

Alerts and Recalls

Generic Name (Trade Name—Company)

April 16, 2018

Highly concentrated caffeine

(Multiple trade names—Multiple companies)

FDA warns of dangers of extremely concentrated or pure caffeine sold in bulk

Uses/Notes

FDA issued [new guidance](#) to clarify that dietary supplements containing pure or highly concentrated caffeine in powder or liquid forms are dangerous and present a significant or unreasonable risk of illness or injury.

In 2015 and 2016, FDA issued warning letters to seven distributors of pure powdered caffeine. Since that time, FDA has continued to see a proliferation of similar products being sold online.

Highly concentrated and pure caffeine, often sold in bulk packages, has been linked to at least two deaths in otherwise healthy individuals.

A one-half cup of highly concentrated liquid caffeine can contain approximately 2,000 mg of caffeine, and just a single teaspoon of a powdered pure caffeine product can contain approximately 3,200 mg of caffeine. This is equivalent to about 20 to 28 cups of coffee, a potentially toxic dose.

The recommended safe serving of highly concentrated or pure caffeine products is often 200 mg of caffeine, which equates to 1/16 of a teaspoon of pure powder or approximately 2.5 teaspoons of a liquid.

When formulated and marketed appropriately, such as in premeasured packets or containers, in solid dosage forms such as tablets or capsules, or when in formulations that are not highly concentrated, caffeine can be a safe ingredient in a dietary supplement

The guidance does not affect other types of products that might also contain caffeine, such as prescription or OTC drugs or conventional foods such as traditionally caffeinated beverages.

Source URL:

<http://aphanet.org/alerts-and-recalls/fda-warns-dangers-extremely-concentrated-or-pure-caffeine-sold-bulk>

APhA DrugInfoLine is an official publication of, and is owned and copyrighted by the American Pharmacists Association, the national professional society of pharmacists. Materials in APhA DrugInfoLine do not necessarily represent the policy, recommendations, or endorsement of APhA. The publisher, authors, editors, reviewers, and contributors have taken care to ensure that information contained in APhA DrugInfoLine is accurate and current; however, they shall have no liability to any person or entity with regard to claims, losses, or damages caused or alleged to be caused, directly or indirectly, by use of any information contained in the publication. All decisions about drug therapy must be based on the independent judgment of the clinician. Copyright © 2000–2011, American Pharmacists Association. All rights reserved.