FDA to Review Inhalable Caffeine

RODRIQUE NGOWI, Associated Press

BOSTON (AP) — U.S. Food and Drug Administration officials plan to investigate whether inhalable caffeine sold in lipstick-sized canisters is safe for consumers and if its manufacturer was right to brand it as a dietary supplement.

AeroShot went on the market late last month in Massachusetts and New York, and it's also available in France. Consumers put one end of the canister in their mouths and breathe in, releasing a fine powder that dissolves almost instantly.

Each grey-and-yellow plastic canister contains B vitamins, plus 100 milligrams of caffeine powder, about the equivalent of the caffeine in a large cup of coffee.

AeroShot inventor, Harvard biomedical engineering professor David Edwards, says the product is safe and doesn't contain taurine and other common additives used to enhance the caffeine effect in energy drinks.

AeroShot didn't require FDA review before hitting the U.S. market because it's sold

as a dietary supplement. But New York's U.S. Sen. Charles Schumer said he met with FDA Commissioner Dr. Margaret Hamburg and she agreed to review the safety and legality of AeroShot.

"I am worried about how a product like this impacts kids and teens, who are particularly vulnerable to overusing a product that allows one to take hit after hit after hit, in rapid succession," Schumer said.

He planned to announce the AeroShot review Sunday.

Tom Hadfield, chief executive of Breathable Foods, which makes AeroShot in France, said in a statement that the company will cooperate fully with the FDA's review to address the issues raised by Schumer and are confident it will conclude that AeroShot is a safe, effective product that complies with FDA regulations.

The company said that when used according to its label, AeroShot provides a safe amount of caffeine and B vitamins and does not contain common additives used to enhance the effect of caffeine in energy drinks.

It said each AeroShot contains B vitamins and 100 milligrams of caffeine, about the equivalent of caffeine in a large cup of coffee, and that AeroShot is not recommended for those under 18 and is not marketed to children.

Meanwhile, an FDA official who was at the meeting confirmed the decision, telling The Associated Press that the review will include a study of the law to determine whether AeroShot qualifies as a dietary supplement. The product will also be tested to figure out whether it's safe for consumption, the official said.

The official spoke on the condition of anonymity because that official was not authorized to discuss the matter.

Schumer pressed the FDA in December to review AeroShot, saying he fears that it will be used as a club drug so that young people can keep going until they drop. He cited incidents that occurred last year when students looking for a quick and cheap buzz began consuming caffeine-packed alcoholic drinks they dubbed "blackout in a can" because of their potency.

Pressure from the senator and others helped persuade the FDA to stop the marketing, distribution and sale of these beverages, including Four Loko.

"We need to make sure that AeroShot does not become the next Four Loko by facilitating dangerous levels of drinking among teenagers and college students," Schumer said in a statement.

Breathable Foods says the product is different from the potent beverages. The company says that it's not targeting anyone under 18 and that AeroShot safely delivers caffeine into the mouth, just like coffee does.

A single unit costs $2.99 at convenience stores, mom-and-pops, and liquor and online stores. The product packaging warns people not to consume more than three AeroShots a day.

"When used in accordance with its label, AeroShot provides a safe shot of caffeine and B vitamins for ingestion," the manufacturer says on its website. "Caffeine has been proven to offer a variety of potential benefits for health to individuals when consumed in moderation, from providing energy to enhancing attention and focus."

AeroShot, the flagship product of Cambridge, Mass.-based Breathable Foods, is the product of a conversation that Edwards had with celebrity French chef Thierry Marks over lunch in the summer of 2007.

The first venture Edwards worked on with Harvard students was the breathable chocolate, called Le Whif. Now he's preparing to promote a product called Le Whaf, which involves putting food and drinks in futuristic-looking glass bowls and turning them into low calorie clouds of flavor.

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