, 2014

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Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane
Room 1061, HFA-305
Rockville, MD 20852

CITIZEN PETITION

The Center for Science in the Public Interest (CSPI), representing 800,000 members and supporters, petitions the Food and Drug Administration (FDA) to ban the retail distribution of pure and highly concentrated caffeine as a dietary supplement. The recent commencement of pure or highly concentrated caffeine marketing has been associated with ill effects in consumers, including deaths. CSPI thus requests that FDA limit the form in which caffeine is sold to prevent unreasonable risks to adolescents and others from overdoses of caffeine.

FDA should find that pure caffeine marketed as a dietary supplement presents "a significant or unreasonable risk of illness or injury under conditions of use suggested or recommended in the labeling," or, in the absence of such labeling, "under ordinary conditions of use."[1] Alternatively, the Secretary of Health and Human Services should declare that caffeine sold in pure or highly concentrated form "pose[s] an imminent hazard to public health or safety," and institute an immediate ban to that effect.[2] Under either standard, highly concentrated caffeine must be deemed adulterated and removed from the market under the Federal Food, Drug, and Cosmetic Act (FDCA) and the Dietary Supplement Health and Education Act (DSHEA).

I. Actions Requested

CSPI calls on the FDA and/or HHS to:

1. Ban the retail distribution of highly concentrated caffeine marketed as a dietary supplement because it presents a "significant or unreasonable risk of illness or injury" or an "imminent hazard to public health."[3]

2. Specify limits on the form in which caffeine is sold, including its labeling, serving sizes, and potency, to minimize the risk of accidental overdose by all potential users, including younger consumers.

[1] 21 U.S.C. § 342(f)(1)(A).
[2] 21 U.S.C. §§ 331(a); 354(f)(1)(C).
[3] 21 U.S.C. §§ 342(f)(1)(A); 331(a); 354(f)(1)(C).

II. Statement of Grounds

This petition relates to pure or highly concentrated caffeine, which is currently sold in bulk online in a powder form by retailers of dietary supplements.[4] This petition does not address caffeine sold in energy drinks, energy shots, or other novel retail products, although we applaud the FDA's efforts to understand the potential hazards of these products.[5] While we recognize that substantial data and analysis will be necessary to forge new policies to ensure the safe use of energy drinks and other caffeinated products, CSPI believes that highly concentrated caffeine presents a unique, self-evident danger to consumers that justifies an immediate ban and corresponding adjustments to FDA's regulations.

Pure or highly concentrated caffeine is dangerous due to the possibility of consuming unintentionally large quantities. Just one teaspoon of powder caffeine, which amounts to approximately 3 grams, is equivalent to drinking 25 cups of coffee.[6] It is so concentrated, in fact, that its suggested serving size – generally between 1/32 and 1/16 of a teaspoon – is beyond the measurement capabilities of a typical consumer and would require specialized equipment not found in a typical kitchen. Because consumers do not have the ability to measure out a safe dose, the risk of unintentional overdose is significant. We can also envision some youths experimenting to see how much caffeine they could consume without realizing the substantial risks. Symptoms of caffeine overdose can include rapid or dangerously erratic heartbeat, seizures, and even death. The dangers of pure, powdered caffeine were tragically illustrated earlier this year when an Ohio high school student, Logan Stiner, died after consuming caffeine powder that he obtained from a friend who purchased it on the Internet.[7] Another young man, a 24 year old in Georgia, James Wade Sweatt, also tragically died last summer after ingesting caffeine powder and suffering cardiac arrest at his home. Statements from the parents of Logan Stiner and Wade Sweatt are attached to this Petition as Exhibit B.

FDA specifically acknowledged the danger of pure, powdered caffeine by issuing a consumer advisory in 2014.[8] While the advisory was a useful first step, we urge FDA to take more effective action by banning this dangerous substance before its popularity and lethal effects

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[4] *See, e.g.*, 100% Pure Caffeine Anhydrous USP Powder, NutriVita Shop, http://www.nutrivitashop.com/caposat6for1.html (accessed Dec. 5, 2014); Nutrakey Caffeine Unflavored, SanaSana, http://www.sanasana.com/nutrakey-caffeine-unflavored-40-g.html?gclid=CKvdpvCzpcICFcvm7AodBRYAoQ; AI Sports Nutrition Caffeine Powder, All Star Health, http://www.allstarhealth.com/de_p_ref/28526/pla28526/AI_SPORTS_NUTRITION_Caffeine_Powder.htm?utm_source=google&utm_medium=GPS&utm_campaign=28526&gclid=CNHigMamqsICFSdn7Aodc1UAPQ (accessed Dec. 5, 2014). Images of such products are attached as Exhibit A.

[5] Institute of Medicine Workshop Summary, *Caffeine in food and dietary supplements: Examining Safety*, The National Academies Press: Washington, DC (2014); P. Nawrot et al., Effects of caffeine on human health, Food Addit. Contam. 20:1–30 (2003).

[6] U.S. Food and Drug Administration, FDA Consumer Advice on Powdered Pure Caffeine, http://www.fda.gov/Food/RecallsOutbreaksEmergencies/SafetyAlertsAdvisories/ucm405787.htm (accessed Dec. 5, 2014).

[7] Associated Press, Death Of Teen Logan Stiner Puts Focus on Caffeine Powder Dangers (July 19, 2014), http://www.huffingtonpost.com/2014/07/19/logan-stiner-caffeine-pow_n_5601775.html (accessed Dec. 5, 2014).

[8] U.S. Food and Drug Administration, FDA Consumer Advice on Powdered Pure Caffeine, http://www.fda.gov/Food/RecallsOutbreaksEmergencies/SafetyAlertsAdvisories/ucm405787.htm (accessed Dec. 5, 2014).

increase. Several U.S. Senators have already called on FDA to ban the substance,[9] and sales to minors have been banned at the local level by Suffolk County, New York.[10] A petition to FDA to investigate and ban caffeine powder started on Change.org by the family of Logan Stiner has garnered over 6,000 supporters.[11] FDA should heed these pleas and act swiftly. Highly concentrated caffeine provides no benefit worth the risks it poses, and FDA should take immediate steps to remove it from the market.

a. Description of Product

Caffeine, or 1,3,7-trimethylxanthine, is a mild central nervous stimulant that occurs naturally in coffee beans, cocoa beans, tea leaves, and certain other botanical sources.[12] Caffeine (whether derived by decaffeination or manufactured synthetically) is also added to many beverages, such as energy drinks and colas, and to candies, chewing gum, and other non-beverage food items.[13] In addition to caffeinated foods and beverages, caffeine is also produced, sold, and consumed in forms more akin to a dietary supplement.[14] For example, "energy shots" are a specialized form of energy drink sold in 2-oz. containers as a dietary supplement.[15] Caffeine is also marketed in tablet form as an over-the-counter drug or dietary supplement to alleviate fatigue and drowsiness.[16]

Recently, thanks to the Internet, caffeine in pure or highly concentrated form has become more widely available to consumers, allowing consumers to ingest massive quantities nearly instantaneously. Pure or highly concentrated caffeine powder has become popular as a dietary supplement, particularly among athletes, to whom it is marketed as performance enhancing.[17]

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[9] Kristin Stoller, Blumenthal calls on FDA to ban powdered caffeine from stores, New Haven Register (Aug. 21, 2014), http://www.nhregister.com/health/20140821/blumenthal-calls-on-fda-to-ban-powdered-caffeine-from-stores (accessed Dec. 5, 2014); Press Release, Following Tragic Death of Lorain County Teen, Brown Calls for Ban on Powdered Caffeine (Oct. 23, 2014), http://www.brown.senate.gov/newsroom/press/release/following-tragic-death-of-lorain-county-teen-brown-calls-for-ban-on-powdered-caffeine (accessed Dec. 5, 2014).

[10] Carrie Miller, Suffolk County bans sale of pure caffeine products to minors, Suffolk Times (Nov. 6, 2014), http://suffolktimes.timesreview.com/2014/11/53693/suffolk-first-to-regulate-sale-of-pure-caffeine-to-minors/ (accessed Dec. 5, 2014).

[11] Petition to Investigate and Ban Caffeine Powder, https://www.change.org/p/u-s-food-and-drug-administration-investigate-and-ban-caffeine-powder (accessed Dec. 5, 2014).

[12] Leah Rosenfeld et al., Regulatory status of caffeine in the United States, Nutrition Reviews 82(1): 23-33 (2014).

[13] *Id.*

[14] *Id.*

[15] Laszlo Somogyi, Caffeine intake by the U.S. population, Prepared for FDA under Subcontract Number 70000073494 (2010). Pg. 5, *available at* http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofFoods/CFSAN/CFSANFOIAElectronicReadingRoom/UCM333191.pdf (accessed Nov. 6, 2014).

[16] Caffeine comes in both prescription and non-prescription pills and may range from 15–200 mg per pill or tablet. P. Nawrot et al., Effects of caffeine on human health, Food Addit. Contam. 20:1–30 (2003). For example, Walgreen's sells "Stay Awake" tablets containing 200 mg/pill. *See* Walgreens Stay Awake Caffeine Tablets, Walgreens, http://www.walgreens.com/store/c/walgreens-stay-awake-caffeine-tablets/ID=prod2922366-product (accessed Dec. 5, 2014); NoDoz Alertness Aid, http://www.nodoz.com/ (accessed Dec. 8, 2014). Caffeine is also available in tablet form as a dietary supplement. *See, e.g.*, Prolab Nutrition Caffeine Tablets, http://www.vitaminshoppe.com/p/prolab-nutrition-caffeine-100-tablets/xa-7013#.VIXY_DHF83U (accessed Dec. 8, 2014)

[17] *See, e.g.*, AI Sports Nutrition Caffeine Powder, All Star Health, http://www.allstarhealth.com/de_p_ref/28526/pla28526/AI_SPORTS_NUTRITION_Caffeine_Powder.htm?utm_source=google&utm_medium=GPS&utm_campaign=28526&gclid=CNHigMamqsICF

This powder can be purchased online for as little as $10 for 250 grams (or the equivalent of 2,500 cups of coffee containing 100 mg of caffeine each).[18]

b. Caffeine's Effects on Health

Caffeine is consumed daily by a majority of Americans. In the United States, the average daily consumption per adult is 300 mg, or roughly the equivalent of three cups of coffee.[19] At that exposure level, caffeine is generally assumed to be compatible with health; in fact, moderate consumption of caffeine (generally defined as under 400 mg per day) may even be beneficial for healthy, non-pregnant adults.[20] However, FDA has articulated concerns about the considerable increase in caffeine exposure over the past half-century.[21] Today, many individuals consume much more than the 400 mg per day cited as a safe amount for most adults.[22] Moreover, the nature of caffeine-containing products is changing and the impacts that might have on public health are incompletely understood.[23] High daily caffeine intake, especially over 500 mg per day, is considered a significant health risk, and is linked to anxiety, cardiovascular symptoms, and gastrointestinal complaints.[24] Caffeine, of course, also causes insomnia.[25]

While the full implications of high daily caffeine consumption remain unknown, it is undisputed that caffeine is toxic when consumed in large doses. Overdose may result in hypertension, hypotension, tachycardia, vomiting, fever, delusions, hallucinations, seizures, arrhythmia, cardiac arrest, coma, and death.[26] In children, caffeine toxicity is manifested by severe vomiting, tachycardia, and central nervous system agitation.[27] Serious adverse effects are

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Sdn7Aodc1UAPQ (accessed Dec. 5, 2014) (AI Sports Nutrition pure caffeine marketed as "improve[ing] athletic performance" and aiding in "fat loss"); Katherine Hobson, Caffeine Gives Athletes An Edge, But Don't Overdo It, NPR (Aug. 1, 2014), http://www.npr.org/blogs/health/2014/08/01/336886286/caffeine-gives-athletes-an-edge-but-dont-overdo-it (accessed Dec. 5, 2014).

[18] Caffeine Powder (Synthetic), PureBULK, http://purebulk.com/caffeine-powder-synthetic/ (accessed Dec. 5, 2014).

[19] Janet Thorlton et al., Proposed Actions for the US Food and Drug Administration to Implement to Minimize Adverse Effects Associated with Energy Drink Consumption, Am. J. Pub. Health 14(7): 1177 (2014). The amount of caffeine in a cup of coffee is highly variable (as is a serving size), but an 8 oz coffee generally contains between 75 and 150 mg of caffeine. *See* Diane C. Mitchell et al., Beverage caffeine intakes in the US, *Food and Tox.* 63:136–42 (2014). CSPI has compiled a database of caffeine content of various beverages, available on our website at http://www.cspinet.org/new/cafchart.htm#table_coffees. For purposes of illustration in this petition, we will assume that a cup of coffee contains about 100 mg of caffeine.

[20] Institute of Medicine Workshop Summary, *Caffeine in food and dietary supplements: Examining Safety*, The National Academies Press: Washington, DC (2014); P. Nawrot et al., Effects of caffeine on human health, Food Addit Contam. 20:1-30 (2003).

[21] Caffeine in Food and Dietary Supplements: Examining Safety, remarks by Dr. Margaret Hamburg, FDA Commissioner, to a meeting of the Institute of Medicine, Food and Nutrition Board and Board on Health Sciences Policy, National Academy of Sciences, Washington, DC (Aug. 5, 2013), *available at* http://www.fda.gov/newsevents/speeches/ucm363925.htm (accessed Dec. 3, 2014).

[22] Leah Rosenfeld et al., Regulatory status of caffeine in the United States, Nutrition Reviews 82(1): 23-33 (2014).

[23] Institute of Medicine Workshop Summary, *Caffeine in food and dietary supplements: Examining Safety*, The National Academies Press: Washington, DC (2014).

[24] P. Nawrot et al., Effects of caffeine on human health, Food Addit. Contam. 20:1-30 (2003).

[25] Anthony P. Winston, Elizabeth Hardwick & Neema Jaberi, Neuropsychiatric effects of caffeine, *Advances in Psychiatric Treatment* 11: 432–39 (2005).

[26] Sarah Kerrigan & Tania Lindsey, Fatal caffeine overdose: two case reports, *Forensic Sci. Int.* 153(1): 67–69 (Oct. 3, 2005).

[27] P. Nawrot et al., Effects of caffeine on human health, *Food Addit. Contam.* 20:1–30 (2003).

possible at doses as low as 1,000 mg, or roughly the equivalent of ten cups of coffee.[28] Studies estimate a toxic dose to be 20 mg of caffeine per kg, or about 1,300 mg for a 150 lb adult.[29]

Fatalities have been reported following doses of caffeine in excess of 5 grams, though a fatal overdose presumably is lower for children and adults with heart conditions.[30] A lethal dose is estimated to be in the range of 150 to 200 mg/kg of body weight, or about 10 to 14 grams for a 150 lb adult, or 3 to 5 grams for a 50 lb child.[31] Because most caffeine is consumed in relatively diluted beverages (primarily coffee, tea, and colas), fatal overdoses have been rare. It is nearly impossible to consume a lethal amount of caffeine in diluted beverages – even a 5 gram dose would require drinking around 50 cups of coffee, for example. As a result, the vast majority of fatal caffeine poisoning events were caused by intentional overdoses using concentrated caffeine, sold as either as an over-the-counter drug or dietary supplement (often as diet pills).[32] More recently, reports of fatal caffeine overdoses have been linked specifically to pure powder caffeine,[33] some of which appear to have been accidental.[34]

c. FDA Should Find that Pure or Highly Concentrated Caffeine Marketed as a Dietary Supplement is an Unlawful Adulterated Substance under DSHEA and the FDCA.

The recent increase in the marketing of nontraditional, highly concentrated caffeine products makes caffeine toxicity a more pertinent concern because such products allow consumers to ingest mass quantities of caffeine faster than ever before.[35] Accidental caffeine overdose has therefore become a far-too realistic possibility, particularly for young people. Adverse-event reports indicate that accidental or intentional overdose with pure powdered caffeine has led to hospitalizations, seizures, cardiac arrhythmias, and death.[36] Due to the acute threat to public health it poses, the FDA has the regulatory power and obligation to ban highly

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[28] B. Riesselmann et al., Fatal caffeine intoxication, *Forensic Sci. Int.* 139:71–73 (2004).
[29] T. Rudolph & K. Knudsen, A case of fatal caffeine poisoning, *Acta. Anaesthesiol. Scand.* 54(4):521–3 (2010).
[30] Sarah Kerrigan & Tania Lindsey, Fatal caffeine overdose: two case reports, *Forensic Sci. Int.* 153(1): 67-69 (Oct. 3, 2005); Iulian Iancu, Ahikam Olmer & Rael D. Strous, Caffeinism: History, Clinical Features, Diagnosis, and Treatment, *in Caffeine and Activation Theory: Effects on Health and Behavior* (CRC Press: 2006), at 338.
[31] Seema B. Jabbar & Mark G. Hanly, Fatal Caffeine Overdose: A Case Report and Review of Literature, *Am. J. Forensic. Med. Pathol.* 34:321–24 (2013).
[32] Christina Campana et al., Caffeine overdose resulting in severe rhabdomyolysis and acute renal failure. *Am. J. Emerg. Med.* 32(1):111.e3–4 (2014); Per Holmgren et al., Caffeine fatalities—four case reports, *Forensic Sci. Int.* 139(1):71–3 (2004); Christopher P. Holstege et al., Massive caffeine overdose requiring vasopressin infusion and hemodialysis, *J. Toxicol. Clin. Toxicol.* 41(7):1003–7 (2003); Sarah Kerrigan & Tania Lindsey, Fatal caffeine overdose: two case reports, *Forensic Sci. Int.* 153(1): 67–69 (Oct. 3, 2005); T. Rudolph & K. Knudsen, A case of fatal caffeine poisoning, *Acta. Anaesthesiol. Scand.* 54(4):521–3 (2010).
[33] Center for Food Safety and Applied Nutrition, CAERS Reports Allegedly Related to Pure Caffeine, as of Nov. 13, 2014.
[34] Associated Press, Death Of Teen Logan Stiner Puts Focus On Caffeine Powder Dangers (July 19, 2014), http://www.huffingtonpost.com/2014/07/19/logan-stiner-caffeine-pow_n_5601775.html (accessed Dec. 5, 2014).
[35] Caffeine Powder (Synthetic), PureBULK, http://purebulk.com/caffeine-powder-synthetic/ (accessed Dec. 5, 2014).
[36] Center for Food Safety and Applied Nutrition, CAERS Reports Allegedly Related to Pure Caffeine, as of Nov. 13, 2014; Seema B. Jabbar & Mark G. Hanly, Fatal Caffeine Overdose: A Case Report and Review of Literature, *Am. J. Forensic. Med. Pathol.* 34:321–24 (2013); Mathias Poussel et al., Fatal arrhythmia following voluntary caffeine overdose in an amateur body-builder athlete. *Int. J. Cardiol.* 166(3):e41–2 (2013); B. Riesselmann et al., Fatal caffeine intoxication, *Forensic Sci. Int.* 139:71–73 (2004).

concentrated caffeine marketed as a dietary supplement, and we urge the Agency to exercise that authority.

FDA has the authority to regulate dietary supplements under the Dietary Supplement Health and Education Act of 1994 (DSHEA). DSHEA defines "dietary supplement" as a "product . . . intended to supplement the diet" that contains a vitamin, mineral, herb, amino acid, or dietary substance but is not intended "for use as a conventional food."[37] Under DSHEA and the FDCA, FDA may restrict use of a dietary ingredient in a dietary supplement if it is determined to be adulterated.[38]

Under the law, FDA may invoke two separate grounds for finding pure powder caffeine adulterated under DSHEA. First, FDA may find a product to be adulterated if it can demonstrate that the ingredient presents an unreasonable risk of illness or injury under the conditions of use recommended in the labeling of the supplement.[39] This requires FDA to show that a dietary supplement, when taken as recommended, presents a significant or unreasonable risk to consumers.[40] Second, DSHEA provides authority for the Secretary of Health and Human Services to declare any old or new dietary supplement or dietary ingredient to be an illegal imminent hazard to public health or safety, and immediately remove the product from the market.[41] We submit that pure or highly concentrated caffeine powder may be banned under either standard.

i. FDA should find that pure or highly concentrated caffeine powder presents an unreasonable risk under its recommended conditions of use and is therefore an adulterated substance under 21 U.S.C. § 342(f)(1)(A).

Pure or highly concentrated caffeine powder presents an unreasonable risk of illness or injury under the conditions of use recommended in the labeling of the supplement. DSHEA requires evidence of a "significant or unreasonable risk" of illness or injury,[42] but the law does not require that there be evidence proving that the product has caused actual harm to specific individuals, only that scientific evidence establishes the existence of risk.[43] In past rulemakings interpreting that provision, the FDA has determined that its burden of proof for "unreasonable risk" under DSHEA is met when a product's risks outweigh its benefits in light of the directions for use in the product's labeling or, if the labeling is silent, under ordinary conditions of use.[44] It further found that, "[i]n the absence of a sufficient benefit, the presence of even a relatively small

[37] 21 U.S.C.A. § 321(ff).
[38] 21 U.S.C.A. §§ 331(a); 342(f).
[39] 21 U.S.C. § 342(f)(1)(A).
[40] Peter Barton Hut, FDA's Statutory Authority to Regulate the Safety of Dietary Supplements, 31 *Am. J. L. & Med.* 155, 160–61 (2005).
[41] 21 U.S.C. § 342(f)(1)(C).
[42] 21 U.S.C. § 402(f)(1)(A).
[43] Final Rule Declaring Dietary Supplements Containing Ephedrine Alkaloids Adulterated Because They Present an Unreasonable Risk, 69 FR 6788 (Feb. 11, 2004) (codified at 21 CFR § 119.1).
[44] *Id.* at 6788.

risk of an important adverse health effect to a user may be unreasonable."[45]

The standard for "unreasonable risk" is easily met with regard to pure or highly concentrated caffeine powder. It is well established that caffeine in large doses is highly toxic to adults and in smaller amounts when it comes to young children. The inherent problem with caffeine powder is that its highly concentrated form makes it extraordinarily difficult for consumers to differentiate between a safe dose and a potentially lethal dose – if they are even aware that large amounts can be toxic. Caffeine powder thus presents an "unreasonable risk" when used as directed for the simple reason that it is essentially impossible to use as directed: just one teaspoon of pure caffeine powder contains the amount of caffeine in 30 cups of coffee. The dose of caffeine powder recommended by the labeling of some products is 1/32 to 1/16 of a teaspoon – an amount that the typical consumer is not capable of measuring using implements available in a typical kitchen. Because the recommended dose of caffeine powder is difficult to administer, this particular form of caffeine substantially heightens the risk of unintentional overconsumption and overdose. In 2014, there were at least two deaths that were apparently caused by accidental overdoses of pure caffeine.[46] News reports indicate that there have been as many as 30 cases of pure caffeine overdoses reported to poison control centers nationally during the first nine months of this year.[47] How many other overdoses occurred, but were not reported, is unknown.

This risk of unintentional overdose far outweighs any putative benefits of pure or highly concentrated caffeine. Even if moderate caffeine consumption can be beneficial, its benefits are easily obtained via safer means, such as coffee or tea. As a result, the benefits offered by caffeine marketed in powder form do not justify its risks. As FDA has noted, "[i]n the absence of a sufficient benefit, the presence of even a relatively small risk of an important adverse health effect to a user may be unreasonable."[48] FDA should thus find that powder caffeine's significant risks, when balanced with its minimal benefits, render the product an "unreasonable risk" under DSHEA.

This conclusion is supported by, and is in fact far simpler than, FDA's one previous finding of "unreasonable risk" under the statute, when it concluded that dietary supplements containing ephedrine alkaloids were adulterated.[49] In that case, FDA banned the use of ephedrine alkaloids in *all* dietary supplements; as a result, any purported benefits of ephedrine would not be readily available from other sources. That required FDA to make a much higher showing of ephedrine's risks in order to demonstrate that they outweighed its benefits.[50] By contrast, here, CSPI merely proposes that one especially dangerous and totally unnecessary form of caffeine be declared adulterated and removed from the market. We do not argue that caffeine should be banned in all forms, nor that it is unsafe when used in moderation by healthy, non-

[45] *Id.*
[46] See Exhibit B for statements from the families of Logan Stiner and James Wade Sweatt.
[47] Laura Ungar, Caffeine powder raises overdose concerns, *The Courier-Journal* (Sept. 12, 2014), http://www.courier-journal.com/story/life/wellness/health/2014/09/12/caffeine-powder-raises-overdose-concerns/15512267/ (accessed Dec. 5, 2014).
[48] Final Rule Declaring Dietary Supplements Containing Ephedrine Alkaloids Adulterated Because They Present an Unreasonable Risk, 69 FR 6788 (Feb. 11, 2004) (codified at 21 CFR § 119.1).
[49] *Id.*
[50] Dietary supplements containing ephedrine alkaloids, 21 C.F.R. § 119.1.

pregnant adults. Rather, it is only the highly dangerous concentrated form that must be banned.

FDA has already acknowledged the dangers of caffeine powder in a consumer advisory issued during the summer of 2014. In the advisory, FDA noted many of the dangers of caffeine marketed in this form, and recommended that consumers avoid such products. It also warned the public that even seemingly modest amounts (e.g., a quarter teaspoon) of caffeine may be risky, and it cautioned parents that such products may be particularly appealing and dangerous to young people.[51] While a useful first step, FDA should not stop at a mere consumer advisory. Because the risks and harms of caffeine powder far outweigh any potential benefits, FDA has the authority and the obligation to promulgate regulations banning the substance.

While it is axiomatic that the dose makes the poison, when caffeine is sold in pure or highly concentrated form, the consumer has a very limited ability to administer a safe dose. That renders the substance unavoidably poisonous. Thus, FDA should find that caffeine powder, due to its form and bulk packaging, inherently poses an unreasonable risk to consumers, even if low doses of caffeine are safe. Pure or highly concentrated caffeine should therefore be declared an adulterated substance and banned under 21 U.S.C. § 342(f)(1)(A) for posing a significant and unreasonable risk to consumers.

ii. The Secretary of Health and Human Services should declare that pure or highly concentrated caffeine poses an imminent hazard to public health or safety and is therefore an adulterated substance under 21 U.S.C. § 342(f)(1)(C).

DSHEA also permits the Secretary of Health and Human Services to declare pure or highly concentrated caffeine to be an illegal imminent hazard to public health or safety.[52] According to FDA regulations, an "imminent hazard" exists where the evidence is "sufficient to show that a product or practice, posing a significant threat of danger to health, creates a public health situation (1) that should be corrected immediately to prevent injury and (2) that should not be permitted to continue while a hearing or other formal proceeding is being held."[53] Once the Secretary declares a supplement to be an imminent hazard, the substance is immediately banned, and administrative proceedings are automatically instituted to determine whether to affirm or withdraw the ban.

While this provision of DSHEA has not been exercised to date, we believe that pure or highly concentrated caffeine powder presents an appropriate instance for HHS to employ this statutory authority. The danger of caffeine powder, as a result of caffeine's toxicity and the inherent danger of the concentrated form, is clear. That is reflected by reports of adverse events that have occurred as pure caffeine has become more readily available to consumers. However, the data on the dangers of pure or highly concentrated caffeine are (fortunately) limited because the product has only been marketed and monitored recently. To assess the safety of dietary supplements, FDA typically reviews adverse event reports that are submitted in accordance with

[51] U.S. Food and Drug Administration, FDA Consumer Advice on Powdered Pure Caffeine, http://www.fda.gov/Food/RecallsOutbreaksEmergencies/SafetyAlertsAdvisories/ucm405787.htm (accessed Dec. 5, 2014).
[52] 21 U.S.C. § 342(f)(1)(C).
[53] 21 CFR § 2.5.

the requirements of DSHEA. At this juncture, the data on adverse event reports associated with pure powder caffeine are limited because the National Poison Control Center only added a specific code for the substance in July 2014. These reports will be available to CSPI early in 2015 and we will supplement this petition at that time; however, we also encourage FDA to conduct its own inquiries into the adverse event reports it has received.

However, even on the basis of limited data, it is evident that caffeine sold directly to consumers in bulk, pure form poses an imminent hazard. Pure caffeine is too dangerous to keep on the market while the FDA awaits additional information, particularly when it is so readily available to vulnerable children and adolescents. Thus, CSPI urges HHS to exercise its authority under DSHEA to declare a dietary supplement to "pose an imminent hazard to public health or safety" and remove these products from the market while initiating an administrative proceeding to affirm or withdraw the declaration.[54]

III. Conclusion and Requested Actions

Because pure or highly concentrated caffeine has only recently become widely available to consumers, the full extent of its dangers have yet to be discovered. FDA has the opportunity to get in front of a problem that has the potential to grow exponentially, and to address its risks before they can be fully realized. FDA should act now to ban direct sales of caffeine powder because even when used as directed, it presents an unreasonable risk to consumers, and the benefits it provides are easily obtained from other, safer sources. Failure to act swiftly will inevitably result in additional tragic and all-too-preventable overdoses and deaths.

IV. Environmental Impact

Nothing requested in this petition will have an impact on the environment.

V. Economic Impact

No statement of the economic impact of the requested action is presented because none has been requested by the Commissioner.[55]

VI. Certification

The undersigned certify, that, to the best knowledge and belief, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully submitted,

Michael F. Jacobson, Ph.D., Executive Director
Laura MacCleery, Chief Regulatory Affairs Attorney
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[54] 21 U.S.C. §§ 331(a); 354(f)(1)(C).
[55] 21 C.F.R. 10.30(b).

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EXHIBIT A – IMAGES OF BULK CAFFEINE POWDER

EXHIBIT B – FAMILY STATEMENTS

STATEMENT OF DENNIS AND KATIE STINER

Before May 27, 2014 we had never heard of "caffeine powder" Now we think about it everyday.

Our son, Logan James Stiner died on that day as a result of this drug.

We were preparing for our son's high school graduation a spring filled with joy, celebration and anticipation.

Logan was more than a prom king, an athlete, and a graduating senior, he was our son and Dylan's little brother.

Just days before his graduation with friends Logan had grown up with in our close knit community of Lagrange, Ohio in the Keystone school system, Logan ingested caffeine powder.

Hs brother Dylan found him unresponsive on the floor of our home.

We had no idea what had happened. Logan was only 18 years old. His whole life was ahead of him, graduation then college at University of Toledo to study chemical engineering. Through Logan's hard work in the classroom he earned an academic scholarship.

The Lorain County Coroner, Dr Evans originally told us that Logan died of natural causes. 18 years young and his death is natural?

We found a small bag containing a white powder substance that we gave to the authorities; Dr Evans determined that this bag contained pure caffeine powder. Dr Evans then ran some other tests and told us that Logan died as a result of caffeine overdose.

Dr Evans told us he was shocked, he never would have looked for caffeine as the cause of Logan's death.

So what do we do?

We attend the graduation and watch Logan's friends receive their diplomas, we are moved by the outpouring of love and support from his classmates, Keystone and the community.

Everyday, almost every waking thought;

How could this have happened?

What is caffeine powder?

How could Logan have died from caffeine?

Could it happen to others?

We started doing research – we became horrified when we learned more about caffeine powder.

Caffeine powder can be easily purchased on the internet

Caffeine powder should not be available- we decided that we must do everything we can to get this product off the market and away from other children.

We retained Attorney Brian K. Balser to investigate and take appropriate legal action against the companies involved in Logan's death.

With Attorney Balser's help we have set up a web site to tell Logan's story: loganstiner.org

We also started a petition to have the FDA ban this substance- please go to Logan's website and sign the petition.

We are very thankful for Senator Brown's assistance in our battle to have the FDA ban caffeine powder.

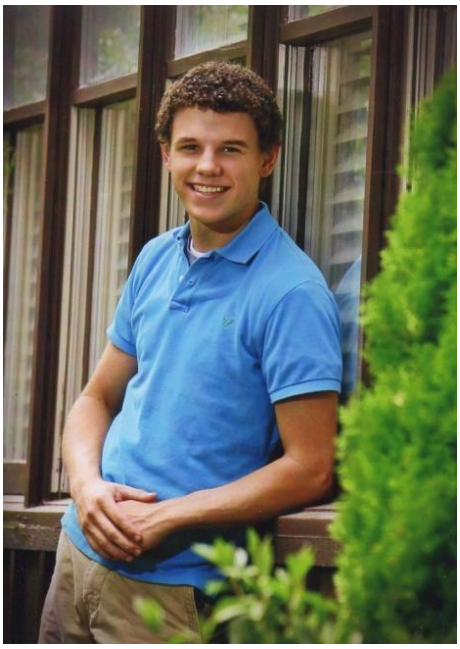
We look forward to meeting with Senator Brown, Senator Blumenthal and other representatives in Washington D.C. in December.

We are also going to meet with members of the FDA in December as we continue our fight to have this lethal substance banned.

Dennis and Katie Stiner

STATEMENT OF JIM AND JULIE SWEATT

Our son, James Wade Sweatt, at twenty-four years old, died as a result of ingesting caffeine powder on June 23rd, 2014.



Wade was a brilliant young man and a fine son. He was recently graduated from electrical engineering school at the University of Alabama at Birmingham and was working at a company he loved doing work he loved in Alpharetta, Georgia. Wade was newly married and he and his wife had plans to begin trying to have children soon.

Wade purchased the caffeine powder from a company named Hard Rhino on Amazon.com. The very first time he ever used the product, he mistakenly took too much and it killed him. ***Why would such a dangerous product be allowed to be sold to individuals?***

Georgia state law does not give us, as Wade's parents, any rights to take legal action against the companies that make this horrible product. We contacted Dennis and Katie Stiner after we learned that their son Logan had died in a very similar manner to Wade.

We are very pleased and encouraged to find that the Stiners, aided by their attorney Brian Balser, Senator Brown of Ohio and the Center for Science in the Public Interest have done much to raise awareness and take action against these companies. **Caffeine powder is extremely dangerous and should not be available.** The Stiners' have started a petition to have the FDA ban this substance. Please see loganstiner.org for Logan's story. Please go to Logan's website and sign the petition.

We look forward to being with the Stiners in meetings with Senator Brown, Senator Blumenthal and other senators and congressmen/women in Washington D.C. on December 9th. We will also meet with members of the FDA that same day. We are thrilled to join the fight to have the sale of caffeine powder banned in the United States.

Jim and Julie Sweatt