FDA Update: Adulterated and Illegal – FDA's New Guidance on Highly Concentrated Caffeine Dietary Supplement Products

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On April 13, 2018, the Food and Drug Administration (FDA or Agency) issued a guidance for industry entitled "Highly Concentrated Caffeine in Dietary Supplements." The guidance was described by FDA as "an important step to better protect consumers from the dangers of highly concentrated and pure caffeine products,[1]" given the high risk of these products being "erroneously used at excessive, potentially dangerous doses.[2] " To date, these products have been linked to at least two deaths in the United States, and while FDA has previously issued warning letters[3] against several distributors and warned the public of concerns, the products continue to present a "significant public health threat.[4] "

As noted by FDA, dietary supplements containing pure or highly concentrated caffeine in both powder and liquid forms are being increasingly marketed to consumers, most often on the internet.[5] The products are often marketed in bulk with up to thousands of servings per container, leaving it up to the consumer to measure out a "safe serving" wherein over-serving can be a toxic or even lethal amount.

For example, just one teaspoon of powdered pure caffeine product can contain approximately 3200 mg (or 3.2 g) of caffeine, or the equivalent to 28 cups of coffee – in other words, two and half times a toxic dose. A half a cup of the representative liquid concentrated caffeine products contains approximately 2,000 mg of caffeine, which is the equivalent to more than twenty typical cups of coffee and is well more than a toxic dose.[6]

In the guidance, FDA addressed two types of products: 1) powdered dietary supplements containing highly concentrated caffeine and 2) liquid dietary supplements containing highly concentrated caffeine. For both types of products, FDA concluded that they are adulterated under Section 402(f)(1)(A) of the Federal, Food, Drug and Cosmetic Act (FD&C Act) because they present a significant risk of injury under the conditions of use recommended in the labeling.

While the packaging for the bulk powder products often recommends that consumers only take 50 to 200 mg of caffeine per occasion, to do so, a consumer must be able to "accurately and precisely measure out a recommended serving in the

range of 1/64 of a teaspoon (50 mg of powder) to 1/16 of a teaspoon (200 mg of powder).[7] " The packaging for the bulk liquid products suggests that consumers use 1 teaspoon or 80 mg of caffeine; however, these products are sold to consumers in packages as large as one gallon.[8] The products are also typically meant to be diluted before being consumed. Thus, in both situations, consumers are placed at a high risk of measuring the wrong dose and ingesting a potentially lethal dose of caffeine.

FDA acknowledged that some products contain a warning statement on their labeling and/or websites, however, the Agency concluded that these products are "sufficiently dangerous that a warning cannot remedy the adulteration.[9]" Moreover, FDA noted that because consumers are familiar with caffeine from coffee or soft drinks, and they have not had safety issues when consuming it in those ways, consumers could "incorrectly assume that they are personally able to disregard a warning statement and safely consume the product without diluting it properly, or without careful attention to the precise measurement and serving recommendations.[10]"

FDA's findings are limited to dietary supplement products containing highly concentrated caffeine and do not apply to other products that contain caffeine such as prescription or over-the-counter drugs, or traditionally caffeinated beverages (e.g., coffee or soft drinks).[11] Moreover, in the guidance, FDA noted that it does not expect to consider the followings types of dietary supplements to be adulterated, assuming they comply with all applicable laws and regulations:

A. Dietary supplements sold in solid dosage forms, such as tablets or capsules that do not provide an excessive amount of caffeine per item. Products in these forms eliminate the need for consumers to accurately measure the appropriate serving.

B. Dietary supplements containing powdered or liquid caffeine (either diluted or undiluted) that are sold in premeasured packets or containers, with each premeasured unit containing an amount of caffeine that is not excessive. Products that are sold in pre-measured quantities eliminate the need for a consumer to measure the appropriate amount.

C. Bulk powdered or liquid caffeine dietary supplement products that have been significantly diluted to low enough concentrations of caffeine, such that a reasonably foreseeable measurement error, misreading of the directions, or misunderstanding about the nature of the product would not normally be expected to lead to toxic or life-threatening symptoms.[12]

Nevertheless, according to the guidance, the Agency intends to carefully review any dietary supplements products that contain potentially dangerous amounts of caffeine in any form. Companies that manufacture, market or distribute dietary supplements that contain highly concentrated caffeine should carefully review the guidance to ensure their products are not considered adulterated by FDA.

A copy of the guidance document can be found here.

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[1]See FDA News Release "FDA takes step to protect consumers against dietary supplements containing dangerously high levels of extremely concentrated or pure caffeine," available at, https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm604485.htm

[2]Id.

[3] On September 1, 2015, the FDA issued warning letters to five distributors of pure powdered caffeine finding that the products were dangerous and presented a significant or unreasonable risk of illness or injury to consumers. In March 2016, FDA issued an additional two warning letters. A link to the warning letters can be found here, https://www.fda.gov/Food/DietarySupplements/ProductsIngredients/ucm460095.htm.

[4] Guidance at 1.

[5]Id. at 2.

[6]Id.

[7]Id. at 3

[8]Id. at 5.

[9]Id. at 3, 5.

[10]Id. at 5

[11] See FDA News Release "FDA takes step to protect consumers against dietary supplements containing dangerously high levels of extremely concentrated or pure caffeine," available at, https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm604485.htm.

[12] Guidance at 7.