



CENTER FOR
Science IN THE
Public Interest

The nonprofit publisher of
Nutrition Action Healthletter

April 26, 2016

The Honorable Robert Califf, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Califf:

Re: Docket No. FDA-2015-P-0059-0003, Petition to Ban the Retail Distribution of Pure and Highly Concentrated Caffeine Sold in Powder Form as a Dietary Supplement.

The Center for Science in the Public Interest writes to supplement the Citizen Petition we submitted on December 9, 2014, seeking an immediate ban on the retail sale and distribution of pure caffeine products as dietary supplements.¹

In May 2014, 18-year-old Logan Stiner of Ohio died from an accidental overdose of powdered caffeine.² In July 2014, 24-year-old Wade Sweatt died after ingesting caffeine powder the first time he used it.³ A third death occurred in 2014 when a 39-year-old man ingested 12 grams of pure anhydrous caffeine.⁴ Just a teaspoon of powdered caffeine is equivalent to roughly 28 cups of coffee,⁵ and the suggested “safe” dose is a scant 1/32 to 1/16 of a teaspoon.⁶ In December 2014 parents of both young men met with officials at the FDA’s Center for Food Safety and Applied Nutrition. Senators Blumenthal, Brown, Durbin, Gillibrand, Markey, and Schumer, and later Senator Casey, also called on FDA to ban bulk sales of caffeine.⁷

¹ CSPI Petition to ban the retail distribution of pure and highly concentrated caffeine in powder form as a dietary supplement. Dec. 9, 2014. <http://cspinet.org/new/Caffeine-petition-CSPI-12-9-2014.pdf>.

² Death of Teen Logan Stiner Puts Focus on Caffeine Powder Dangers (July 19, 2014), *Associated Press*, http://www.huffingtonpost.com/2014/07/19/logan-stiner-caffeine-pow_n_5601775.html (accessed Dec. 5, 2014).

³ National Public Radio. Potent powdered caffeine raises safety concerns. Jan. 2, 2015. <http://www.npr.org/sections/health-shots/2014/12/31/371692640/potent-powdered-caffeine-raises-safety-worries>.

⁴ 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).

⁵ The USDA nutrition database reports that one cup (8 oz.) of ground coffee contains 95 mg of caffeine: <https://ndb.nal.usda.gov/ndb/foods/show/4277>.

⁶ See CSPI petition at 8

⁷ Comment from CSPI to FDA Docket No. FDA-2015-P-0059-0003. July 21, 2015. <http://www.regulations.gov/#!documentDetail:D=FDA-2015-P-0059-0005>. Teresa Bonner. “Sen. Casey to FDA: Ban sale of powdered caffeine,” Feb. 2, 2015. http://www.pennlive.com/midstate/index.ssf/2015/02/sen_casey_to_fda_ban_sale_of_p.html

In lieu of issuing a ban, in September 2015 FDA sent warning letters to five dietary supplement companies stating that highly concentrated caffeine has been associated with dangerous side effects in consumers, including deaths.⁸ Those companies voluntarily removed pure powdered caffeine from their retail sites.

But pure caffeine in powdered (PPC), liquid (PLC), and now inhalable (IC) forms is still widely available for purchase online. CSPI recently conducted a basic internet search for pure caffeine products and found that at least fifteen online suppliers—a short list is below—are still selling products identical or similar to those that killed Logan Stiner, Wade Sweatt, and others.⁹ Thus, FDA's actions thus far are sorely inadequate to ensure consumer safety and prevent future deaths or other serious harm from highly concentrated (and inadequately labeled) forms of caffeine.

Through a simple (and non-exhaustive) Internet search for PPC, CSPI found five domestic suppliers that still sell PPC to retail consumers and ten international suppliers (based in Canada, the United Kingdom, India, and China) that ship to the United States. Through these suppliers, which are both international and domestic, consumers have access to quantities of PPC ranging from 10g to 1000kg. Packages containing 10kg include enough caffeine to kill 500 people at a lethal dose of 10g—which is 25 times the level FDA cites for daily adult caffeine consumption to avoid “dangerous, negative effects”¹⁰—and cost less than \$120.¹¹ Of the products we ordered, only a single company included a means by which consumers could measure a “safe” (1/32 tsp) dose of PPC (not that simply enclosing a measuring spoon is an appropriate solution to the problem, as such spoons can be misplaced); nor do the labels sufficiently warn consumers that exceeding this extraordinarily small dose can result in death.

PPC is also available through online marketplace platforms, such as Ebay and its counterparts abroad, which is additional cause for concern, because accountability through these platforms is difficult to achieve. In contrast, a ban would clearly indicate to Ebay and other platform hosts that such products are illegal.

In sum, FDA's five letters appear to have ceased the sale of powdered caffeine at only the companies to which the agency addressed its letters. In the larger marketplace, sales of PPC remain commonplace, and the substance is still widely available. This compelling evidence demonstrates why a ban is the only step that will protect consumers from the hazards of PPC. Moreover, a ban would prevent legal importation of this dangerous substance into the country from foreign suppliers.

⁸ U.S. Food and Drug Administration (FDA). Pure Powdered Caffeine. Sept. 9, 2015. <http://www.fda.gov/food/dietarysupplements/productsingredients/ucm460095.htm>.

⁹ It appears there may have been three additional known fatalities. See Sarah Kerrigan & Tania Lindsey, Fatal caffeine overdose: two case reports, *Forensic Sci. Int.* 153(1): 67–69 (Oct. 3, 2005); Seema B. Jabbar and Mark G. Hanly, Fatal Caffeine Overdose: A Case Report and Review of Literature, 34 *Am J Forensic Med Pathol* 321 (2013).

¹⁰ FDA Consumer Health Information. FDA to investigate added caffeine. May 2013. <http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM350740.pdf>.

¹¹ Jabbar & Hanly, *id.*

Adding to the risks, PLC (which FDA did not address in its warning letters to companies selling powdered caffeine) is also marketed as a healthier, and even safer, alternative to energy drinks or regular coffee, with “no sugar, no added chemicals, no gut rot...[and] without the “crash” or ups and downs caused by typical energy drinks.” (LiquidCaffeine.com, see reference below).¹² Additionally, the product’s label recommends a serving size in “pumps,” but the product CSPI received was a pour-cap, which makes a recommended serving in pumps meaningless and thereby reduces a consumer’s ability to measure a safe serving of the product.

From a supplier in Minnesota, we were able to obtain Purecaf, a gallon jug of caffeine in liquid form, which looks surprisingly like water, yet a single full measuring cup of the substance would be more than a lethal dose. The label indicates only that consumers should use it “sparingly.” And from a supplier in South Korea came three small bottles of CafeDrops, a shockingly concentrated liquid caffeine—the largest, which is the size of small shampoo bottle, indicates it contains 9,000 mgs of caffeine, and has no serving size information on the label whatsoever except the instruction to drop some “amout” [sic] and not to “overuse it.”

Another PLC product, Kaffn8, markets itself to health-conscious people through its website, which mimics the hip aesthetic of an outdoor sporting-goods store. The home page of Kaffn8 shows a man kayaking on a calm lake in the early morning, and an entire section of its website called “Get Inspired,” features a photo collage of happy people exercising, taking photos, playing music, etc. Nowhere does the website warn consumers that overdosing on the product can be lethal.

Kaffn8 comes with an “EZ-Dose” measuring bottle, which measures “one serving” of PLC to be 240 milliliters, or roughly equal to the caffeine in about 2–3 cups of coffee. This measurement and method is worrisome, because consumers are most familiar with dosing cups from taking cold medicines or cough syrups, where precision in serving size is not the difference between life and death. Many people take two or three times the recommended serving of such over-the-counter products to relieve symptoms. Some consumers might well misunderstand the suggested 240 milliliters of PLC to mean a minimum dose that could be increased two or three times without risk of harm.

¹² CSPI purchased a bottle of Liquid Caffeine (pictures enclosed with this comment) that was advertised online to be 16 ounces, but had no net volume label on the actual product, which likely violates 21 C.F.R. § 101.105(a), requiring that the principal display panel of a dietary supplement declare the net quantity of its contents. If “Liquid Caffeine” does not meet the exception for small businesses that have less than \$50,000 in gross sales or less than \$500,000 in gross business done (*See* 21 C.F.R. 101.36(h)(1)), it appears to violate these additional regulations:

- 21 C.F.R. § 101.36(b)(1)(i) (requiring that the serving size of a dietary supplement be indicated under the heading “Supplement Facts” on its label);
- 21 C.F.R. § 101.36(b)(1)(ii) (requiring that a dietary supplement indicate the amount of servings per container);
- 21 C.F.R. § 101.36(b)(2)(i) (requiring that a dietary supplement list the RDI/DRV for specific dietary ingredients (e.g., total calories, sugars, etc.));
- 21 C.F.R. § 101.36(e) (providing the formatting requirements for the “Supplement Facts” table).

Similarly, another PLC product, Café Drops, features a promotional video on its homepage, which shows two extremely tired people indiscriminately pouring (without measuring) PLC into water to wake up. Elsewhere on the website it recommends a serving size of 200ml and a warning not to exceed 600ml in a day, which exceeds FDA's recommendation that adults consume no more than 400ml per day. More importantly, a dosing instrument to measure a 200ml serving is not included with the product, which increases the likelihood that consumers could improperly measure a safe dose.

IC is also emerging as a trendy way for young people to ingest pure caffeine. Yet FDA has sent warning letters to companies marketing inhalable caffeine indicating that the product has not been shown to be safe, as the safety data describes hazards from ingestion, not inhalation.¹³

CSPI's investigation produced the following, non-exhaustive list of current suppliers of PPC, PLC, and IC. (Hardcopy screen shots of the companies' products are enclosed.)

- **Powder City, LLC.** – (American Company; PPC available in 10g, 50g, 100g, 500g, 1kg, 5kg)
- **NutriVita Shop** – (American Company; PPC available in 50g, 100g, 250g, 500g, 1kg, 2kg, 5kg, 8kg, 10kg, 25kg)
- **PureCaffeine.org** – (American Company; PPC available in 10g, 30g, 90g, 500g, 1kg)
- **LuxNaturesSuppliers via Etsy.com** – (American Company; PPC available in 1 oz)
- **Transcendence Nootropics** – (American Company; PPC available; server down at time of access)
- **Flavor West** – (American Company, PPC available in 100g, 250g, 500g, 1kg)
- **TJM Resale's Synaptik Supplements & Ligand Solutions** – (American Company; PPC available in 100g, 250g, 1kg, 5kg, 10kg, 25kg)
- **MyProtein.com** – (UK Company, ships to USA; PPC available in 100g, 500g)
- **Bulk Powders** – (UK Company, ships to USA; PPC available in 100g, 500g, 1kg)
- **Blackburn Distributions** – (UK Company, ships to USA; PPC available in 100g, 250g, 500g, 1kg, 2kg, 5kg, 10kg, 15kg, 20kg, 40kg, 100kg, 250kg, 500kg, 1000kg)
- **Buy Caffeine** – (UK Company, ships to USA; PPC available in 500g, 1kg, 2kg, 5kg, 10kg, 15kg)
- **Durachem Distribution** – (Canadian Company, ships to USA; PPC available in 250g, 500g, 1kg, 2kg)
- **PureCaffeinePowder.com** – (Canadian Company, ships to USA; PPC available in 250g, 500g, 1kg, 2kg, and larger custom orders)
- **GBY.uk Supplements** – (UK Company, ships to USA; PPC available at 250g, 500g, 1kg, 5kg, 10kg)
- **PureCaffeine.info** – (UK Company, ships to USA; PPC available in 250 g, 500g, 1kg, 2kg, 5kg, 10kg)

¹³ FDA Warning Letter to Breathable Foods, Inc. CEO, Thomas Hadfield. Mar. 5, 2012. <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2012/ucm294774.htm>.

- **PureCaffeine.co.uk** – (UK Company, ships to USA; PPC available in 1kg, 2kg, 5kg, 10kg, 20kg, 40kg, 100kg, 250kg, 500kg, 1000kg)
- **Vapor Boost** – (American Company, IC with undisclosed concentration of caffeine)
- **Café Drops** – (American Company, PLC in bottles up to 500ml, equal to 9000mg of caffeine)
- **Liquid Caffeine** – (American Company, PLC (100% pure) in jugs up to 1 gallon)

Given the evidence, and vocal support from experts, parents, and trade associations, CSPI reiterates the need for a complete ban on the retail distribution of highly concentrated caffeine marketed as a dietary supplement. This includes specifying 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. It is unreasonable and unacceptable for FDA to expect consumers to be able to differentiate between sixteenths of teaspoons—the difference between a safe dose and a potentially lethal dose of powdered caffeine—especially because many concentrated caffeine products, powdered and liquid, are sold without warning labels or precise dosing instructions.

We also submit the enclosed supplementary materials from a dietary supplement trade association to the docket for the record, including:

- Seidman B *et al.* Pure powdered caffeine: stakeholders take measure of FDA’s warning letters. *The Food and Drug Law Institute’s Food and Drug Policy Forum*. Feb. 10, 2016. Vol. 6. Iss. 1.

The volume includes a statement from the Council for Responsible Nutrition (CRN), which summarizes CRN’s support of FDA and industry in regulating consumer access to pure powdered caffeine:

*“CRN supports FDA’s issuance of Warning Letters to distributors of pure powdered caffeine. The Federal Food, Drug, and Cosmetic Act (FFDCA) authorizes the agency to take enforcement action if a dietary supplement presents a significant or unreasonable risk of illness or injury under the conditions recommended or suggested in the labeling. In the present case, although pure, powdered caffeine is a legal dietary ingredient, when sold in bulk form it presents an unreasonable risk to consumers because the margin between the recommended serving size and a toxic amount is miniscule. A simple mistake in accurately measuring a safe dose of the product could result in a serious adverse event or possibly death. **Because the hazards associated with caffeine overdose are significant, CRN supports restrictions on the sale of bulk pure powdered caffeine (PPC) directly to consumers.**”* (Emphasis added).

- Mister S. Wake up and smell the pure powdered caffeine. Council for Responsible Nutrition. Sept. 9, 2015. <http://www.nutraingredients-usa.com/Regulation/Wake-Up-and-Smell-the-Pure-Powdered-Caffeine>.

Steve Mister, President and CEO for CRN, describes a helpful precedent, in

which FDA worked out solutions to reduce dosage errors in over-the-counter (OTC) pediatric cough/cold medicines:

*“Despite dosage instructions on packaging, the agency raised legitimate concerns that many consumers couldn’t determine the appropriate dose for children of various ages and weights and that the measuring devices provided with many of those products only contributed to confusion. So OTC manufacturers collaborated with FDA to develop clearer instructions, new measuring devices that accompany the products, and consumer education to teach parents how to appropriately medicate their children. That’s what a responsible industry does. **Similarly, marketers of pure powdered caffeine could develop packaging for their purified caffeine in single serve dosages if they want to sell it directly to consumers.**”* (Emphasis added).

Thank you for your urgent consideration of further agency action, including a ban on sales of pure powdered caffeine and other appropriate restrictions on highly concentrated forms of caffeine that pose a risk to consumers of an unintentional, harmful overdose.

Sincerely,

Michael Jacobson, President

Laura MacCleery, Directory of Regulatory Affairs

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and DRUG
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Pure Powdered Caffeine:
Stakeholders Take Measure of FDA's
Warning Letters

Brenda Seidman

Seidman Regulatory Toxicology

Jay Sirois

Consumer Healthcare Products Association

Rend Al-Mondhiry

Council for Responsible Nutrition

Duffy MacKay

Council for Responsible Nutrition

Laura MacCleery

Center for Science in the Public Interest

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THE FOOD AND DRUG LAW INSTITUTE
1155 15TH STREET NW, SUITE 910 // WASHINGTON, DC 20005
www.fdpi.org



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1155 15th Street NW, Ste. 910, Washington, D.C. 20005
Tel: (202) 371-1420; Fax: (202) 371-0649
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Pure Powdered Caffeine:

Stakeholders Take Measure of FDA's Warning Letters

By Brenda Seidman, Seidman Regulatory Toxicology, Jay Sirois, Consumer Healthcare Products Association, Rend Al-Mondhiry, Council for Responsible Nutrition, Duffy MacKay, Council for Responsible Nutrition and Laura MacCleery, Center for Science in the Public Interest

I. INTRODUCTION TO THE COMPENDIUM

On August 27, 2015, the US Food and Drug Administration (FDA) issued Warning Letters to five companies selling pure powdered bulk caffeine to consumers as a dietary supplement.^{1,2,3,4,5} Each letter stated that the agency considers their product to be: *"adulterated within the meaning of section 402(f)(1)(A)(i) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 342(f)(1)(A)(i)] because they are dietary supplements that present a significant or unreasonable risk of illness or injury under the conditions of use recommended or suggested in the labeling."*

While this is not FDA's first caffeine action^{6,7} or its first demonstration of concern,^{8,9} it does highlight the agency's continuing concerns about this stimulatory substance, particularly when caffeine's use as a food product is promoted for use at levels it considers unsafe and/or promoted to vulnerable populations, such as children and adolescents. Its concerns have related to caffeine-containing dietary supplements and energy drinks (a group of products that are marketed both as supplements and conventional food)^{10,11,12} as well as to other conventional food, including caffeine-containing confectionary.^{13,14}

To promote discussion of the best approach to regulating powdered bulk caffeine, the volunteer editor of this compendium invited a number of stakeholders to share their views on the August 2015 action.

Participants in this issue of Policy Forum were asked if they believed FDA was justified in issuing the Warning Letters on pure powdered caffeine and, more broadly, to address FDA's and their own roles in assuring the safety of dietary supplement products on the market.

This compendium begins with an overview of the regulatory and legal underpinnings of dietary supplements, including a brief discussion of the 1994 amendment to the Federal Food Drug & Cosmetic Act (FFDCA), the Dietary Supplement Health and Education Act (DSHEA), which provided a legal definition of these products, and established a new regulatory framework. The introductory overview also provides background on caffeine, including how much Americans consume daily, differences in how individuals respond to caffeine, how the body processes caffeine, and what is known about its toxicity. This is followed by the contributions from participating stakeholders (trade associations and a consumer group) outlining their perspectives on the risks posed by pure powdered bulk caffeine and their responses to this regulatory challenge.

Invited stakeholders included: Center for Science in the Public Interest (CSPI), Consumer Healthcare Products Association (CHPA), Council for Responsible Nutrition (CRN), FDA, Natural Products Association (NPA), and United Natural Products Alliance (UNPA). Although FDA, NPA, and UNPA chose not to participate, each has made their position known. UNPA issued a fact sheet on pure powdered bulk caffeine, which, although preceding FDA's action, suggests support for it, since UNPA has a retail "no-sale" policy of pure powdered

1

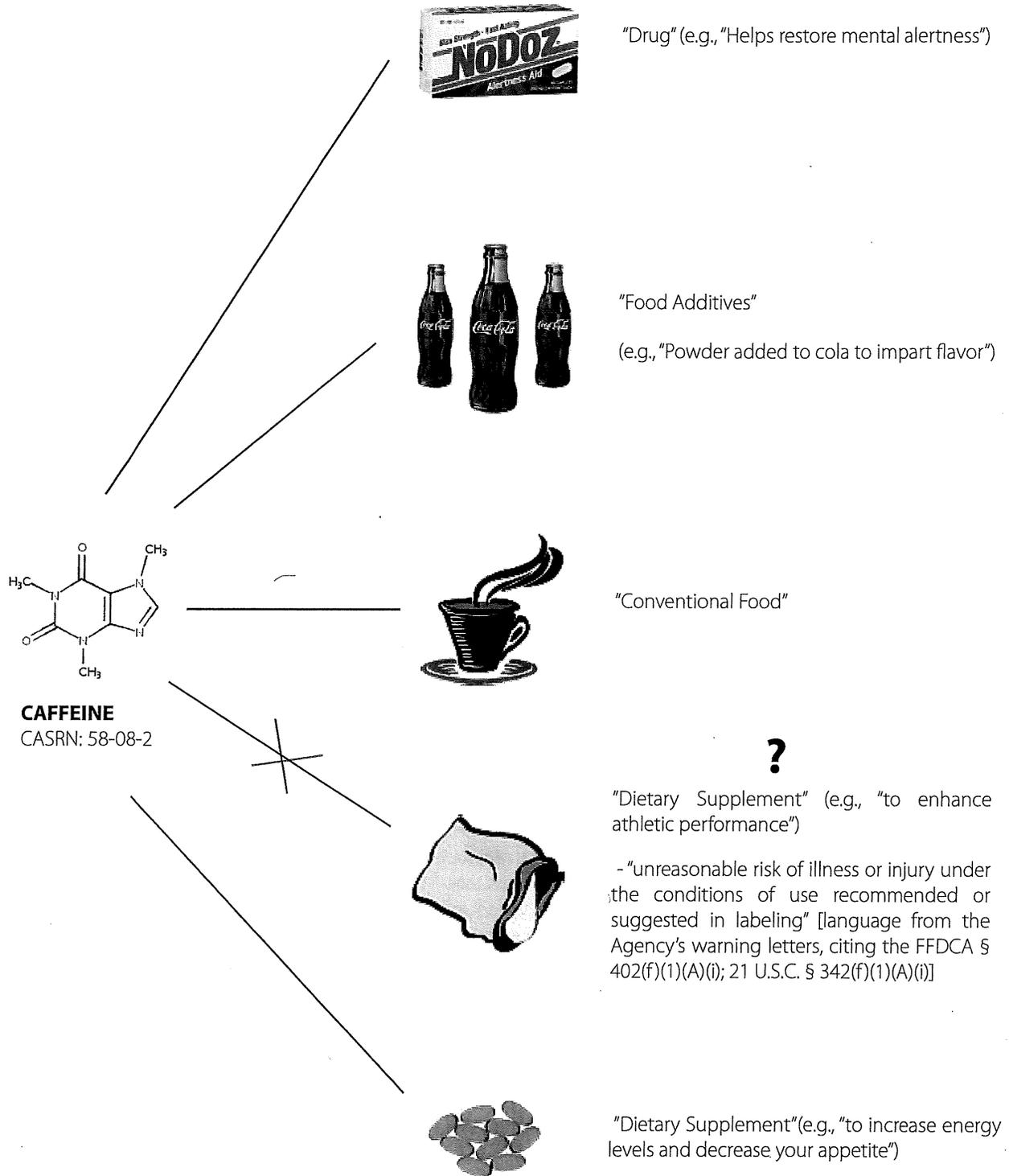
bulk caffeine as a condition of membership in the Association.¹⁵ In contrast, NPA expressed its apparent disagreement with FDA's position in its press release on the action, stating: "FDA is missing the target by claiming the product is dangerous because it can't be measured, not that the product is dangerous..." and, "Does the FDA really believe that consumers are unable to read a correctly labeled product?"¹⁶

A. What is a Dietary Supplement?

The DSHEA defines "dietary supplement" as a product (other than tobacco) that is ingested and is intended to supplement the diet and contains one or more of the following: a vitamin; mineral; herb or other botanical; amino acid; dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of any of these.¹⁷ The Act does not distinguish between naturally-derived dietary supplement ingredients from those that are synthesized or extracted and chemically purified,¹⁸ or whether they are marketed as free powder; in capsules; in solid form, such as tablets; or in liquids. Importantly, the DSHEA states: "...a dietary supplement shall be deemed to be a *food* within the meaning of this Act." [emphasis added]. As such, a dietary supplement does not require premarket approval.¹⁹ However, the DSHEA neither considers dietary supplements as "conventional" food nor as "food additives." Also, the DSHEA does not consider dietary supplements to be "drugs," although it does allow dietary supplement manufacturers to make certain health-related claims provided such statements are "truthful and not misleading" under sections 201(g)(1) and 403(r) of the Act.

However, a single chemical that might be a dietary supplement or an ingredient in a dietary supplement can be regulated by FDA in another product category and under different regulations. FDA regulates caffeine as a drug (as an active ingredient), conventional food (e.g., coffee, tea, or energy drink²⁰), a food additive (e.g., a substance added to cola), or dietary supplement (e.g., as green tea extract or as an ingredient in other dietary supplements, including energy drinks²¹). Legal product designations (e.g., drug, conventional food, food additive, or dietary supplement) are important. The development and marketing of products in a given product category are subject to a unique set of regulations. Depending on the category, these may include: premarket demonstration of safety and efficacy, labeling (including claims), good manufacturing practices, and adverse event reporting (AER). Caffeine provides a useful illustration of how one product may be regulated in multiple categories based on intended use. See Figure 1 for a schematic of the different ways in which the FDCA categorizes caffeine.

Figure 1



3

Figure 1 Source: The concept for this figure was developed by F.A. Hoffman & T. Garvey. IV: Textbook of Legal Medicine (5th ed. 2001).

FDA's pure powdered bulk caffeine Warning Letters do not object to caffeine's use in dietary supplements or to use of pure powdered caffeine itself. However, the letters do object to the marketing of pure powdered *bulk* caffeine products.²² Judging from users' comments on at least one of the enforcement letters recipients' websites, it appears that it is common practice among such users to add caffeine to gel capsules or to beverages of their own making.²³ Therefore, FDA's concerns seem largely related to an interplay between human factors and toxicity issues, specifically, consumers' difficulty following label directions in "separating out a safe serving from a potential lethal amount."²⁴ The bulk packaging of these pure caffeine products, which have been sold in quantities as large as 25 kg, is integral to this problem. FDA, therefore, concluded that these contributing factors comprise an "unreasonable risk."²⁵ Perhaps unstated is concern about the young consumers to whom high dose/pure caffeine dietary supplements are marketed, as well as the unfortunate human tendency to think that if something is good for us, then "more is better."^{26,27}

B. What is Caffeine?

Caffeine (1,3,7-trimethylxanthine),²⁸ a white, bitter crystalline solid, is a central nervous system stimulant, and is found in botanical sources that include coffee beans, tea leaves, cola nuts, and cocoa pods.²⁹ It can be isolated from these sources by solvent extraction, providing pure caffeine as a byproduct. It can also be chemically synthesized. It is generally recognized for its ability to prevent or relieve drowsiness and to boost energy and focus. Crystalline caffeine (pure anhydrous powder) has historically been sold in bulk, mostly for use as a food additive (e.g., in colas and other beverages) and for the manufacture of caffeine-containing prescription and over-the-counter pharmaceuticals (e.g., Fioricet®, Excedrin Migraine, and No-Doz). The marketing of pure crystalline (powdered) caffeine targeted to consumers, mostly via the Internet, is a relatively new development. FDA apparently first became aware of the marketing of these products to consumers in 2014, after the report of the death of a user of pure powdered bulk caffeine.³⁰

C. How Much Caffeine Do Americans Consume Daily?

Caffeine is widely consumed in a range of food products, although almost 90 percent of adults in the US consume caffeine in the form of coffee or tea.³¹ Not surprisingly, caffeine consumption (from multiple sources) varies among individuals, as well as age groups. Data analyzed using the National Health and Nutrition Examination Survey (NHANES) from 2007-2010 (N=17,387), indicates that caffeine intake by Americans during this period was primarily in the form of beverages (coffee, tea, soda, and energy drinks), and was highest among those between the ages of 50-59, who had an average caffeine consumption of approximately 250 mg/day³² (the equivalent of approximately 2.5 cups of coffee/day³³). In the 50-59 year-old age group, the 90th percentile intake from beverages was 515 mg/day (approximately five cups of coffee/day).³⁴ FDA requires that added caffeine in a food product, including dietary supplements, be noted on the label; however, there is no requirement that the amount of caffeine in that product be identified.³⁵ Some have noted that the lack of information on amounts of caffeine, both that added and naturally present in conventional food products, makes it difficult for consumers to estimate how much caffeine they are ingesting.³⁶

D. Why Do Some People Tolerate Caffeine Better Than Others?

The ability of individuals to respond to the same amount of caffeine differs for a number of reasons, including *body weight*; *time* or *frequency* of caffeine ingestion during the day; *health* and *smoking status*; *genetic variations in enzymes* responsible for caffeine's metabolism and actions, and; *medications*. Since children weigh less, they receive a higher effective dose on a body weight basis, compared to an adult consuming the same amount. Consequently, a specific amount of caffeine consumed by a child or adolescent may have a greater effect on younger individuals than on adults. Also, we all process (absorb, metabolize, and

eliminate) caffeine differently, despite some common features. Caffeine is nearly entirely absorbed by the gastrointestinal tract after we consume it, and is then quickly transferred to the blood, metabolized in the liver, and excreted (primarily in the urine). Peak blood (plasma) concentrations are reached between only 15 minutes to two hours after ingestion.³⁷ All things being equal, a slow metabolizer's caffeine blood level will be higher than a fast metabolizer's. This depends on the nature of an individual's metabolizing enzymes; pregnancy or smoking status; whether or not the individual has liver disease and; interactions of caffeine with medications or St. John's Wort.^{38,39,40,41,42,43,44,45,46,47,48,49,50} Individual caffeine consumption patterns also influence caffeine's actions and peak blood caffeine levels. For example, a single, very high dose of caffeine during the day can result in a higher caffeine blood level at a single point in the day relative to multiple, moderate doses of caffeine. This is because a specific amount of caffeine that is broken up into smaller amounts and ingested during the day is incrementally metabolized and excreted, resulting in lower caffeine blood levels than that expected after ingestion of that same amount all at one time. In addition to metabolic differences among individuals, there are differences in various receptors that affect individuals' sensitivity to the effects of caffeine.^{51,52,53,54} All of these factors influence caffeine's desired stimulatory effects in an individual, as well as its toxicity.

E. What Levels of Caffeine Are Generally Considered Safe?

The US Department of Agriculture (USDA) states that the daily intake of <400 mg/day "is not associated with increased risk of chronic diseases, such as cardiovascular disease (CVD) and cancer and premature death in healthy adults"⁵⁵ and FDA has concurred.⁵⁶ For caffeine added to cola, FDA considers acceptable a caffeine level of < 200 ppm (0.02%), equivalent to 71 mg of caffeine in a 12-oz serving of cola⁵⁷—a little less than that contained in a cup (eight ounces) of most coffees.⁵⁸ However, this determination for cola does not apply to levels of caffeine that might be used in other products, or total caffeine intake per day. Some who ingest caffeine on a daily basis at levels that are considered safe experience sleep disturbances,⁵⁹ headaches or heart palpitations,⁶⁰ and other effects, such as jitteriness. Others experience symptoms of withdrawal with a decrease or cessation in caffeine consumption.⁶¹ However, none of these effects from moderate doses of caffeine are considered safety risks in healthy individuals. On the other hand, not many would dispute that large doses of caffeine can be extremely toxic, as well as fatal,⁶² and that the dose ranges related to its adverse effects can be expected to significantly differ among individuals.

It is possible that consumers' familiarity and comfort with caffeine moderates possible concerns about excessive consumption.⁶³ Still, overdosing on caffeine is rare. Sometimes overdosing is intentional, such as with suicide attempts. However, it has also been known to occur as a result of an apparent lack of awareness of safety risks or dose estimation errors,⁶⁴ such as when taking high, single doses, or an excessive number of doses (especially if there is a misperception that bulk quantities should be handled with no greater care than protein powder), or due to a lack of understanding of the inherent variability in sensitivity to caffeine in the general population.

F. What Level of Caffeine Is Toxic or Lethal?

Due to the great variability in how individuals respond to caffeine, there appears to be no bright line between a safe and a toxic dose, although, as noted above, < 400 mg of caffeine per day is generally considered safe for healthy adults. Toxicity may occur at doses greater than 400 mg of caffeine per day, resulting in hypertension, hypotension, tachycardia, and vomiting,⁶⁵ and death may occur if 10 g of caffeine is ingested (roughly equivalent to 100 cups of strong coffee), or if blood caffeine levels reach 100 µg/ml,^{66,67,68} although cardiac arrest has been reported with a consumption of "only" 15-20 cups of coffee/day.⁶⁹ Fatalities from high doses of caffeine, some of which have been attributed to caffeine-containing energy drinks, have been reported. These appear to have been from a single and very high dose of caffeine, or from several sufficiently high

doses within perhaps a relatively short period. A non-exhaustive list of documented fatalities appears below. Note that isolated fatalities, which can sometimes be related to exposure to several substances, are generally published as case reports in the scientific literature, filed as cases with poison control centers, or reported to FDA as adverse events.⁷⁰ As with pharmaceuticals, adverse event reporting for dietary supplements can be problematic and is also associated with incomplete information and under-reporting.⁷¹

- A 39-year old man died from the ingestion of approximately 12 g of pure powdered caffeine; his autopsy blood caffeine level was 350 mg/liter (or 350 µg/ml).⁷²
- A 22-year old woman died of cardiac arrest after ingesting mail order diet pills containing caffeine as the only active ingredient. Her blood serum caffeine level was 1560 µg/ml.⁷³ [Note that a single cup of coffee, which provides a dose of 0.4-2.5 mg of caffeine/kg of body weight, and which is considered safe, may yield a peak blood concentration of < 2 mg caffeine/liter (or 2 µg caffeine/ml blood).⁷⁴]
- A 38-year old woman on an anti-depressant that caused dry mouth, drank up to eight liters/day of Pepsi Max (equivalent to 1555 mg caffeine/day)⁷⁵ to alleviate the drug's side effect. A post-mortem examination determined that her death was due to "excessive consumption" of both caffeine and the anti-depressant drug's active ingredient.⁷⁶
- An 18-year old male died as a result of taking pure powdered caffeine.⁷⁷
- A 24-year old male died as a result of taking pure powdered caffeine.⁷⁸
- A 14-year old girl (with a pre-existing cardiac defect) died of cardiac arrhythmia, which her family attributed to a caffeine-containing energy drink (Monster), of which she drank two 24-oz cans (equivalent to 480 mg of caffeine) within a 24-hour period before her death.^{79,80}

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In summary, FDA issued Warning Letters to distributors of pure powdered bulk caffeine sold to consumers as a dietary supplement. The agency stated that its actions were related to caffeine's lethal properties at very high doses, but also cited the potential for users of the products to make seemingly trivial, but deadly, measurement errors. Caffeine is considered safe at daily doses of <400 mg, but high single or multiple doses, such as those that appear to be related to fatalities attributed to caffeine, are a risk.

FDLI and this novice volunteer editor are grateful to the organizations contributing to this compendium in the following pages, providing the reader with a chance to learn of their reactions to FDA's action on pure, powdered bulk caffeine and to gain an understanding of what each organization is doing to assure the safety of all dietary supplements marketed in the US.

II. CONSUMER HEALTHCARE PRODUCTS ASSOCIATION (CHPA) STATEMENT

FDA Actions on Powdered Caffeine and the Role of Responsible Industry

Caffeine (1,3,7-trimethylxanthine), widely considered the most commonly used psychoactive drug in the world,⁸¹ is a naturally-occurring mild central nervous stimulant found in the leaves, seeds and fruits of several

botanical sources (e.g., coffee and cocoa beans, tea leaves).⁸² A wide variety of foods (including dietary supplements), beverages (energy drinks and colas), and prescription and over-the-counter (OTC) drugs also contain caffeine from naturally derived or synthetic sources. The average daily consumption of caffeine by a typical US adult is approximately 300 mg (e.g., three to four cups of coffee).⁸³

Caffeine-containing products, when consumed in moderate amounts, have an excellent safety profile.^{84,85,86} Side effects associated with greater intake of caffeine may include relatively mild cases of nervousness and tremors with higher doses associated with nausea, headache, fever, dizziness, and agitation. Excessive caffeine intake is associated with more serious health effects, including rapid or erratic heartbeat, seizures and, in rare cases, death.⁸⁷ Some studies estimate that serious adverse effects of caffeine may occur at a total dose of 1,000-1,300 mg⁸⁸ and that caffeine-naïve individuals may exhibit increased sensitivity.⁸⁹ The stimulant effects of caffeine on the cardiovascular and central nervous system have been well-described.⁹⁰

The Consumer Healthcare Products Association (CHPA) members who market dietary supplements are committed to providing quality products manufactured according to current Good Manufacturing Practices (GMPs), labeled appropriately per regulation, and advertised in a responsible manner. We support strong action by FDA against those who market illegal products masquerading as dietary supplements. Also, CHPA and its members are taking voluntary action to improve consumer and retailer awareness of unsafe supplements and to keep these products off the market. In 2013, the CHPA Board of Directors approved voluntary labeling guidelines for caffeine-containing dietary supplements, a measure adopted following FDA's announcement that the agency would investigate the safety of caffeine in food products.⁹¹ These guidelines were recently updated to indicate that CHPA's members agree not to market powdered caffeine for sale to consumers.

On August 27, 2015, FDA issued Warning Letters to five distributors of pure powdered caffeine,⁹² noting that the products were adulterated, as they represented a significant or unreasonable risk to consumers. Citing the potentially small difference between safe amounts of powdered pure caffeine and those causing potentially serious adverse effects, FDA noted that consumers would not likely be able to accurately measure a safe dose of powdered caffeine (1/16 to 1/32 of a teaspoon in some cases) with common kitchen measuring tools. Differences in the density of powdered caffeine products could also result in administration of a greater total dose with some products even when the correct amount is taken. One teaspoon of pure powdered caffeine is equivalent to the amount of caffeine in about 28 cups of regular coffee.

Under the Dietary Supplement Health and Education Act (DSHEA), FDA may find a product to be adulterated if the ingredient presents an unreasonable risk of illness or injury under the recommended conditions of use. FDA in this case has determined that an unreasonable risk exists due to the difficulty in measuring a safe level of caffeine. The risk of unintentional overdose is therefore heightened in this case. FDA had previously issued a Consumer Advisory⁹³ recommending that consumers avoid use of powdered caffeine following the death of two young men who had used a pure powdered caffeine product. Others have also called on FDA to restrict or ban the sale of powdered caffeine, including the Center for Science in the Public Interest⁹⁴ (CSPI) and six US senators.⁹⁵ Due to the potentially serious consequences that may result from errors in measuring extremely small doses of pure powdered caffeine, CHPA believes that FDA's actions to remove powdered caffeine from the market were appropriate.

Consumers relying on dietary supplements to support their overall health and wellness should be assured that there are extensive rules in place regulating the manufacturing, labeling, and marketing of these products. FDA is responsible for ensuring that all companies follow the mandatory GMP regulations for dietary supplement products defined under the DSHEA. Under the DSHEA, FDA is also responsible for reviewing New

Dietary Ingredient Notifications. Thus, nearly all aspects of dietary supplement manufacturing, advertising, and labeling are covered by extensive regulations issued and enforced by FDA. Moreover, the Federal Trade Commission (FTC) regulates advertising of dietary supplements and requires that health claims be based on “competent and reliable scientific” evidence.

Dietary supplement manufacturers must perform identity testing for each dietary ingredient they use and must establish specifications for the identity, purity, and strength of all dietary ingredients used to manufacture dietary supplements. Manufacturers must also verify a dietary ingredient supplier’s compliance with GMPs and periodically update these qualifications. Industry-funded trade associations and independent GMP auditors have helped responsible companies to address concerns associated with ingredient quality or identity. Along with the Council for Responsible Nutrition (CRN) and the United Natural Products Alliance (UNPA), CHPA participates in the Standardized Information on Dietary Ingredients (SIDI) Workgroup, which has developed voluntary guidelines intended to assist dietary supplement companies with supplier qualification activities as part of complying with the GMP regulations.

CHPA believes that the current regulatory framework for dietary supplements, defined under DSHEA, is adequate. We have voiced our support for increased agency action against manufacturers marketing illegal products containing active pharmaceutical ingredients or undeclared substances masquerading as dietary supplements. Along with the other dietary supplement trade associations, we have also expressed a willingness to work with the agency in helping it in this regard.

Periodically, accusations of an “unregulated” dietary supplement industry are published in the mainstream media implying that the entire industry operates in a “wild-west” type of environment. Of course, this is simply not true and such statements fail to recognize the long-standing differences in the regulatory structures governing drugs and dietary supplements. This often results in consumer confusion about these beneficial health products that millions of Americans rely on to support their overall health and wellness.

The dietary supplement industry has grown considerably since the passage of the DSHEA. Although the vast majority of dietary supplement manufacturers responsibly adhere to all aspects of GMPs, there are unfortunately those who do illegally spike their products with active pharmaceutical ingredients or undeclared substances with similar structural or pharmacological properties. CHPA member companies are committed to manufacturing and marketing their dietary supplement products in a responsible fashion, and we support increased efforts by the agency to remove illegal products sold as supplements from the market. Along with the other supplement trade associations, we believe that FDA would be better able to perform its functions if it had increased funding and we are supportive of the elevation of the Division of Dietary Supplements to an Office.⁹⁶

Concerns have been expressed about FDA’s issuance of Warning letters to marketers of pure powdered caffeine, noting that these were based on anecdotal evidence.⁹⁷ CHPA believes that the potential for caffeine overdose and the ensuing serious consequences that could result provide sufficient basis for the FDA action. In this instance, pure powdered caffeine presents a unique risk—consumers are required to accurately measure out an appropriate and very low dose using measures (1/16 to 1/32 teaspoon) that are not commonly employed or likely recognized by the average consumer.

CHPA believes that the dietary supplement industry can help to keep illegal and/or unsafe products sold as dietary supplements from reaching the marketplace. Just as FDA has a role in exercising a more rigorous enforcement of the current laws in an effort to prevent the marketing of illegal products, industry trade

associations can help by increasing consumer awareness of safe dietary supplement use. In 2013, CHPA developed voluntary guidelines for industry addressing the labeling, packaging, and promotion of dietary supplements containing caffeine.⁹⁸

CHPA recently updated the guidelines to include an agreement that the Association's members will not market pure powdered caffeine to consumers; CHPA's members are also expected to comply with other significant aspects of the guidelines. These include: 1. disclosure of the total caffeine content per serving in a dietary supplement (a disclosure that is not required by FDA); 2. inclusion of a statement on the label of any supplement containing more than 100 mg total caffeine per serving noting that the product is not intended/recommended for children less than 18 years of age, or those sensitive to caffeine; 3. inclusion of information on labeling that notes the serving size and safe daily intake recommendations; 4. a commitment to "not advertise, market, or otherwise promote the use of caffeine-containing dietary supplements in combination with alcohol, or to counter the acute or immediate effects of alcohol."

In collaboration with CRN, we have published articles in journals targeted to convenience store owners stressing the need to adequately monitor the products sold in these and other similar type stores (e.g., gas stations).^{99,100} CHPA provides consumers with easy to understand information on the safe use of dietary supplements. These tips stress the need for consumers to share information with their healthcare provider regarding the types of supplements they are taking, to avoid purchasing supplements promising "miracle" effects, and to only purchase supplements from companies that consumers know and trust. Dietary supplement trade associations also hold regular meetings to discuss current events regarding supplements, including ways to support educational efforts and how best to work with FDA to ensure that dietary supplement manufacturers are compliant with all applicable regulations.

CHPA has a long history of working with partners to promote and enhance the safe and effective use of OTC products. The CHPA Educational Foundation, established in 2004, educates consumers on how to use, store, and dispose of OTC medicines and dietary supplements. Information and materials representing the latest medical and scientific thinking and research address specific areas identified by CHPA as those for which consumers need guidance and support. The CHPA Educational Foundation developed and launched KnowYourOTCs.org, a website providing facts and educational tools geared to consumers, and presented in a user-friendly format that is intended to help them take charge of their own healthcare. This includes examples of dietary supplement products, an explanation of dietary supplement health claims, important tips for safe use, and commonly asked questions about dietary supplements.

CHPA believes that educating consumers on the best practices for choosing dietary supplement products manufactured and marketed in a responsible fashion can make a difference in consumer understanding and public health. CHPA is committed to working with FDA in whatever capacity necessary to ensure the public's continued access to safe, beneficial dietary supplement products, and to working with FDA to prevent the marketing of illegal or potentially unsafe products.

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III. COUNCIL FOR RESPONSIBLE NUTRITION (CRN) STATEMENT

Preventing Consumer Access to Pure Powdered Caffeine: The Role of FDA and Industry Self-Regulation

A. Introduction

CRN's mission is to sustain and enhance a climate for our members to responsibly develop, manufacture, and market dietary supplements and nutritional ingredients. CRN supports a comprehensive regulatory framework that provides consumers with access to a wide variety of affordable, high quality, safe, and beneficial dietary supplement products, while also encouraging innovation, research, and product development based on sound science.

B. Summary of CRN's Position

CRN supports FDA's issuance of Warning Letters to distributors of pure powdered caffeine. The Federal Food, Drug, and Cosmetic Act (FFDCA) authorizes the agency to take enforcement action if a dietary supplement presents a significant or unreasonable risk of illness or injury under the conditions of use recommended or suggested in the labeling.¹⁰¹ In the present case, although pure powdered caffeine is a legal dietary ingredient, when sold in bulk form it presents an unreasonable risk to consumers because the margin between the recommended serving size and a toxic amount is miniscule. A simple mistake in accurately measuring a safe dose of the product could result in a serious adverse event or possibly death. Because the hazards associated with caffeine overdose are significant, CRN supports restrictions on the sale of bulk pure powdered caffeine (PPC) directly to consumers.

C. Role for Industry and FDA

Industry and FDA have unique but complementary roles in ensuring the safety of dietary supplements. Many dietary supplements and the ingredients used in these products, including caffeine, have a long and established history of safe use. Therefore, the FFDCA does not require FDA's approval of dietary supplements or their ingredients. However, manufacturers intending to market new dietary ingredients (NDIs) must notify the FDA at least 75 days before marketing an NDI.¹⁰² Whether or not an ingredient is an NDI, the FFDCA requires companies intending to market them to assure the safety of products before they are marketed. In addition, companies must comply with various FDA laws and regulations, including current Good Manufacturing Practices (GMPs), Adverse Event Reporting (AER) requirements, as well as with the more recent Food Safety Modernization Act (FSMA).¹⁰³ The purpose of the FSMA is to ensure safety in the US food supply by shifting the focus from responding to contamination to preventing it. Under the FFDCA, as amended by FSMA, companies that manufacture, process, pack, or hold human food, including dietary ingredient suppliers, must identify food-safety hazards and implement preventive controls.¹⁰⁴ Certain provisions, such as facility registration,¹⁰⁵ administrative detention,¹⁰⁶ and mandatory recall authority,¹⁰⁷ also apply to dietary supplement manufacturers.

The FFDCA also addresses requirements for structure/function claims.¹⁰⁸ These claims may describe the role of a nutrient or dietary ingredient intended to affect the normal structure or function of the human body, e.g., "calcium builds strong bones," or may characterize the means by which a nutrient or dietary ingredient acts to maintain such structure or function. In 2000, FDA issued a final rule, "Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body,"¹⁰⁹ which establishes the types of statements that may be used on a dietary supplement's immediate product label or packaging, as well as statements that are placed physically apart from the product's container, such as promotional material including that on websites. Unlike health claims or qualified health claims, *structure/*

function claims do not require FDA's approval. However, the FFDCA requires marketers to substantiate that the claims are truthful and not misleading, and marketers must also notify FDA within 30 days of first marketing the product(s) associated with these claims.¹¹⁰ In addition, the product must include a mandatory disclaimer statement stating that the product has not been evaluated by FDA and "is not intended to diagnose, treat, cure, or prevent any disease."¹¹¹ The agency's "Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act" describes in detail the substantiation requirements for structure/function claims.¹¹² This guidance, which was modeled after FTC's "Dietary Supplements: An Advertising Guide for Industry,"¹¹³ recommends the amount, type, and quality of evidence that is necessary for the manufacturer's substantiation of a claim to be compliant with the FFDCA. Trade associations, such as CRN, promote industry compliance with federal requirements and agency guidance, and encourage responsible industry practices through self-regulatory programs. These programs establish guidelines for CRN's members, such as those for labeling and dosage, which go beyond federal requirements and seek to promote responsible manufacturing and marketing of dietary supplements.

FDA fulfills its public health mission with regard to supplements through continuous monitoring of firms' compliance with requirements promulgated under the FFDCA and related regulations. The agency routinely inspects manufacturers' facilities to ensure compliance with the GMP and the FSMA requirements, reviews product labels and claims, and monitors AERs. For example, FDA will review claims noted on either the product's label and packaging itself, or the company's website, for potential violations. FDA may also review company records during an inspection to ensure compliance with adverse event reporting and recordkeeping requirements. Failure to comply with any of these requirements can result in Warning Letters, product seizures or injunctions, import refusals, consent decrees, criminal proceedings, and even debarment from the industry (an action that causes the company to no longer be able to legally market dietary supplements). FDA also has the authority to declare a product unsafe (adulterated) and order its removal from the market, as the agency did with products containing androstenedione in 2004.¹¹⁴ In addition, the agency issues consumer advisories and health alerts that are intended to notify consumers and healthcare providers of important new safety information about marketed products, as it did with pure powdered caffeine in 2014.¹¹⁵

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D. Current Law and Regulations

CRN has concluded that FDA acted appropriately and within its legal authority when it issued the Warning Letters on PPC and declared PPC adulterated under the law. Section 402(f)(1)(A)(i) of the FFDCA provides that a dietary supplement is adulterated if it presents a significant or unreasonable risk of illness or injury under the conditions of use recommended or suggested in the labeling. The pure powdered caffeine products at issue clearly fall under this provision. First, because pure powdered caffeine is a pure compound, the difference between a safe and a toxic dose of caffeine in these products is unacceptably small. To put it in perspective, one teaspoon of pure, powdered caffeine is equivalent to the amount of caffeine in 28 cups of coffee, while a typical recommended serving size for these pure, powdered caffeine products is 1/16 or even 1/32 of a teaspoon. Second, measuring a safe dose of pure powdered caffeine is difficult without precise measuring tools. As an example, the directions for one pure powdered caffeine product describe a 200 mg serving as a "rounded 1/32 tsp" and state that an "[a]ccurate measurement of caffeine powder... may be performed with a digital gram weight scale precise to 0.01 grams (10mg) or better."¹¹⁶ Many bulk PPC products contain 100 or even 1000 servings, so without the right tools to precisely measure such a small serving size, consumers could easily take an incorrect and possibly toxic dose. Third, FDA has already documented at least two deaths of otherwise healthy individuals following the use of pure powdered caffeine. These products may also pose a threat to those with pre-existing conditions or sensitivities to caffeine. Therefore, CRN considers FDA justified in taking its most recent action in an effort to prevent additional pure powdered caffeine-related adverse events and deaths.

Finally, the nature of this action is not unique for FDA. For example, FDA has taken similar action with over-the-counter (OTC) pediatric liquid acetaminophen and liquid vitamin D. In 2011, the agency raised concerns regarding dosage instructions for pediatric liquid acetaminophen after receiving reports of accidental overdoses.¹¹⁷ OTC manufacturers worked with FDA to develop clearer instructions, new measuring devices to accompany the products, and a consumer education campaign to raise awareness among parents and caregivers.¹¹⁸ Also, in 2010, FDA alerted parents and consumers that some liquid vitamin D dietary supplements were sold with droppers that could allow for excessive dosing of vitamin D to infants. Manufacturers of these products were advised by FDA to modify droppers so that they hold no more than the recommended dose and that the dose is clearly marked on the dropper.¹¹⁹ Likewise, FDA has an obligation to warn consumers about the potentially serious hazards associated with products such as pure powdered caffeine, especially when there are documented cases of adverse events and deaths. Without a doubt, caffeine is a safe and legal dietary ingredient; however, similar to the issue with liquid acetaminophen and liquid vitamin D, this safe ingredient becomes a potential hazard when measuring or dispensing a safe dose is not a simple process. Thus, makers of pure powdered caffeine could consider working with FDA to reformulate their products or packaging their products in a way that promotes safe use of caffeine.

E. CRN's Objectives and Actions in Contributing to the Goal of Keeping Unsafe Products from Entering the US Market

A key component of CRN's mission and strategic objectives is promoting responsible industry practices. CRN's Code of Ethics requires its members' compliance with all federal and state regulations governing dietary supplements and food in the areas of manufacturing, marketing, quality control, and safety. CRN's members also agree to adhere to additional voluntary guidelines that go beyond federal requirements. CRN has a robust self-regulatory program that includes labeling guidelines for caffeine, among others.¹²⁰ CRN approved its caffeine guidelines in 2013 to help consumers make informed decisions about caffeine in the dietary supplements they purchase.¹²¹ The guidelines address disclosure of caffeine content and set forth consumer advisories to promote the safe, responsible use of dietary supplements. They also specifically recognize that caffeine, whether natural or synthetic, is a safe and legal dietary ingredient. The guidelines call on manufacturers to disclose on the product label the total amount of caffeine, from both natural sources like green tea extract; coffee bean extract; guarana or yerba mate; as well as added caffeine. In addition to the recommendation for label disclosure of total caffeine content, the guidelines recommend that products with a total caffeine content of more than 100 mg per serving include label advisories for children, those sensitive to caffeine, pregnant or nursing women, and those with a medical condition or taking medication. The guidelines also discourage companies from marketing or promoting the use of caffeine-containing dietary supplements in combination with alcohol, or to counter the acute or immediate effects of alcohol.

Immediately after FDA issued its consumer advisory on pure powdered caffeine, CRN amended its guidelines to include restrictions on the bulk sale of pure powdered caffeine directly to consumers. The guidelines do, however, recognize the legitimate sale of bulk pure powdered caffeine as part of business-to-business transactions (i.e., ingredient suppliers selling directly to finished product manufacturers). CRN also issued press statements supporting the FDA Warning Letters on pure powdered caffeine.¹²²

Additional CRN self-regulatory efforts include the following guidelines: "Recommended Guidelines: Labeling and formulation of melatonin-containing dietary supplements for sleep support,"¹²³ "Recommended Guidelines: Iodine Quantity in Multivitamin/Mineral Supplements for Pregnancy and Lactation,"¹²⁴ "Best Practices Guide for Enzyme Dietary Supplement Products,"¹²⁵ and, "CRN Guidelines for Labeling of Protein in Dietary Supplements and Functional Foods."¹²⁶ CRN also issued a guideline on the dosage and labeling of DHEA, kava, and ephedra in supplement products: "CRN Safety Considerations for Dosage Recommendations

and Labeling.”¹²⁷ Finally, in 2006 CRN partnered with the National Advertising Division (NAD)¹²⁸ on an initiative to increase monitoring of advertising for dietary supplements. This program targets deceptive, false, and misleading dietary supplement advertising which is then reviewed by the NAD to determine whether the claims are truthful and supported by competent and reliable scientific evidence. The program enhances the marketplace for dietary supplements by increasing consumer confidence in the truth and accuracy of advertising claims for dietary supplement products and encourages fair competition within the industry.¹²⁹ CRN will continue to implement such programs that go above and beyond the legal requirements and support appropriate FDA enforcement actions targeting unsafe products.

IV. CENTER FOR SCIENCE IN THE PUBLIC INTEREST (CSPI) STATEMENT

The Case of Powdered Caffeine and the Need to Fix Dietary Supplements Oversight

On May 27, 2014, 18-year-old Logan Stiner was discovered on the floor of his family’s home by his brother. Logan, an Ohio high school athlete and scholar with a bright future, died of an accidental overdose of powdered caffeine.¹³⁰ In June 2014, James Wade Sweatt, a 23-year-old engineer, died after repeatedly going into cardiac arrest, despite multiple attempts to revive him. “That powder is making me sick,” Wade told his wife, before collapsing.

CSPI, a non-profit organization that works to improve nutrition and public health, filed a Citizen Petition with FDA in December 2014¹³¹ asking the agency to ban the sale of pure powdered caffeine and highly concentrated caffeinated powders and liquids. CSPI argued that pure powdered caffeine and other highly concentrated forms of caffeine present “a significant or unreasonable risk of illness or injury under conditions of use suggested or recommended in the labeling,”¹³² and are thus “adulterated or misbranded”¹³³ and cannot be sold. CSPI also proposed that a ban on caffeine sold in a highly concentrated form to consumers is justified because it “pose[s] an imminent hazard to public health or safety.”¹³⁴ Lastly, CSPI encouraged FDA to impose requirements for clearer labeling and potency restrictions to minimize risk of an accidental overdose.

A single teaspoon of pure, powdered caffeine is the equivalent of drinking 25 8-ounce cups of coffee.¹³⁵ It is so concentrated that the suggested serving size—generally between 1/32 and 1/16 of a teaspoon—is beyond the measurement capabilities of a typical consumer.

In August 2015, FDA issued five enforcement letters to companies selling powdered bulk caffeine directly to the public. Shortly thereafter, CSPI renewed its call for FDA to ban all highly concentrated powdered and liquid caffeine products to prevent harm to consumers.¹³⁶ While the companies to which FDA addressed enforcement actions appear to have suspended sales of the products named in the Warning Letters, the sale of such a hazardous product highlights the extent to which the current regulatory scheme for dietary supplements fails to protect consumers. A recent study published by FDA and the Centers for Disease Control and Prevention underscores that conclusion. Based on surveillance data from 63 emergency departments from 2004 through 2013, the authors found that supplements cause, on average, an estimated 23,000 emergency room visits per year.¹³⁷ Adverse-event reports (AERs) from 2008-2015 describe 2,100 incidents involving serious outcomes, including life-threatening illnesses and deaths.¹³⁸

There are considerable gaps in reporting. In the case of powdered caffeine, for example, in addition to the two deaths, news reports indicate there were 30 cases of overdoses of pure caffeine reported to poison

control centers nationally during the first nine months of 2014.¹³⁹ AERs received by CSPI (via a Freedom of Information Request), as well as other sources, indicate that accidental or intentional overdose with pure powdered caffeine has led to hospitalizations, seizures, cardiac arrhythmias, and death.¹⁴⁰ How many other overdoses occurred, but were not linked to powdered caffeine, is unknown.

Consumers have a legitimate expectation of both safety and efficacy for any product sold to the public. Dietary supplements, unlike drugs or food additives, currently undergo no premarket review for either safety or effectiveness. Yet a 2002 study found that 50 percent of consumers are unaware that supplements are not reviewed or approved by a government agency prior to being marketed, despite the legally required disclaimer.¹⁴¹

It is obvious why consumers are confused. First, many supplements appear indistinguishable from over-the-counter drugs; second, the legal disclaimer that FDA did not approve a product's claims is typically printed in the smallest font size used on the label; and third, advertising and labels often make disease claims exclusively permitted for drugs. A 2003 review of claims made on 273 websites selling herbal dietary supplements found that 55 percent of representations made on these herbal products included unauthorized and illegal claims to treat, prevent, diagnose, or cure specific diseases.¹⁴²

Even where the claims are permissible "structure/function" claims,¹⁴³ companies lack evidence to support them. A 2012 investigation by the Department of Health and Human Services Inspector General concluded that none of the products evaluated with human studies met all of FDA's evidentiary standards for such claims, and 20 percent of the supplements it evaluated made prohibited disease claims.¹⁴⁴ Furthermore, in 2011, the General Accounting Office concluded that research shows that consumers do not understand distinctions between these different types of claims, or the relationship between the claims and the level of scientific support associated with a certain claim category (e.g., "health claim," "qualified health claim," "structure/function claim."¹⁴⁵ Ironically, structure/function claims, although lacking any review by FDA, are actually most persuasive to consumers.¹⁴⁶

Lack of enforcement and deliberate or unintentional adulteration of labeled products also pose serious threats. FDA conducts just 400 inspections "for more than 15,000 domestic and international manufacturers of dietary supplements sold in the United States...find[ing] significant deficiencies in about two-thirds of all the inspections it conducts, with most facilities cited for multiple, serious violations."¹⁴⁷ Yet since 2007, FDA identified 673 adulterated supplements containing hidden, illegal ingredients, including steroids, amphetamines, and prescription drugs.¹⁴⁸ Between 2010 and 2012, FDA cited 444 of 626 supplement companies—a stunning 70 percent—for violations of good manufacturing practices, and improvement has been slow: in FY2014, the percentage of firms cited dropped only by 8 points to 62 percent of firms inspected (298 out of 483 inspections).¹⁴⁹ A 2013 investigation of the industry by *USA Today* documented that supplements containing drugs were being produced by companies operated by convicted criminals.¹⁵⁰ In addition, the Department of Justice (DOJ) recently issued 11-count criminal indictments to officials at USPlabs, alleging the company intentionally sold hazardous recalled products.¹⁵¹

While the DSHEA exempts a wide swath of ingredients previously in the food supply, for supplements containing "new dietary ingredients" (NDIs),¹⁵² manufacturers must provide FDA with information showing the ingredient will "reasonably be expected to be safe."¹⁵³ FDA issued a flawed draft industry guidance document on this subject in 2011, and has not issued it yet in final form.¹⁵⁴

It is troubling that the draft guidance permits companies to exempt new dietary ingredients by self-designating them “generally recognized as safe” (i.e., using procedures for so-called self-affirmed “GRAS”).¹⁵⁵ This is clearly inconsistent with Congress’s intent. While the DSHEA exempted ingredients that were already “present in the food supply,”¹⁵⁶ this exemption was due to a mistaken presumption that food ingredients are all already subject to FDA oversight.¹⁵⁷ A recent report found that this loophole allows companies to self-affirm the safety of food ingredients and dub an ingredient exempt under DSHEA,¹⁵⁸ meaning that FDA may never review evidence on the riskiest ingredients in either food or dietary supplements.

Under current law, FDA may remove products from the market only after they pose a “significant or unreasonable risk of harm” or an “imminent hazard” to the public.¹⁵⁹ It is clear from the numerous failures described herein that this post-market, ad hoc approach inflicts unacceptable risks on the public.

Reforms of dietary supplement oversight should include:

- Mandatory third-party premarket oversight of safety and efficacy, with attention to classes of products posing a particular threat because of their ingredients, contaminants, or susceptibility to being adulterated;
- More meaningful product labeling, including changes to the clarity, prominence, and font size of disclaimers, and warning labels for hazardous products;
- A requirement for manufacturers, ingredient suppliers, and distributors to register marketed dietary supplements with FDA, including annual sales data;
- More stable funding for FDA through modest user fees, and improved mechanisms for obtaining and disseminating adverse event and related health information from emergency rooms, poison control centers, consumers, and other sources;¹⁶⁰
- FDA should finalize its draft NDI guidance through a binding rulemaking process. The final rule should specify the quantity and quality of evidence for safety determinations and excise the exemption from the NDI notification requirement for self-affirmed GRAS food ingredients;
- To address efficacy, Congress should require the agency to develop a process for evaluating evidence for all dietary supplement claims and develop sensible standards for review of new claims;¹⁶¹
- FTC should continue its ongoing efforts to police dietary supplements for unsupported claims of efficacy and DOJ should bring criminal and civil prosecutions where supported by evidence.¹⁶²

Images of Bulk Caffeine Powder



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ENDNOTES

1. See William A. Correll, FOOD & DRUG ADMIN. *FDA Warning Letter to Bridge City LLC. August 27, 2015, available at* <http://www.fda.gov/iceci/enforcementactions/warningletters/2015/ucm460203.htm>, last access Nov. 25, 2015.
2. See William A. Correll, FOOD & DRUG ADMIN. *FDA Warning Letter to Hard Eight Nutrition LLC. August 27, 2015, available at* <http://www.fda.gov/iceci/enforcementactions/warningletters/2015/ucm460200.htm>, last access Nov. 25, 2015.
3. See William A. Correll, FOOD & DRUG ADMIN. *FDA Warning Letter to Kreativ Health Inc Db a Natural Food Supplements. August 27, 2015, available at* <http://www.fda.gov/iceci/enforcementactions/warningletters/2015/ucm460208.htm>, last access Nov. 25, 2015.
4. See William A. Correll, FOOD & DRUG ADMIN. *FDA Warning Letter to PureBulk. August 27, 2015, available at* <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2015/ucm460204.htm>, last access Nov. 25, 2015.
5. See William A. Correll, FOOD & DRUG ADMIN. *FDA Warning Letter to Smartpowders. August 27, 2015, available at* <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2015/ucm460201.htm>, last access Nov. 25, 2015.

6. For example, in 2010, due to FDA's concern that the addition of caffeine to alcoholic beverages could mask some of the "sensory cues" individuals rely on to determine their level of alcohol intoxication, the agency issued warning letters to manufacturers of caffeinated alcoholic beverages; FOOD & DRUG ADMIN., FDA News Release, FDA Warning Letters Issued to Four Makers of Caffeinated Alcoholic Beverages (Nov 17, 2010), *available at* <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm234109.htm>, last access Nov. 25, 2015.
7. See Leah S. Rosenfeld et al., *Regulatory status of caffeine in the United States*, 72 NUTRITION REVIEWS (s1) 23 (2014).
8. See Gwendolyn Prothro, *The Caffeine Conundrum: Caffeine Regulation in the United States*, 27 CUMBERLAND LAW REVIEW 65 (1996-1997).
9. Michael R. Taylor. FOOD & DRUG ADMIN. *FDA Consumer Health Information, FDA to Investigate Added Caffeine, May 2013*, *available at* <http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM350740.pdf>, last access Nov. 27, 2015.
10. See label for "5-hour Energy, Berry," *available at*: <http://5hourenergy.com/wp-content/uploads/Berry-Fans-05.jpg> [Note "Dietary Supplement" printed two lines below "6-Pack" on lower left side of carton, last access Nov. 17, 2015]; See also Table 2 in *What's all the Buzz About? A Survey of Popular Energy Drinks Finds Inconsistent Labeling, Questionable Ingredients and Targeted Marketing to Adolescents*, A Report Written by the Staff of Congressman Edward J. Markey (D-MA) in Coordination with the Staff of Senators Richard J. Durbin (D-IL) and Richard Blumenthal (D-CT), *available at* <http://www.markey.senate.gov/documents/04-10-13%20-%20Energy%20Drink%20report%20FINAL.pdf>, last access Nov. 27, 2015.
11. FOOD & DRUG ADMIN., ENERGY "DRINKS" AND SUPPLEMENTS: INVESTIGATIONS OF ADVERSE EVENT REPORTS (Nov. 16, 2012), *available at* <http://www.fda.gov/Food/RecallsOutbreaksEmergencies/SafetyAlertsAdvisories/ucm328536.htm>, last access Nov. 27, 2015.
12. REDBULL Co., *Is Red Bull Regulated by the FDA?*, <http://energydrink-us.redbull.com/red-bull-is-fda-approved>, last access Nov. 17, 2015.
13. Rosenfeld et al., *supra* note 7.
14. Michael R. Taylor. FOOD & DRUG ADMIN. *FDA Consumer Health Information, FDA to Investigate Added Caffeine, May 2013*, *available at* <http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM350740.pdf>, last access Nov. 25, 2015.
15. United Natural Products Alliance®. Press Release, United Natural Products Alliance Announces "No-Sale" Policy for Bulk-Powdered Caffeine as a Condition of Membership, *available at* https://unpa.com/assets/news_resource/asset/88/15_0301_UNPA_Policy_Bulk_Powdered_Caffeine.pdf, last access Nov. 27, 2015.
16. Natural Products Association. News Release, Natural Products Association Responds to FDA Action on Powered [sic] Caffeine, Sept. 2, 2015, *available at* https://www.npainfo.org/App_

Themes/NPA/docs/regulatoryLegislative/FDA/Powdered%20Caffeine%20Response3.pdf, last access Nov. 27, 2015.

17. Dietary Supplement Health and Education Act of 1994, Pub. L., No. 103-417, 108 Stat. 4325 (1994); 21 U.S.C. §321.
18. FDA appears to have tentatively taken the position that synthesized herbal/botanical constituents, including caffeine, do not qualify as dietary ingredients. See FOOD & DRUG ADMIN., DRAFT GUIDANCE FOR INDUSTRY: DIETARY SUPPLEMENTS: NEW DIETARY INGREDIENT NOTIFICATIONS AND RELATED ISSUES (July 2011), *available at*: <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/DietarySupplements/ucm257563.htm>, last access Nov. 23, 2015.
19. Although such products do not require approval from FDA before marketing, dietary supplement manufacturers are expected to notify the agency, or risk the product being deemed adulterated, if they intend to market a supplement containing an ingredient that was not marketed as a dietary ingredient before October 15, 1994 (or if the dietary supplement itself was not marketed before this date), i.e., a “a new dietary ingredient.” 21 U.S.C. §350b.
20. Caffeine-containing energy drinks can be marketed as either a conventional food or dietary supplement, a determination that is based on a number of factors. See FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY. DISTINGUISHING LIQUID DIETARY SUPPLEMENTS FROM BEVERAGES, (January 2014), *available at* <http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/ucm381189.htm>, last access Nov. 24, 2015.
21. *Id.*
22. FOOD & DRUG ADMIN. *FDA Takes Action on Bulk Pure Powdered Caffeine Products. Constituent Update (Sept. 1, 2015)*, *available at*: <http://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm460097.htm>, last access Jan. 15, 2015.
23. For example, on the bulksupplements.com website, on Aug. 27, 2014, “John” wrote, “I filled the capsules with 300 mg...” and on Mar. 2, 2015, “James” wrote, “I purchased this to add to my home made [sic] preworkout.” Others commented positively on its miscibility, which suggests they mixed the powder with a liquid and ingested it in beverage form BULKSUPPLEMENTS.COM, <http://www.bulksupplements.com/caffeine-powder-anhydrous.html>, last visited Nov. 6, 2015.
24. Correll, *supra* note 2. Note: Identical or similar language appears in the other Warning Letters.
25. Per 21 U.S.C. §342(f)(1)(A), an “unreasonable risk” causes a dietary supplement to be considered “adulterated.” Also, 21 U.S.C. §342(f)(1)(A)(i) specifically states that such an unreasonable risk includes “conditions of use recommended or *suggested* in labeling.” [emphasis added]
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27. AMER. CANCER SOC., DIETARY SUPPLEMENTS: WHAT IS SAFE? *Megadosing: The 'More is Better' Myth*, available at <http://www.cancer.org/treatment/treatmentsandsideeffects/complementaryandalternativemedicine/dietarysupplements/dietary-supplements-toc>, last access Nov. 23, 2015.
28. Uniquely identified by its Chemical Abstract Service Number: 58-08-2. Also known by other names: 3,7-Dihydro-1,3,7-trimethyl-1H-purine-2,6-dione (9CI); Anhydrous caffeine, Coffeine, Coffeinum, Guaranine, Methyltheobromine, Methylxanthine theophylline, Thein, Theine, 1,3,7-Trimethyl-2,6-dioxopurine [NATIONAL LIBRARY OF MEDICINE. CHEMIDPLUS, <http://chem.sis.nlm.nih.gov/chemidplus/rn/startswith/58-08-2>, last access Nov. 6, 2015.
29. See INST. OF MED., CAFFEINE IN FOOD AND DIETARY SUPPLEMENTS: EXAMINING SAFETY: WORKSHOP SUMMARY (2014).
30. Personal communication, Siobhan DeLancey, FOOD & DRUG ADMIN. (Oct. 30, 2015).
31. Bill J. Gurley et al., *Multi-ingredient, Caffeine-containing Dietary Supplements: History, Safety, and Efficacy*, 37 CLINICAL THERAPEUTICS no. 2, 275 (2015).
32. INST. OF MED., *supra* note 29.
33. Note: The amount of caffeine in eight ounces (one cup) of coffee can vary significantly. See CENTER FOR SCIENCE IN THE PUBLIC INTEREST, *Caffeine Content of Food & Drugs*, <http://www.cspinet.org/new/cafchart.htm>, last access Nov. 25, 2015. [CSPI net]
34. INST. OF MED., *supra* note 29.
35. See CONSUMER Q&A: CAFFEINE-CONTAINING DIETARY SUPPLEMENTS, <http://crnusa.org/caffeine/Q+A.html>, last access Nov. 10, 2015.
36. Prothro, *supra* note 8.
37. See INST. FOR SCI. INFO. ON COFFEE, *Caffeine in the Body*, <http://coffeeandhealth.org/topic-overview/caffeine-in-the-body/>. [Coffee trade association informational resource], last access Nov. 5, 2015.
38. *Id.*
39. Parkinson & Ogilvie, ABSORPTION, DISTRIBUTION, AND EXCRETION OF TOXICANTS, IN CASARETT AND DOULL'S TOXICOLOGY: THE BASIC SCIENCE OF POISONS, (Curtis D. Klaassen ed, 7th ed 2008).
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42. *Id.*
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44. Fredholm et al., *supra* note 40.
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46. J.A. Carrillo and J. Benitez, *Clinically Significant Pharmacokinetic Interactions Between Dietary Caffeine and Medications*, 39 CLINICAL PHARMACOKINETICS, no. 2, 127-153 (2000).
47. See Parkinson & Ogilvie, *supra* note 39.
48. *Id.*
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59. See NATIONAL SLEEP FOUNDATION, *Caffeine and Sleep*, <https://sleepfoundation.org/sleep-topics/caffeine-and-sleep>, last access Nov. 27, 2015.
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and Nonprescription Drug Consumer Protection Act, September 2013, available at, <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/DietarySupplements/ucm171383.htm>, last access Nov. 27, 2015; also see Dietary Supplement and Nonprescription Drug Consumer Protection Act, Pub. L. No. 109-462. Dec. 22, 2006.

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106. *Id.* § 304(h); 21 U.S.C. 334(h).
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159. 21 U.S.C. § 342(f)(1).
160. FDA should report this information publicly annually and labels should be required to include a toll-free telephone number and Web address for incidents to be reported. Congress should also require reporting of mild and moderate adverse events.
161. For example, Congress could ask the National Academy of Medicine (NAM) to use existing evidence from the National Institutes of Health, the U.S. Preventive Services Task Force, and other sources, and prepare a list of allowed claims for products, as in Europe and Canada. Congress should require FDA to review claims for products prior to market to assure there is an evidentiary basis for them consistent with NAM’s guidelines.

ABOUT THE CONTRIBUTING ORGANIZATIONS AND AUTHORS

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Brenda Seidman, M.S., Ph.D. RAC is a regulatory toxicologist and Principal Consultant of Seidman Regulatory Toxicology, LLC in the Washington, D.C. metropolitan area. She served as a volunteer editor of this issue and one of its contributors, and thanks Ms. Judy Rein, *Policy Forum’s* Editor, for giving her this opportunity, and for her guidance and patience. Seidman also thanks Ms. Jeanne Faubell for generously donating her time and expertise in assisting Seidman with the preliminary formatting of this issue’s endnotes, and to each of the participants, not only for their willingness to participate, but also for their hard work and professionalism.

Consumer Healthcare Products Association

The Consumer Healthcare Products Association (CHPA) is the 134-year-old national trade association representing the leading manufacturers and marketers of over-the-counter (OTC) medicines and dietary supplements. CHPA is committed to empowering consumer self-care by preserving and expanding choice and availability of consumer healthcare products.

~ **Jay Sirois**, Ph.D. is responsible for regulatory and scientific affairs activities, including cooperative programs with the U.S. Food and Drug Administration, ingredient safety, and dietary supplement programs at CHPA.

He is experienced in pharmaceutical, medical device, and dietary supplement regulatory affairs, pharmacovigilance, Rx-to-OTC switch, product safety, and clinical research. Sirois is a member of the Regulatory Affairs Professionals Society and is an ad hoc reviewer for the *Neurotoxicology* journal.

Council for Responsible Nutrition

The Council for Responsible Nutrition (CRN), founded in 1973, is a Washington, D.C.-based trade association representing 150+ dietary supplement and functional food manufacturers, ingredient suppliers, and companies providing services to those manufacturers and suppliers. Learn more about CRN at www.crnusa.org.

- ~ **Rend Al-Mondhiry** is associate general counsel for CRN. Ms. Al-Mondhiry provides legal counsel and advice to CRN's staff and members in the areas of legislation; regulatory compliance and advocacy; and international policy development with respect to dietary supplements and nutrition issues.
- ~ **Duffy MacKay**, N.D., Senior Vice President, Scientific and Regulatory Affairs, oversees CRN's Science and Regulatory Affairs Department, ensuring that the association's scientific, policy, and legislative positions are based on credible scientific rationale.

Center for Science in the Public Interest

The Center for Science in the Public Interest (CSPI) is a leading national non-profit advocacy organization for nutrition, health, food safety, public health, and scientific integrity. CSPI works on behalf of consumers to bring accountability and transparency to public health policy. The organization accepts no government or corporate funding.

- ~ **Laura MacCleery** is CSPI's Director of Regulatory Affairs, and an experienced advocate for improvements to public health. She has served the public interest in a wide range of issue areas, from women's health to campaign finance reform, and now has turned her attention to improving the safety and health of dietary products sold to consumers. She graduated from Stanford Law School in 1999 and clerked for Justice Gregory Hobbs of the Colorado Supreme Court.

ABOUT THE FOOD AND DRUG POLICY FORUM

FDLI's *Food and Drug Policy Forum* provides a marketplace for the exchange of policy ideas regarding food and drug law issues. The *Forum* welcomes articles on cutting-edge state, national, and international policy issues related to food and drug law.

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Each issue of the *Forum* presents an important policy topic, provides background information and detailed discussion of the issues involved in the policy question, relevant research, pertinent sources, and policy recommendations. This publication is digital-only, peer-reviewed, and smartphone enabled.

The *Forum* is published monthly (12 times a year) and is provided as a complimentary benefit to FDLI members. Individual issues of the *Forum* are also available for separate purchase.

The *Food and Drug Policy Forum* Editorial Advisory Board, comprised of representatives of government and leading associations interested in food and drug law issues, as well as food and drug and healthcare professionals, provides peer review and guidance on articles considered for publication.

ABOUT FDLI

The Food and Drug Law Institute, founded in 1949, is a non-profit organization that provides a marketplace for discussing food and drug law issues through conferences, publications, and member interaction. FDLI's scope includes food, drugs, animal drugs, biologics, cosmetics, diagnostics, dietary supplements, medical devices, and tobacco. As a not-for-profit 501(c)(3) organization, FDLI does not engage in advocacy activities.

FDLI's mission is to provide education, training, and publications on food and drug law; act as a liaison to promote networking as a means to develop professional relationships and idea generation; and ensure an open, balanced marketplace of ideas to inform innovative public policy, law, and regulation.

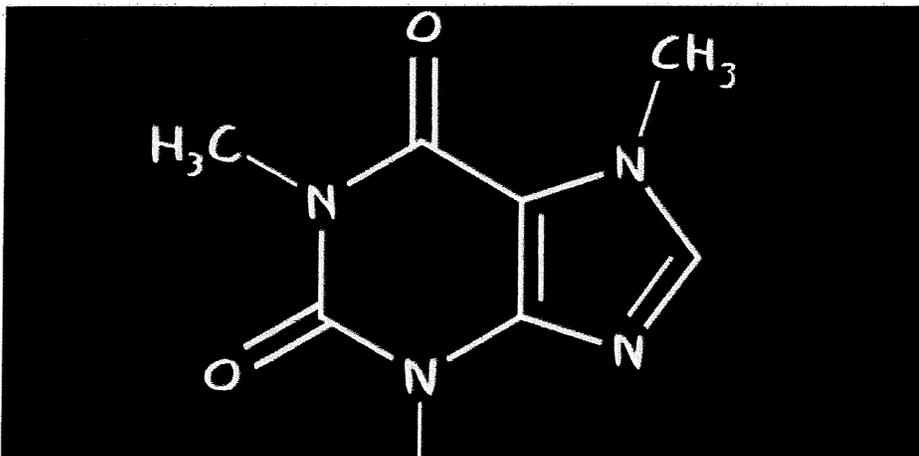
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Wake Up and Smell the Pure Powdered Caffeine

By Steve Mister, President & CEO, Council for Responsible Nutrition , 09-Sep-2015 1 comment

Last updated on 09-Sep-2015 at 15:43 GMT



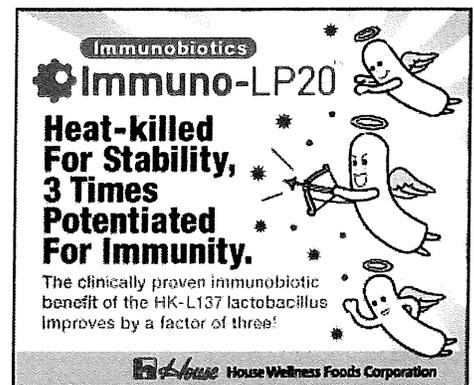
Caffeine: Image © iStockPhoto / makaule

Related tags: Pure powdered caffeine, Caffeine, CRN, Dietary supplements

Once again the dietary supplement industry finds itself having to make tough decisions. Today the issue is pure powdered caffeine being sold directly to consumers. And the options are a lot more momentous than merely "would you like cream and sugar with that?"

Recently FDA issued warning letters to several marketers of pure powdered caffeine declaring that the bulk sale of this substance to consumers violates the Food, Drug & Cosmetic Act because, when sold in bulk, pure powdered caffeine presents a serious risk of illness or injury despite the suggested serving level on the labeling. At issue is whether consumers can appropriately dose themselves when the ingredient is sold in its purified form in large quantities.

Pure powdered caffeine is a white powder that is essentially 100 percent synthetic caffeine without any of the binders and fillers that might be added to finished products to "cut" its potency. In that form, anywhere from 1/32 to 1/14 of a teaspoon can provide about 200 milligrams of caffeine—the same amount as one would expect to find



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in two cups of coffee. It is being sold in bulk bags of anywhere from 25 grams (about 125 servings) to 25 kilograms (about 125,000 servings!).

The problem is not the ingredient as much as it is the concentration of pure powdered caffeine and the fact that so little carries so much of a punch. Even if the bulk bags provide directions that 1/16 of a teaspoon equals a serving, can average consumers use the product according to those directions? And will they? Can a consumer population accustomed to measuring sports nutrition products with 1/8 cup scoops appreciate the risks of exceeding 1/16 teaspoon? Even if consumers have a 1/16 measuring device (often called a "pinch" measuring spoon) or a milligram scale in their kitchen, it's too easy to make a mistake. Add a little too much salt or pepper to your pot roast and you change the taste; but add a little too much of pure powdered caffeine in your post-workout smoothie and you might never be able to taste—or do anything else—again.

FDA has already documented two cases in which young, otherwise healthy men overdosed themselves (apparently unintentionally) with pure powdered caffeine and died.

Which brings us back to the industry's moment of decision: Will supplement manufacturers and marketers support FDA's action and join the call to remove pure powdered caffeine from the consumer marketplace, or will they dig in and defend a few companies' ability to sell a potentially dangerous product under the banner of DSHEA?



One teaspoon of pure powdered caffeine is equivalent to the amount of caffeine in about 28 cups of regular coffee.
Image © iStockPhoto / Ozgur Coskun

We decided to support FDA's call for the removal of this product

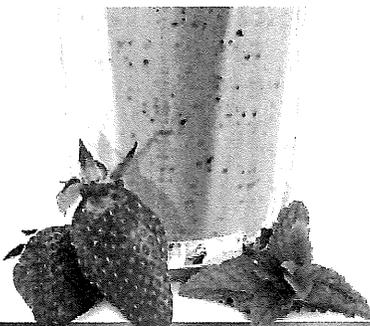
At CRN, that decision was easy. We decided to support FDA's call for the removal of this product from the consumer marketplace. Do consumers really need to buy five kilogram bags? The safety risks of mismeasuring or overdosing outweigh the benefits. Moreover, hunkering down to protect a hypothetical "right" to sell a dietary ingredient in bulk would put the industry on the wrong side of consumer safety and cultivate the impression that we are defending the right of a few marketers to peddle a dangerous substance.

So CRN amended its existing Recommended Guidelines Caffeine-Containing Dietary Supplements

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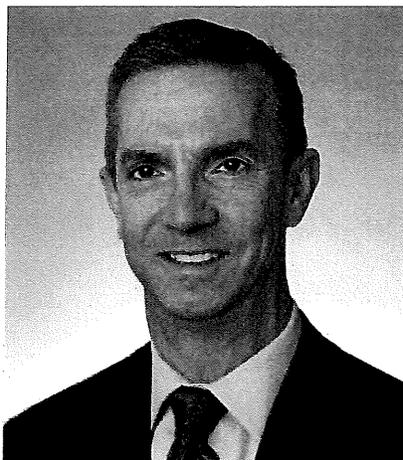
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to include a recommendation against selling pure powdered caffeine in bulk to consumers (legitimate business-to-business transactions are permitted). Further, CRN has supported FDA's action by calling for non-CRN members to stop selling this product as well as urging FDA to act swiftly, using the full extent of the enforcement tools the law provides to remove it from the market.

FDA has already persuaded industry action with regard to over-the-counter (OTC) pediatric cough/cold medicines. Despite dosage instructions on packaging, the agency raised legitimate concerns that many consumers couldn't determine the appropriate dose for children of various ages and weights and that the measuring devices provided with many of those products only contributed to the confusion. So OTC manufacturers collaborated with FDA to develop clearer instructions, new measuring devices that accompany the products, and consumer education to teach parents how to appropriately medicate their children. That's what a responsible industry does. Similarly, marketers of pure powdered caffeine could develop packaging for their purified caffeine in single serve dosages if they want to sell it directly to consumers. That would certainly make the "conditions of use" described in their labeling more feasible and realistic.



Steve Mister, CRN

Some have suggested that to acquiesce to FDA and to remove, or even repackage, these products would lead to the metaphoric slippery slope, and before we know it, FDA would be alleging vitamin C isn't safe. Sometimes the "slippery slope" is no slope at all, and a clear demarcation exists. Is pure powdered caffeine an ingredient for which we want to fall on our proverbial swords? Does the industry think that any dietary ingredient potent enough that a teaspoon of it could kill someone should be available to consumers in bulk form—whether it's ephedrine or caffeine or the purified form of an herbal extract? Consumers don't need access to purified ingredients that are sold in a manner that turns a blind eye to, if not invites, accidental and intentional misuse.

CRN has taken the right path here. We are protecting our consumers from a safe ingredient that becomes dangerous when sold in a bulk pure powdered form directly to consumers. CRN has chosen to put public safety first and we urge other companies to demonstrate that ours is a responsible, mature industry that self-polices as well as knows when to work with our regulators. It's time to wake up and smell the coffee.

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This should be classified as hazardous

If you ship products in bulk, it should have a hazardous marking on the product if it can cause injury to a person. We work in the bulk bag industry and this applies to any chemical that is being transported in bulk, so caffeine should be no different.

[Bulk Bags](http://custom-packaging-products.com/bulk-bags/)

Posted by Brent

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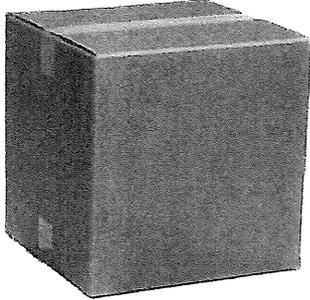
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This caffeine pure powder is offered to corporation for professional food & supplement formulation, R&D (research and development), cosmetic, or any other proper business purpose only. Please Contact to Verify to Order.

This Item is 100 grams (3.52 oz) Caffeine pure powder which complies with US Pharmacopeia (USP) quality standard. There is not any additive or filler inside. Assay > 99.5%. There are 2.5~3.5 years shelf life available.

Appearance: White crystalline powder. Taste: Bitter. Solubility: Soluble in water.

Caffeine (sometimes called guaranine when found in guarana, mateine when found in mate, and theine when found in tea) is a xanthine alkaloid found in the leaves and beans of the coffee tree, in tea, yerba mate, guarana berries, and in small quantities in cocoa, the kola nut and the Yaupon holly. Caffeine is a central nervous system stimulant, having the effect of warding off drowsiness and restoring alertness. It's also a phosphodiesterase inhibitor in body, resulting in cAMP accumulation, and boosting energy level. Beverages containing caffeine, such as coffee, tea, soda and energy drinks are popularly consuming in all over the world.

General Serving Size: 1/20 teaspoon (about 100 milligram) each serving, DO NOT consumption above 200 milligram within 24 hours. An electronic milligram scale is strongly recommended for an accurate dose measurement. **Overdose is seriously dangerous. Any individual should consult his/her doctor before taking caffeine containing product.**

Storage Conditions: In a tightly sealed container, store in cool and dry place, keeping away from light and heat. Keep out of the reach of children.

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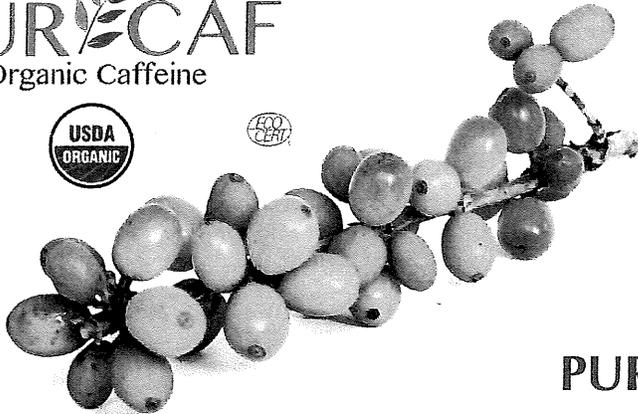
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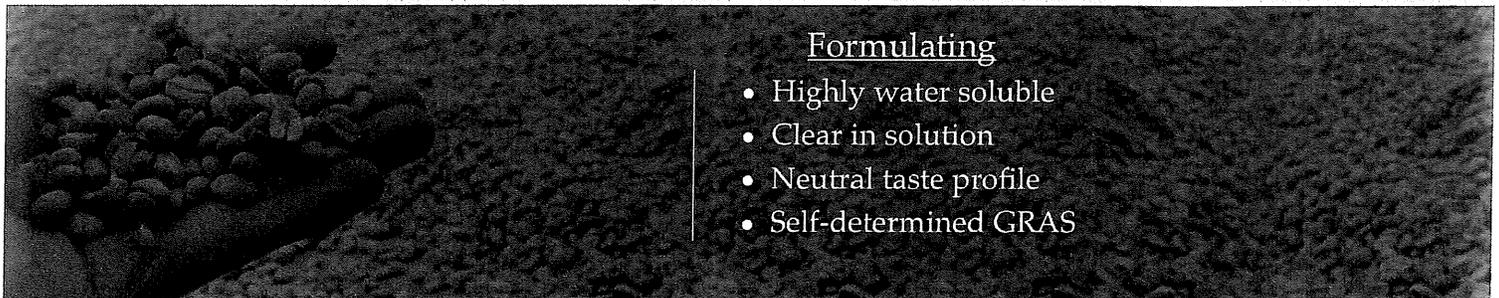
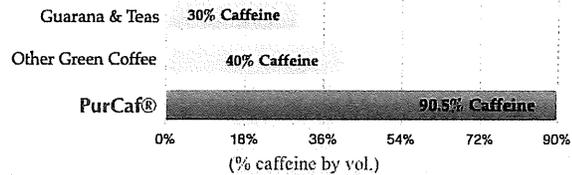
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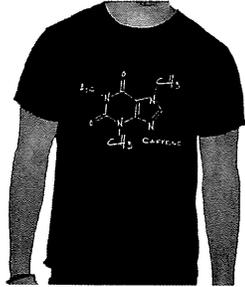
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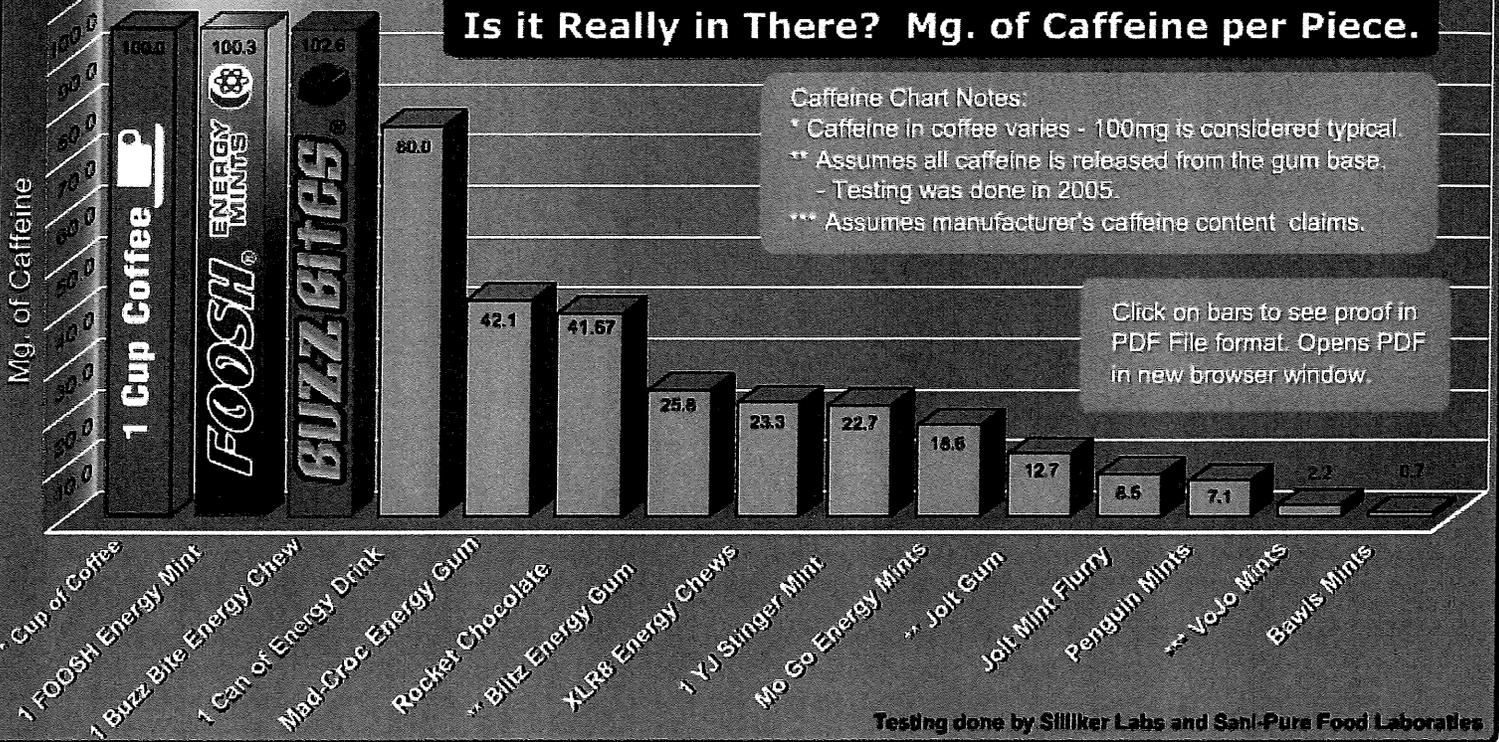
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How Much Caffeine Will Kill You?

By Arielle Pardes (/author/arielle-pardes)

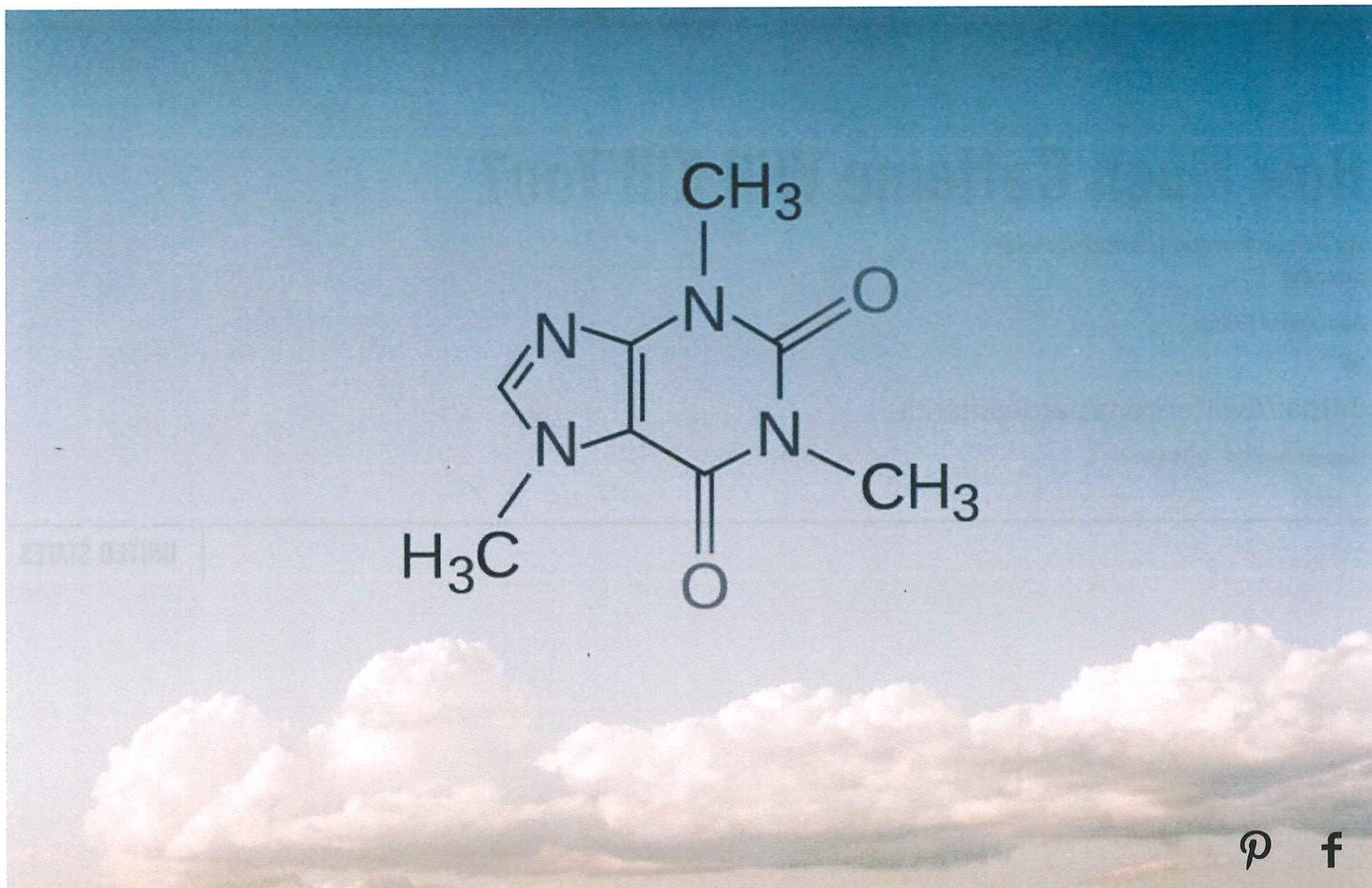
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December 22, 2014

UNITED STATES



The caffeine molecule. Image by [Nikoloz Jorjikashvili](https://www.flickr.com/photos/my_december/) (https://www.flickr.com/photos/my_december/)

Caffeine is the lifeblood of a productive civilization. Behind every bridge, monument, and skyscraper in America was a workforce fueled by caffeine. If society were Popeye, coffee would be its spinach. But, like everything good in life, if you do too much of it, it will kill you. That's what the Food and Drug Administration (FDA) was trying to get across last week when they issued a **stern warning**

(<http://www.fda.gov/Food/RecallsOutbreaksEmergencies/SafetyAlertsAdvisories/ucm405787>

against powdered caffeine. The official discouragement came after two people, an 18-year-old and a 24-year-old, overdosed from the stuff earlier this year. And those weren't the first times someone has expired from caffeine, either. A **24-year-old woman in Scotland**

(<http://www.inquisitr.com/1670533/cara-reynolds-raspberry/>) reportedly died earlier this

month after taking too many caffeine-packed diet pills; a **23-year-old man in England**

([http://www.nottinghampost.com/Strong-caffeine-products-banned-says-grandmother-](http://www.nottinghampost.com/Strong-caffeine-products-banned-says-grandmother-Notts-boy-overdosed/story-12264014-detail/story.html)

Notts-boy-overdosed/story-12264014-detail/story.html) died a few years ago after mixing two

spoonfuls of caffeine powder into an energy drink at a party; and **another man in the UK** (<http://www.bbc.com/news/uk-england-birmingham-24492833>) died from eating a tin of HERO Energy Mints last May, just to name a few.

But how much caffeine, exactly, does it take to kill you? The FDA says that you can safely consume about 400 milligrams per day, but it's extremely unlikely that you'll die even if you consume more than that (400 milligrams is roughly equal to four eight-ounce cups of joe). A **study** (<http://www.ncbi.nlm.nih.gov/pubmed/15935584>) from 2005, which investigated two caffeine-related deaths, suggested that you'd have to ingest around five grams of caffeine—more than ten times the FDA's figure—to overdose. **Other sources** (http://books.google.com/books/about/The_World_of_Caffeine.html?id=YdpL2YCGLVYC) suggest it's more like ten grams, which would be like downing 50 shots of 5-Hour Energy. But in 2011 **a girl died** (<http://www.today.com/health/teen-girl-dies-caffeine-toxicity-after-downing-2-energy-drinks-506441>) from "caffeine toxicity" after drinking just two cans of Monster—only 480 milligrams of caffeine, **roughly the same** (<http://www.abqjournal.com/513473/living/food/moderate-caffeine-intake-safe-for-most.html>) amount in a Venti-sized Starbucks coffee.

So there are a lot of figures floating around out there. To get to the bottom of it, I asked Dr. Patricia Broderick who, among many other medical accolades, is the editor-in-chief of the *Journal of Caffeine Research*. Our conversation got off to a rough start ("Can somebody overdose on caffeine? No, no, caffeine can't kill you," was, oddly, the first thing she said), but she eventually told me something interesting: We just don't really know how much caffeine it takes to put you in lethal danger. That's because caffeine tolerance is a highly individualized thing. "Women are *much* more susceptible to the effects of caffeine than are men," said Dr. Broderick, who added that young people also have much lower tolerances.

I found the same conclusions in a really old study on "**factors affecting caffeine toxicity**" (<http://onlinelibrary.wiley.com/doi/10.1002/j.1552-4604.1967.tb00034.x/abstract?systemMessage=Wiley+Online+Library+will+be+disrupted+on+20th+Dec+from+10%3A00-14%3A00+GMT+%2805%3A00-09%3A00+EST%29+for+essential+maintenance.>)" The study

—basically a review of preexisting research—points out that caffeine affects people differently on the basis of age, gender, body mass, tolerance to the drug, any concomitant disorders, and any other drugs the person may have consumed. Caffeine is most toxic when consumed intravenously, but can also reach lethal levels by "oral, rectal, or subcutaneous routes." The lethal dose depends on the administration of the drug, but it seems to be somewhere around 200 milligrams per kilogram—slightly more if you're consuming it through your butt, and slightly less if you're consuming it through your veins. (If you don't feel like reading the academic study from 1967, try this [handy calculator \(http://www.caffeineinformer.com/death-by-caffeine\)](http://www.caffeineinformer.com/death-by-caffeine) instead.)

This gets to what the FDA wrote in their statement about pure caffeine powder: It's dangerous because "a single teaspoon [is] roughly equivalent to the amount in 25 cups of coffee." But as Dr. Broderick reminded me, "**Coffee is to a square as caffeine is to a rectangle** (<http://online.liebertpub.com/doi/abs/10.1089/jcr.2014.1239>)"—they just aren't the same thing. Drinking 25 cups of coffee is insane, but wouldn't have the same immediate effect as snorting or swallowing pure powder. Part of that has to do with the actual substance (Dr. Broderick's research suggests that coffee and tea have mitigating factors in caffeine absorption) and part of that has to do, again, with the method of administration. Think of it as the difference between swallowing an Adderall or crushing it up and huffing it. Caffeine is the same way: It will fuck you up way faster if you snort it in the powdered form, and you're a lot more likely to overdose that way.

Continued below.

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Given the relatively high dose of caffeine necessary to bring on death, you'd think reports of possible overdose would be pretty uncommon. Surprisingly, that's not so. The **American Association of Poison Control Centers** (<http://www.aapcc.org>) receive thousands of calls each year from people concerned that their hearts are going to explode from caffeine. Last year, they received **3,033 of these types of calls** (<http://www.aapcc.org/alerts/energy-drinks/>) about energy drinks alone, 1,835 of which were from people 18 and younger. Of course, nowhere near all of the people who called actually *were* overdosing on caffeine—they just thought they were. And many of these calls come from people who are also on **other substances** (<http://www.caffeineinformer.com/caffeine-drug-interactions>)—alcohol, uppers, or other narcotics—so caffeine isn't strictly responsible for all of this, but it's still kind of crazy to think about.

The craziest thing is that getting high on caffeine isn't even a good time. (We tested it out earlier in the year, when one of our writers tried **smoking coffee** (<http://www.vice.com/read/smoking-coffee-is-stupid>). This is most definitely not recommended behavior.) In low doses, caffeine increases dopamine, which makes your brain feel nice. But when you take too much of it, that "reward" disappears, leaving you feeling jittery, anxious, and even physically ill. Taking too much caffeine can also make you feel irritable, headachy, tired—basically the opposite of what you'd expect to feel from caffeine. So there's really no benefit in trying to edge toward that 200 milligram per kilogram figure, or injecting caffeine into your veins, or snorting spoonfuls of the powder. It won't get you to that "high" place—and it just might make your heart feel like it's going to explode.

Follow Arielle Pardes on **Twitter** (<https://twitter.com/pardesoteric>).



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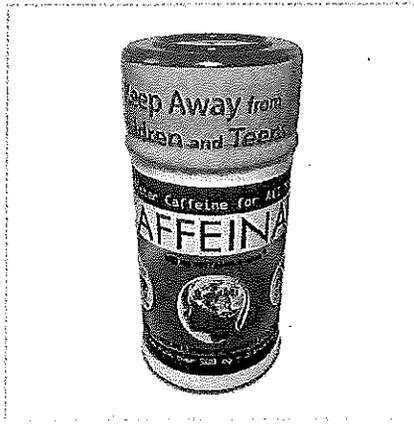
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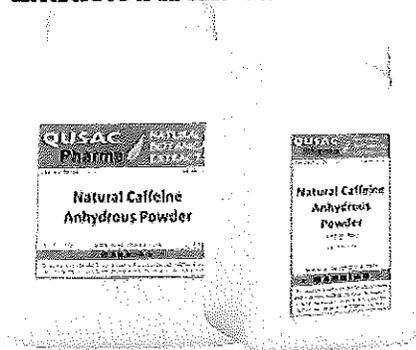
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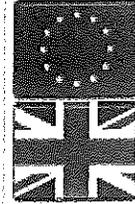
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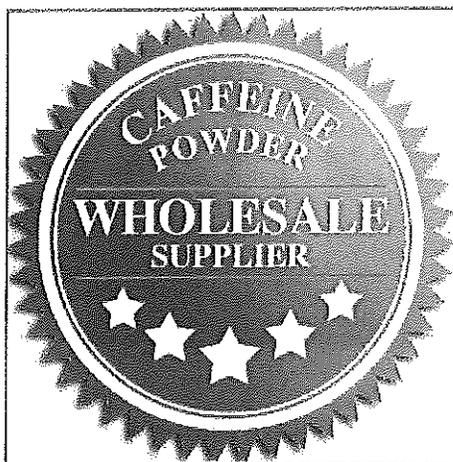
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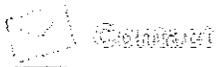
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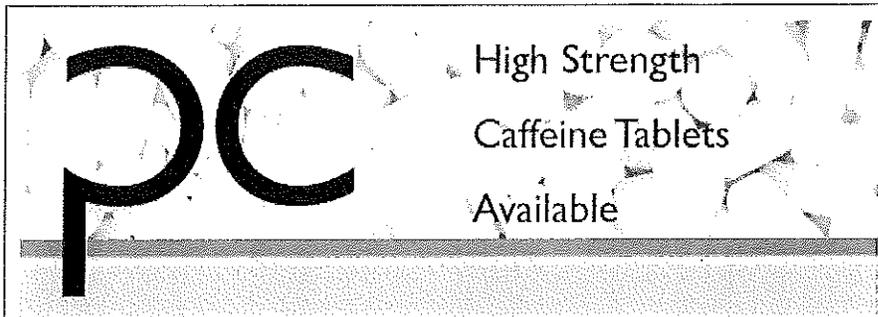


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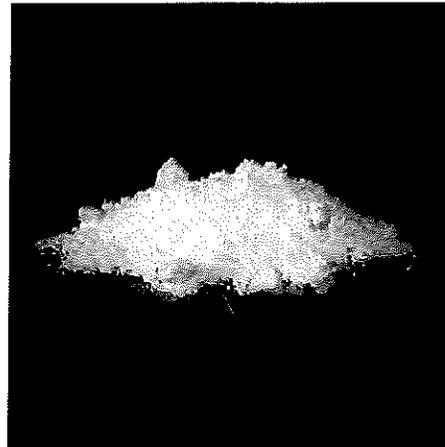


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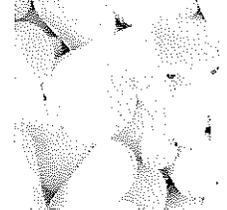
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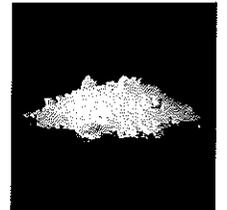
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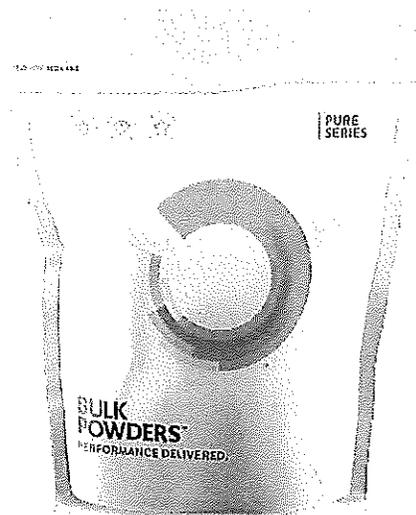
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CAFFEINE POWDER



Improves focus
Reduces rate of perceived exertion
100% pure Caffeine Powder

SIZE

500g	▼
100g	
500g	
1kg	

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CUSTOMER RATING

★★★★★

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30



TASTE

★★

MIXABILITY

★★

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At this price you really can't go wrong. If you need caffeine but don't have the time or desire for coffee and you want it at a RIDICULOUSLY low price compared to OTC caffeine pills then this is for you.

- Damien

WHAT IS CAFFEINE POWDER?

Warning: High Caffeine Content (200mg/100ml) . Not recommended for children or pregnant or breast feeding women.

Caffeine is a popular pre-workout ingredient – BULK POWDERS™ Caffeine Powder gives you the flexibility to dose Caffeine at the amount you require. Individual tolerance to Caffeine can vary, so this flexibility can be advantageous. Please not the warning at the top of the product page regarding accurate dosing.

RATING SUMMARY

99%

★★★★★

16 Reviews

5	15
4	1
3	
2	
1	

[WRITE A REVIEW](#)

100% pure caffeine powder

pharmaceutical grade



International shipping

If you are buying caffeine to any destination outside the UK please ensure you make your purchase through this page. If you try to buy from any of the other pages your order will be refused as the correct shipping charge will not be calculated.

All international orders are sent by Royal Mail airmail and can be **posted anywhere in the world**. Please allow 5-7 working days for international orders to arrive. Shipping and handling to non-UK destinations is automatically added on checkout.

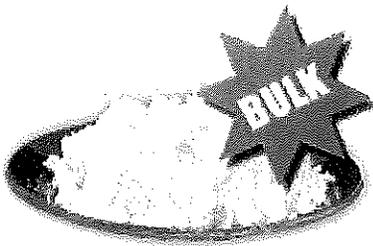
Worldwide international shipping now starts at **only \$5**.

We treat all orders very discreetly and do not pass your personal details onto anyone as per our [privacy policy \(/privacy/\)](/privacy/) - please refer to it before making any purchase for more details.

You can be sure that our caffeine is the **best quality available** as we have had it tested in a laboratory (/files/COA.pdf) as **99.9% pure**. To show that you won't find purer caffeine elsewhere we have provided a sample COA (/files/COA.pdf).

We now also ship **bulk orders (/bulk/)** worldwide. Just select the amount you want from the sidebar on the right on this page..

As ever if you have any further questions at all or want to request prices

**SPECIAL OFFER!****just £64 for 1 kg!**[Info](#)[Buy](#)**All bulk options**

→ 500g

→ 1kg

→ 2kg

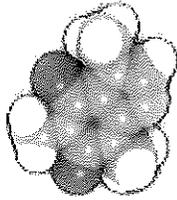
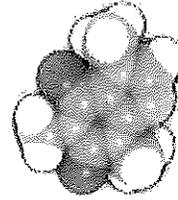
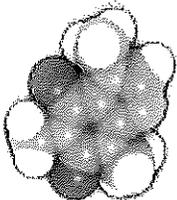
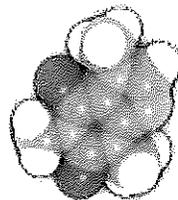
→ 5kg

→ 10kg

→ 15kg

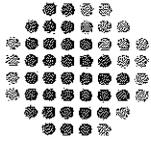
Disclaimer

Do not exceed over 800 mg in any 24 hour period. Seek advice of a doctor before use. Too much caffeine may cause nervousness, irritability, sleeplessness and possibly rapid heartbeat. For occasional use only. Not intended for use as a substitute for sleep. If fatigue or drowsiness persists or continues to occur, consult a physician. Do not use if you are diabetic. As with any dietary supplement, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product.

Pure caffeine powder**25 grams****100% pure caffeine powder (equivalent to 2000 ProPlus)****only £4.50****Out of stock****50 grams****100% pure caffeine powder (equivalent to 2000 ProPlus)****only £6.50****Out of stock****100 grams****100% pure caffeine powder (equivalent to 2000 ProPlus)****only £10.50****Out of Stock****250 grams****100% pure caffeine powder (equivalent to 2000 ProPlus)****only £19.00**[Info](#)[Buy](#)**Caffeine news and blog****Reasons To Buy Bulk Caffeine Powder Instead Of Caffeine Pills**

One of the best ways to get caffeine is through bulk caffeine powder instead of pills. While caffeine pills can be easy to take, they do not get absorbed by the body as quickly as the powder does and they can be harder to swallow. Not everyone is comfortable swallowing pills, and not everyone is good at it. If they aren't good at it, they might not want to take the chance, may be concerned about choking, or might otherwise want to avoid taking pills for some reason. If you buy caffeine powder, you can add it to just about any drink that you have. You can get 100% pure caffeine powder, and it's not that expensive. If you buy bulk caffeine, it's even cheaper. That's one of the best options for





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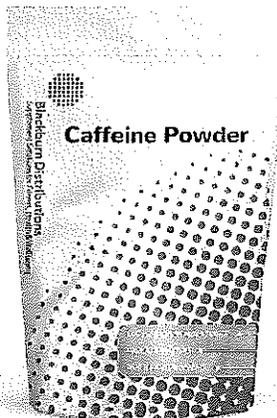
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PURE CAFFEINE POWDER

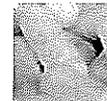
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From **£10,846.16**

Quick Overview:

- **Caffeine Powder** can support increases in heart rate and mental alertness.
- **Pure Caffeine Powder** can help to maintain awareness.
- **Caffeine Powder** has the potential to maintain an increase in work rate for maximising

Related Products



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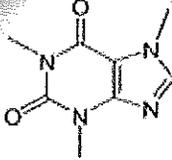
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White Gelatine Capsules Size

alv **Supplement Direct**

Anhydrous Caffeine Bulk Powder



Multiple Sizes

Serving Size: 50mg-100mg

Ingredients: pure Caffeine powder >99.9%

Warning: For manufacturing purposes only, not for direct consumption. Caffeine can be dangerous in large amounts. Contains pure caffeine which requires an accurate scale for proper measurement. Not for use by those under 18 years.

ANHYDROUS CAFFEINE POWDER USP GRADE 25G-25KG

TJM SYNAPTIK SUPPLEMENTS & LIGAND SOLUTIONS

Size

25g

\$ 4.50 \$ 3.99

ADD TO CART *Only 4 left!*

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THE EXTRA
CONCENTRATION



What is Liquid Caffeine?

Liquid Caffeine is CLEAN ENERGY, CLEAN TASTE. This means caffeine with no sugar, no added chemicals, no gut rot, best of all no crash! You get a steady flow of energy from the caffeine without the "crash" or ups and downs caused by typical energy drinks. Turn your coffee into an energy drink with Liquid Caffeine! Simply add the recommended amount to your drink and feel the energy that lasts all day!

Guarantee the Best Price, Quality, and use Caffeine



CAFEDROPS - THE LIQUID CAFFEINE (✓)

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CafeDrops + CafeDrops Big+ CafeDrops mini

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\$51.99

CafeDrops + CafeDrops mini

\$18.99

CAFEDROPS - THE LIQUID
CAFFEINE (✓)

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TOO MUCH CAFFEINE HAS CONSEQUENCES

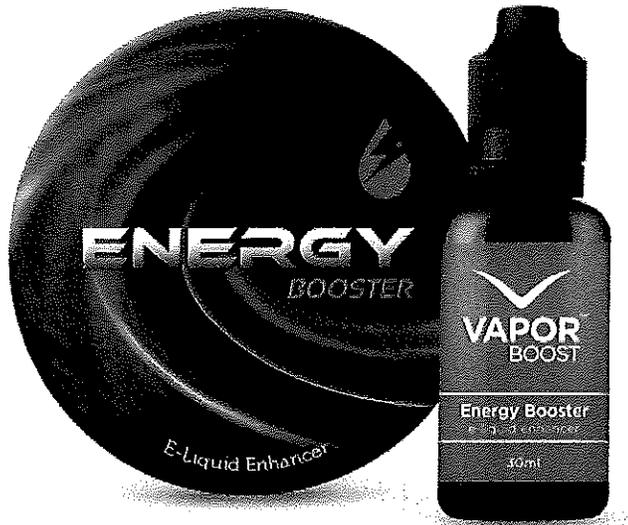
TOXICITY WARNING!

When you add CafeDrops to food or drinks, do not take more than 200 mg per single serving or more than 600 milligrams per day. Individual needs vary depending on caffeine consumption from other sources. (Coffee, Tea etc) Do not take CafeDrops if you have a known history of heart disease, or if you are pregnant or nursing.

Each person's tolerance for caffeine is different, and can provide many benefits, but too much caffeine can have many ill effects, including:

- Anxiety
- Heart palpitations
- Irritability
- Muscle tremors
- Sleeplessness
- Diarrhea or other gastrointestinal problems

A recognized medical syndrome, known as caffeine intoxication is presented with nervousness, restlessness,



Energy Booster - E-Liquid Enhancer

★★★★★ 54 Reviews

Availability: In stock

Ships today if ordered in the next 15 minutes!

\$19.95

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Add dropper bottles for easy mixing with your e-liquid?

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 Elect "SECURE" before disconnecting or turning it off.

Add Purecaf's LIQUID CAFFEINE to anything!

Shipping prices are for Domestic Orders Only!

International orders will be invoiced via Paypal. Please email your order.

Please allow 2 weeks for delivery

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\$4.99 per 1oz Bottle (500mg caffeine)

Out of Stock \$3.99 per 1oz Bottle

(sold in quantities of 4)

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100% pure caffeine powder

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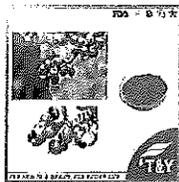


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Nature guarana extract,100% pure guarana seed extract powder 200g

Brand Name: T&Y ; Model Number: Guarana Seed Extract ; Brand Name:: T&Y ; Part:: Seed ; Appearance:: Brown Fine Powder

Shaanxi Teng Yun Biotech Co., Ltd.

Chat now!

US \$0.17 / Gram

Free Shipping

Min. Order: 200 Gram



high quality and Nature guarana extract,100% pure guarana seed extract powder

Brand Name: T&Y ; Model Number: Guarana Seed Extract ; Type:: Herbal Extract ; Extraction Type: : Solvent Extraction

Teng Yun Herb Extract Biotech

Offline

US \$0.12 / Gram

Free Shipping

Min. Order: 1000 Gram



high quality and Nature guarana extract,100% pure guarana seed extract powder

Brand Name: T&Y ; Model Number: Guarana Seed Extract ; Type:: Herbal Extract ; Extraction Type: : Solvent Extraction

Teng Yun Herb Extract Biotech

Offline

US \$0.16 / Gram

Free Shipping

Min. Order: 250 Gram



Nature guarana extract,100% pure guarana seed extract powder 500g/lot free shipping by EMS

Brand Name: herb Sky ; Model Number: Guarana Extract ; Type:: fruit extract ; variety:: Guarana Extract(Guarana Extract)

Shaanxi Herb Sky Biotech Co.,Ltd.

Chat now!

US \$0.20 / Gram

Free Shipping

Min. Order: 500 Gram



100% Natural and Pure Caffein Guarana EXTRACT, 100g/lot

Feedback(1) | Orders (3)

Brand Name: G&E ; Model Number: Caffein Guarana Extract ; Brand Name: : G&E Nutrition ; Model Number:: Caffein Guarana EXTRACT

Xian Teng Yun Biotech Co.,Ltd.

Chat now!

US \$25.00 / Gram

Free Shipping

Min. Order: 1 Gram



100% Pure Natural Guarana Seed Extract Powder 10%caffein 300g/lot

Brand Name: T&Y ; Model Number: Guarana Extract ; Type:: Herbal Extract, ; Part:: Seed ; Extraction Type:: Solvent Extraction

ShaanXi Teng Yun Bio-Technology Co.,Ltd

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Min. Order: 300 pieces

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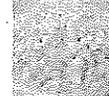


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LuxNaturesSupplies

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201 items

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Q zoom



Request a custom order and have something made just for you.

Item Details

★★★★★ (2,577)

Shipping & Policies

Caffeine Natural Coffee Bean is an anhydrous natural extract of caffeine from coffee beans. Caffeine is a chemical found in coffee, tea, cola, guarana, mate, and other products. Caffeine is most commonly used to improve mental alertness, but it has many other uses. Can be used in soaps, creams, especially for matures skin, to prevent wrinkles.

Listing is for 1 oz, free shipping USA \$75 orders.

International shipping available.

Pure Caffeine Natural Coffee Bean Powder 1 oz

\$12.00 USD

Ask a Question

Quantity

1

Overview

- Material: coffee beans powder
- Ships worldwide from Arlington Heights, Illinois
- Feedback: 2577 reviews
- Favorited by: 37 people

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in Arlington Heights, Illinois

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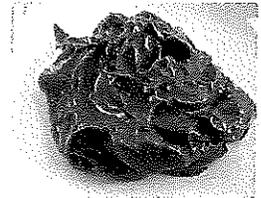
Learn more about the shop and process.



Lux Natures Supplies



Menthol crystals pick size... \$3.25 USD



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CAFFEINE ANHYDROUS POWDER



Brand: TRANSCENDENCE NOOTROPICS
Product Code: TRANSCENDENCE NOOTROPICS-
CAFFEINE ANHYDROUS
Availability: In Stock

\$15.99

AVAILABLE OPTIONS

* SIZE

(500 Grams (+\$13.24) ↕)

- +

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Pure Caffeine Powder



* Special Introductory Offer - Buy 1 Get 1 FREE! Select the item below to order::

- Buy 10 Grams - Get 10 Grams FREE! - \$24.97 USD + p&h
- Buy 30 Grams - Get 30 Grams FREE! - \$49.70 USD + p&h
- Buy 90 Grams - Get 90 Grams FREE! - \$99.77 USD + p&h
- Buy 500 grams - Get 500 Grams FREE! - \$249.00 USD + p&h
- Buy One Kilogram - Get One Kilogram FREE! - \$398.00 USD + p&h



Qty: [Add to Cart](#)

Description

Pure Caffeine Powder

FUNCTIONS/USES

Dozens of College Findings positively verifies and shows that caffeine is a successful, potent, physical and mental performance booster. This is underlined by the fact that a lot of sporting bodies, such as the IOC, have it on their list of banned or restricted substances. The good news for performance competitors nonetheless is that it is possible to obtain an ergogenic or performance boosting result from caffeine at levels which are thought about 'legal'. An additional little known fact is merely how unbelievably effective it is at breaking down and discharging stored fats so that they can be burnt as energy. Researches have actually shown that caffeine results on fat metabolic price are considerable and it can easily enhance fat burning throughout aerobic exercise by virtually 100 % (around double!)

IDEAL FOR

- **FAT LOSS AND PHYSIQUE ENHANCEMENT:** Males or females that wish to burn much more body fat by taking caffeine simply before aerobic activity. Taking before a weightlifting exercise improves the intensity of training whilst lessening perceived effort. This improved training capacity results in more fat being burnt, and more muscle being developed.
- **PERFORMANCE IMPROVEMENT: CAFFEINE ADVANTAGES FOR THE RIVAL:** Opponents wanting to enhance their performance can quickly consume to 6mg / kilo of bodyweight and experience performance boosting results without going over the 'legal limit'. Caffeine is a popular performance enhancer amongst cyclists.

HOW TO USE PURE CAFFEINE POWDER

Ironpower Caffeine comes with a green measuring scoop which holds 250mg when level (flat). To boost performance, take between 250mg - 500mg half an hour prior to the exercise occasion. Take 1/2 an hour before working out with weights. Take 3 hrs merely prior to aerobic work to optimize fat burning.

OTHER USES: Increases muscle fiber recruitment and intensity of muscular contraction, represents a diuretic, bronchodilator (helps breathing), and mental stimulant.

Orders received by 8 AM ET
Monday-Saturday will ship the same day*.

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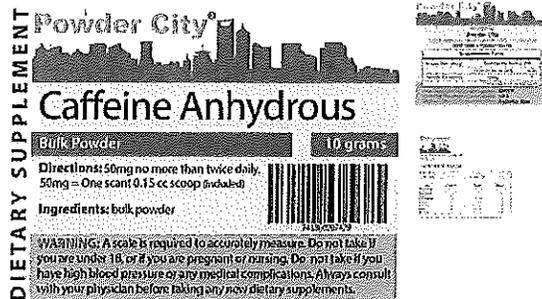
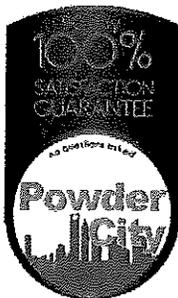
Caffeine Anhydrous Powder

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Health & Wellness

FREE shipping
on orders
over \$25
(US orders only)



Select a Size:

10 Grams - \$1.94

- 1 oz Tub (empty)
- DA-20 Digital Milligram Scale
0.001 G - \$18.83

Caffeine Dose: 50mg**Common Misspellings:** Caffine Powder, Caffiene Powder, Pure Caffeine**Caffeine powder for sale in tubs 100g Caffeine Anhydrous Tub****Goes Well With**

- L-Theanine
- Synephrine
- Milk Thistle

WARNING: Please follow dosage directions on the product label when supplementing with caffeine anhydrous.

Being sleepy, drowsy, cloudy, dopey, tired, and/or drained is simply not fun. That's why coffee and tea is consumed in such large quantities all over the world.

The reason caffeinated beverages are such popular remedies to combat fatigue are that they simply work so efficiently. While most people consider caffeine something that they get in their java, Caffeine Anhydrous is a suitable alternative which provides the added benefits of enhanced effectiveness and accurate tracking of your caffeine dose.[1]

What is Caffeine Anhydrous?

Caffeine is the energizing compound found in things like coffee, tea, and soft drinks, but Caffeine Anhydrous is a form of caffeine found to be much more effective at improving mental and athletic capabilities.[1]

This central nervous system stimulant has many sought after effects such as increased alertness, decreased fatigue, and improved performance under the eroding effects of sleep deprivation and boredom.[2]

Caffeine Anhydrous also improve sports and athletic functions.[1] A considerable ergogenic, caffeine improves athletic performance during both long-term endurance trials and short heats.[1]

How Does Anhydrous Caffeine Work?

Caffeine Anhydrous is a quickly absorbed molecule that efficiently transports throughout the body.[1] Caffeine levels begin to rise as quickly as fifteen minutes after ingestion and don't reach their peak until forty-five minutes later. It has no trouble passing the blood-brain barrier due to its lipid solubility, making it highly effective.[1]

Pure Caffeine Anhydrous Powder Benefits

Caffeine's role as an athletic boost is due to its wide array of mechanisms. It reduces