



Written by [Raven Clabough](#) on November 17, 2010

## Energy Drink Company Sidesteps a Potential FDA Ban

Once the United States Food and Drug Administration turned its attention toward energy drinks, energy drink companies like Four Loko feared that a regulatory ban was in the works. While the FDA had not yet declared how they plan to proceed — even though they have been undertaking a review of the products for almost a year — food safety lawyers who previously worked for the FDA warned that a likely option was for the Food and Drug Administration to issue warning letters that declared the drinks to be unsafe, which is often followed by a regulatory ban.



In anticipation of the FDA's actions, the makers of Four Loko, a top-selling energy drink, have decided to [drop caffeine, guarana, and taurine](#) as ingredients from the beverage.

In recent weeks, energy drink companies have been targeted for adding caffeine to alcoholic beverages, a measure that has been contested as unsafe.

According to the [New York Times](#), the FDA's decision to take a stance on the energy drinks follows "reports of young people falling ill or dying after drinking the potent blends of alcohol and caffeine."

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Allegations that the combination of alcohol and caffeine is dangerous have little standing, as minimal research has been conducted on the effects of mixing the two substances. At most, research has found that caffeine tends to exacerbate the effects of alcohol while simultaneously masking its effects.

Nevertheless, the popular Four Loko has been blamed in recent months for a number of deaths, several in Florida, just as the drink has been made readily available to 47 of 50 states. Sold in 23.5-ounce cans and in a variety of flavors, it has an alcohol content of 12 percent and includes as much caffeine as a cup of coffee.

In August, an 18-year-old died in Palm Coast, Florida, after combining Four Loko and diet pills. One month later, a 20-year-old in Tallahassee, Florida accidentally shot himself after drinking several cans of Four Loko.

In Philadelphia, a 19-year-old male student arrived at Temple University complaining of chest pains and shortness of breath. Doctors later determined that he had suffered a heart attack, but could not determine the cause. After the young man revealed he had spent the night drinking Four Loko, Dr. Robert McNamara decided that the energy drinks were the culprit. "We've seen this with cocaine and speed and other stimulants, but not with an alcoholic drink," he observed. "Our advice when he left the hospital was, 'Don't ever drink Four Loko again.'"

Four Loko seems to have found a niche on college campuses. A junior at the University of California admits that she attended a party where the theme was "Edward Four Loko Hands." Guests at the party had cans of Four Loko taped to each hand.



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In anticipation of a potential ban of the Four Loko drinks, college students were said to be stocking up on the beverage. A Facebook page, called "R.I.P. Four Loko" has also been created and currently has 8,500 friends. On the page, a "friend" posted a picture of nearly 20 stacked cans of Four Loko with a caption that reads, "Stock up."

Maker of Four Loko, Phusion Projects, defends the energy drinks by asserting that they are the equivalent of following a few glasses of wine with a cup of coffee.

"We have repeatedly contended — and still believe, as do many people throughout the country — that the combination of alcohol and caffeine is safe. If it were unsafe, popular drinks like rum and colas or Irish coffees that have been consumed safely and responsibly for years would face the same scrutiny that our products have recently faced," asserts the company.

Dr. Mary Claire O'Brien, professor of emergency medicine at Wake Forest University, disagrees. "There's a particular interaction that goes on in the brain when they are consumed simultaneously. The addition of caffeine impairs the ability of the drinker to tell when they're drunk. What is the level at which it becomes dangerous? We don't know that, and until we can figure it out, the answer is that no level is safe," she claims.

Likewise, food safety experts assert that the length of the FDA review reveals the complexity of the alcohol/caffeine interactions.

Ricardo Carvajal, former associate counsel at the FDA, remarks, "It suggests this is turning out to be a difficult issue for them to get a handle on."

As a result of the uncertainty as well as the death reports, "State and federal regulators have been pressured to address the matter. Several states have moved to ban the drinks on their own, and this weekend New York's largest beer distributors agreed to stop delivering caffeinated alcoholic beverages to retailers by Dec. 10," the *New York Times* writes.

*The Times* adds, "Some state officials, meanwhile, have criticized the F.D.A. for not completing its review sooner."

Democratic Senator-elect Richard Blumenthal of Connecticut — who, as the state's Attorney General, has led a campaign against the energy drinks — has articulated such sentiments: "To be very blunt, there's just no excuse for the delay in applying standards that clearly should bar this kind of witch's brew."

The FDA remained silent on how they planned to proceed. Spokeswoman Beth Martino states, "We're taking a careful and thorough look at the science and the safety of these products."

Marc Scheineson, a former associate commissioner of the FDA explained that as a "last resort," the agency would seize the beverages and ask for a court order that would mandate that the manufacturers discontinue production of the drinks.

As a result, Phusion Projects announced yesterday that they would change their energy drinks to remove the alleged "harmful" ingredients.

The company explained, "We are taking this step after trying — unsuccessfully — to navigate a difficult and politically charged regulatory environment at both the state and federal levels."

It is likely in the company's best interest that it took the proactive step, as New York's Democratic Senator Charles Schumer announced yesterday that the FDA would rule caffeine to be "an unsafe food



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additive” to alcoholic beverages and that the Federal Trade Commission would charge the companies producing the products with marketing unsafe products.

The FDA did not confirm Schumer’s statements to be true.

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