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Too Loko? Safety of Caffeinated Alcoholic Beverages Comes into Question

FDA Issues Warning Letters to Manufacturers of Popular Products Four Loko and Joose

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John J. Richardson

On November 18, 2010, the Food and Drug Administration (FDA) issued Warning Letters to Phusion Projects, LLC (Phusion), United Brands Company, Inc. (United), Charge Beverages Corporation (Charge), and New Century Brewing Company, LLC (New Century Brewing), alerting the companies that their pre-packaged caffeinated alcoholic products are adulterated beverages in violation of § 402(a)(2)(C) of the Federal Food Drug and Cosmetic Act (the Act).

In recent months, these beverages have come under intense scrutiny from the media and legislators at the local, state and federal levels of government because of the cheap and allegedly dangerous high that detractors say they provide to college students and young adults. Sold in attractive, single-serve cans and available in a variety of fruity flavors, these products mix caffeine and up to 12% alcohol by volume, or the alcoholic equivalent of four to five cans of beer, per serving package. Although not new to the market (MillerCoors and Anheuser-Busch previously pulled similar products in 2008 after pressure from state governments), efforts to ban these products increased again this fall after Phusion Projects' popular Four Loko product was implicated in a number of recent accidents and the deaths of at least five individuals, four of whom were under the legal drinking age of 21.

As concerns about the dangerous effects of combining caffeine with alcohol grew, the affected manufacturers attempted to quell the negative publicity that their products were receiving by claiming that they were no different than typical drinks served at bars, such as Red Bull and vodkas or rum and colas. Phusion also pointed out that flavored alcoholic beverages already exist on the market in the form of bubblegum, raspberry and blueberry vodkas, all of which contain several times the alcohol by volume of a can of Four Loko. Likewise, United maintained that its "Joose" product contains only half the caffeine quantity of a Red Bull or Monster energy drink, and less caffeine per ounce than found in a can of carbonated cola. Additionally, both Phusion and United cited aggressive "responsible drinking policies" aimed at promoting safe and legal consumption of their products to retailers and consumers alike.

Officials countered by claiming that the combination of the companies' extreme marketing campaigns, attractive packaging, fruity flavors, and low prices (Four Loko sells for approximately $2.50 per can) make the products overly attractive to young, inexperienced, and potentially underage drinkers. A number of colleges and universities across the nation warned their students to avoid the products. Several states, including Washington, Utah, Michigan, Oregon and New York, went a step further by banning the products outright, citing concerns that the products are marketed specifically to young adults and college students, who they claim are especially susceptible to the adverse health effects associated with consumption of the products. Meanwhile, federal government officials, led by Senator Charles E. Schumer (D-NY) began pushing for a national ban on the products, which Schumer referred to as "toxic brews."

The FDA began the process of instituting a ban by issuing Warning Letters to the four companies, citing

violations of the Federal Food, Drug and Cosmetic Act. Specifically, the agency found that the direct, purposeful addition of caffeine into alcoholic beverages violated § 402(a)(2)(C)'s prohibition against the manufacture and production of adulterated food products, or those containing unsafe food additives. Under § 409 of the Act, a food additive is considered to be unsafe unless it is the subject of prior approval, has generally been recognized as safe (GRAS) by a consensus of qualified experts, or a regulation is in effect that prescribes the conditions under which the additive may be safely used. According to the Warning Letters, the FDA was not aware of any information to establish that caffeine added directly to alcoholic beverages is the subject of a prior sanction or that it had been generally recognized as safe. Similarly, there is no regulation in effect authorizing the use of caffeine as a direct addition to alcoholic beverages.

While Warning Letters do not constitute official agency action nor require responsive action on the part of affected companies or individuals, they are generally seen as an integral part of the process to remove dangerous products from the market. The FDA issues Warning Letters to provide notice of alleged violations of the Federal Food, Drug and Cosmetic Act with the expectation that affected companies will take voluntary action to correct any alleged violations. The FDA also uses the Warning Letter as its chief means of establishing prior notice of such violations, and will later cite to receipt of a Warning Letter to enhance its position in enforcement actions taken against companies who do not take prompt steps to come into compliance with the violations outlined in Warning Letters. Under the Act, such companies face the risk of subjecting themselves to punishment such as product seizure or court ordered injunctions against future manufacture of the product.

In response to the Warning Letters, all four companies took the steps necessary to avoid any such enforcement action by the FDA. Phusion and United informed the agency that they had ceased shipping their caffeinated alcoholic beverages and expected to have remaining products off retail shelves by December 13, 2010. While New Century has argued that its product was unfairly included in the FDA's crackdown, it too has ceased manufacture for the time being. Charge also advised the FDA that it had ceased manufacture of its affected products. Interestingly, Phusion has begun to manufacture new versions of its product without caffeine, while Charge has continued to market its already existing non-caffeinated alcoholic beverages.

While it may seem that the Letters were a knee-jerk reaction by the FDA to the pressures created by the national attention given to the issue, the Warning Letters were actually the culmination of a nearly year-long agency investigation into the safety of caffeinated alcoholic beverages. The FDA had sent letters to the four companies, along with more than 20 other manufacturers of similar products on November 12, 2009, directing them that the agency would take action to remove the products from the marketplace unless the companies could provide evidence that the products were either subject to prior approval or had been generally recognized as safe.

Although Phusion, United and New Century responded to the initial agency letter, the FDA pressed forward with the issuance of the Warning Letters, maintaining that it still had serious safety concerns about the addition of caffeine into alcoholic beverages. While the FDA noted that the companies had attempted to undermine the reliability of some of the studies into the safety of caffeine added directly to alcohol, the agency maintained that the doubt raised by the studies as a whole was sufficient to raise legitimate safety concerns to which the agency response was necessary.

The FDA also acknowledged that all four companies had applied for and received a Certification/Exemption of Label/Bottle Approval from the Alcohol and Tobacco Tax Bureau (TTB), and in their applications had informed the TTB that their products would contain caffeine. Such approvals, however, do not absolve the companies of their responsibility to comply with the provisions of the Food, Drug and Cosmetic Act.

While the Warning Letters do raise the possibility of future research being necessary in order to fully understand the negative consequences of the addition of caffeine to alcoholic beverages, compliance with the agency's interpretation of the Act provides the companies with time to determine whether it is fiscally advisable and/or responsible to participate in such research. Compliance also gives the companies the opportunity to determine whether they can remain economically successful and viable through the sale and

marketing of non-caffeinated alcoholic beverages, which could render participation in future research unnecessary.

As evidenced by the issuance of the initial letters in November 2009 and the follow-up Warning Letters issued in November 2010, it is FDA policy to work with affected individuals and companies to allow them to bring their products into compliance with the Act. Therefore, when notified by the FDA of potential violations of the Act, it is advisable for the affected industry to engage either inside or outside counsel in order to formulate a timely and effective plan for responding to FDA communications.

The myriad of legal and public relations issues presented by this matter may seem overwhelming. Not only must the affected companies deal with federal regulatory compliance issues and negative media attention, Phusion has been named in a number of recent lawsuits which claim that the caffeine in their products desensitizes drinkers to the symptoms of intoxication, thus increasing the possibility of physical injuries and death.

Companies faced with impending and/or potential enforcement action from Federal agencies should consult counsel experienced in dealing with regulatory compliance issues. Action taken by federal agencies increases public awareness of the issue and attracts the attention of the plaintiff's bar, increasing the likelihood of future lawsuits. Accordingly, such counsel should also be familiar with and prepared to defend complex product liability suits.

In dealing with alleged violations of federal regulatory laws, affected industry must take prompt and effective remedial and preventive action. Not only is such action crucial to the continued success and viability of the affected companies, it demonstrates to the responsible agencies that the companies are taking their obligations to comply with applicable federal law seriously. Affected companies and individuals should be aware that changes in company policy and/or practice may be necessary in order to avoid further enforcement action and to ensure future compliance. Companies should not be deterred from making such changes because of the potential negative implications that such changes could have on the defense of pending and potential lawsuits. Due to public policy considerations, evidence of voluntary, subsequent remedial measures, such as the responsive action taken by Phusion, United, Charge and New Century, is generally not admissible in litigation to prove negligence or culpable conduct.

Specific to this issue, the affected companies may want to examine the feasibility of participating in future research and/or studies to determine whether caffeine may be safely added to alcoholic beverages. However, the companies will want to ensure that communications and debate with the FDA regarding such research be relevant, on point, and supported by scientific research and studies that have been conducted or endorsed by well-qualified and knowledgeable experts.

Conclusion

Companies who become subject to FDA investigations should not attempt to deal with the agency on their own. Because of the complex nature of the legal and public relations issues involved, the assistance of counsel experienced in handling regulatory compliance issues and products liability cases is highly advisable in order to ensure that affected companies and individuals are taking proper remedial and responsive action to minimize the negative effects that such cases can have on a company's continued commercial success and viability.

Nicholas Godfrey assisted the author with the article. Godfrey is a student at Duquesne University School of Law and is currently serving a legal internship in Dinsmore & Shohl's Pittsburgh office.