



UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

Bureau of Consumer Protection
Division of Advertising Practices

November 17, 2010

Via Electronic Mail

Andrew J. Strenio, Jr.
Sidley Austin LLP
1501 K Street, N.W.
Washington, D.C. 20005

RE: NOTICE OF POTENTIALLY ILLEGAL MARKETING OF CAFFEINATED
ALCOHOL PRODUCTS

Dear Mr. Strenio:

Your client, Phusion Products LLC (“Phusion”), markets and sells Four Loko and Four Maxed, alcohol beverages containing caffeine directly added as a separate ingredient. Four Loko, a carbonated malt beverage that comes in several fruity flavors, is sold in 23.5 fluid ounce cans containing 11% to 13% alcohol by volume (depending on the state), plus added caffeine, taurine, and guarana. Thus, one can of this product contains the same alcohol content as four regular or five light beers. Four Maxed, also a carbonated malt beverage with added caffeine that comes in fruity flavors, is sold in 16 fluid ounce cans containing 10% alcohol by volume (equivalent to about three regular beers). These products sell for less than \$3.00 a can. This letter serves to advise Phusion that its marketing and sale of Four Loko and Four Maxed may constitute an unfair or deceptive act or practice in violation of the Federal Trade Commission Act, 15 U.S.C. § 45.¹

Consumer safety is among the highest priorities of the Federal Trade Commission (“FTC”). Safety concerns have, in the past, contributed to the Commission’s decision to take action against alcohol marketers.² We are aware of a number of recent incidents suggesting that

¹ The Federal Trade Commission enforces the Federal Trade Commission Act, which, among other things, prohibits unfair or deceptive acts or practices in or affecting commerce, *id.*, and the false advertising of food, drugs, devices, services, or cosmetics, 15 U.S.C. § 52. The Food and Drug Administration is responsible, among other things, for ensuring that any food, drug, device, or cosmetic is not adulterated, misbranded, or otherwise improperly labeled. *See generally* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 321 *et seq.*

² *See, e.g., Constellation Brands, Inc.*, FTC Docket No. C-4266 (Oct. 2, 2009) (deceptive alertness claims for caffeinated alcohol), available at <http://www.ftc.gov/os/caselist/0923035/index.shtm>; *Beck’s North America, Inc.*, 127 F.T.C. 379 (1999) (unfair depiction of drinking while engaged in dangerous activity); *Canandaigua Wine Co.*, 114 F.T.C. 349 (1991) (deceptive alcohol content claim).

alcohol containing added caffeine may present unusual risks to health and safety.³ These incidents suggest that consumers, particularly young adults, may not fully appreciate the potential effects of consuming caffeinated alcohol beverages such as Four Loko and Four Maxed.

We have further been advised that the Food and Drug Administration (“FDA”) has warned you that caffeine, as used in your product, Four Loko, is an “unsafe food additive” under the Federal Food, Drug, and Cosmetic Act.⁴ As a result, this product is deemed adulterated.

The FDA’s warning that caffeine is an “unsafe food additive,” as used in Four Loko, is a relevant consideration in the FTC’s analysis of whether the marketing of caffeinated alcohol products such as Four Loko and Four Maxed is deceptive or unfair under the Federal Trade

³ Over the past several months, consumers in at least four states have been hospitalized following consumption of caffeinated alcohol. *See, e.g.*, Press Release, Office of the Honorable Charles E. Schumer, Schumer Calls on New York State to Immediately Ban Sales of Dangerous Caffeinated Alcoholic Beverages Like Four Loko, Nov. 10, 2010, available at <http://schumer.senate.gov/record.cfm?id=328504&> (describing a 17-year-old female from New York who experienced fatal cardiac arrest after drinking caffeinated alcohol); Jack Broom, AG Wants to Ban Drink That Hospitalized CWU Students, Seattle Times, Oct. 25, 2010, available at <http://seattletimes.nwsourc.com/html/localnews/2013255746cwustudents26m.html> (reporting that nine Washington State students were hospitalized with high blood alcohol levels after drinking caffeinated alcohol); Associated Press, Ramapo College President Pushes for Legislation Banning Caffeinated Alcoholic Drinks, New Jersey Real-Time News, Oct. 19, 2010, available at http://www.nj.com/news/index.ssf/2010/10/ramapo_college_president_push.html (reporting on hospitalization of intoxicated students in New Jersey); Cindy Stauffer, Physicians Warn of Alcohol Energy Drink, Lancaster Online.com, Oct. 26, 2010, available at <http://articles.lancasteronline.com/local/4/298250> (reporting that medical personnel in Pennsylvania have witnessed a significant increase in need for emergency treatment due to caffeinated alcohol consumption); Clayton Sandell & Lynne Guey, Doctors: Alcohol-Caffeine Drinks Post Health Risk to College-Age Fans, abcNEWS/Health, Oct. 20, 2010, available at <http://abcnews.go.com/Health/MindMoodNews/high-alcohol-high-caffeine-drinks-pose-health-danger/story?id=11928034> (reporting that a 19-year-old Pennsylvanian suffered a heart attack following consumption of caffeinated alcohol); CBS News New York, Doc: It’s Crazy Kids Can Buy Four Loko Energy Drink, Aug. 26, 2010, available at <http://newyork.cbslocal.com/2010/08/26/doc-its-crazy-kids-can-buy-four-loko-energy-drink/> (reporting that emergency room doctors in a New York area hospital treated three teenagers who had consumed caffeinated alcohol).

⁴ *See* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 348(a), 342(a)(2)(C).

Commission Act.⁵ In the past, the FTC has accorded significant weight to FDA findings regarding product safety and efficacy.⁶

The FTC staff therefore strongly urges you to take swift and appropriate steps to protect consumers. Even in the absence of express safety claims, the very act of offering goods for sale creates an implied representation that the goods are reasonably fit for their intended uses and free of gross safety hazards.⁷ In addition, the non-disclosure of rare but serious safety risks may constitute an unfair practice.⁸

⁵ See, e.g., *FTC v. Elec. Prods. Distrib., L.L.C.*, No. 02CV888H (AJB) (S.D. Cal. Apr. 22, 2005) (challenging safety claims, noting FDA warnings); *FTC v. Western Botanicals, Inc.*, No. S-01-1332 DFL GGH (E.D. Cal. July 11, 2001) (banning the marketing of products containing comfrey following issuance of an FDA letter to industry); *FTC v. Christopher Enter., Inc.*, No. 2:01 CV-0505ST (D. Utah Nov. 29, 2001) (same); *Formor, Inc.*, 132 F.T.C. 72 (2001) (challenging advertising for products containing St. John's Wort; accompanying Analysis to Aid Public Comment, available at <http://www.ftc.gov/os/2001/06/formoranalysis.htm>, noting discussions with FDA); *Robert C. Spencer*, 132 F.T.C. 174 (2001) (challenging advertising for colloidal silver products; accompanying Analysis to Aid Public Comment, available at <http://www.ftc.gov/os/2001/06/aaronanalysis.htm>, noting discussions with FDA).

⁶ See *Thompson Med. Co.*, 104 F.T.C. 648, 825-27 (1984), *aff'd*, 791 F.2d 189 (D.C. Cir. 1986); see also *Simeon Mgmt. Corp. v. FTC*, 579 F.2d 1137, 1146 n.10 (9th Cir. 1978) (ruling that an FDA finding that a product is not safe and effective may be material information, the omission of which could cause an advertisement to be deceptive); *FTC v. Trudeau*, No. 1-03 CV-03904 (N.D. Ill. Nov. 16, 2007) (citing FDA finding on safety and efficacy).

⁷ *Figgie Int'l, Inc.*, 107 F.T.C. 313, 379 n.17 (1986), *aff'd as mod.*, 994 F.2d 595 (1993); *Int'l Harvester Co.*, 104 F.T.C. 949, 1058-59 (1984) (holding that failure to disclose safety risk from tractor fuel geysering was unfair and articulating alternative theories of liability).

⁸ See *Int'l Harvester Co.*, 104 F.T.C. at 1064.

Andrew J. Strenio, Jr.

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Please notify Janet M. Evans, jevans@ftc.gov, 202.326.2125, and Carolyn L. Hann, chann@ftc.gov, 202.326.2745, in writing, within 15 days, of the specific actions you have taken to address our concerns. You may contact Ms. Evans and Ms. Hann by email or, alternatively, by mail:

Janet M. Evans
Carolyn L. Hann
Federal Trade Commission - Division of Advertising Practices
600 Pennsylvania Ave., NW, Mail Drop NJ-3212
Washington, D.C. 20580

Very truly yours,

Mary K. Engle
Associate Director
Division of Advertising Practices