

## 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
Ms. Rhonda Kallman
New Century Brewing Company, LLC
P.O. Box 163
Boston, MA 02128

RE: NOTICE OF POTENTIALLY ILLEGAL MARKETING OF CAFFEINATED ALCOHOL PRODUCTS

Dear Ms. Kallman:

Your client, New Century Brewing Company ("New Century"), markets and sells Moonshot, an alcohol beverage containing caffeine directly added as a separate ingredient. Moonshot, a malt beverage, is sold in 12 fluid ounce bottles containing 5 % alcohol by volume, plus added caffeine. The product sells for less than \$3.00 a bottle. This letter serves to advise you that New Century's marketing and sale of Moonshot 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.<sup>2</sup> We are aware of a number of recent incidents suggesting that alcohol containing added caffeine may present unusual risks to health and safety.<sup>3</sup> These

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.* 

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).

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

incidents suggest that consumers, particularly young adults, may not fully appreciate the potential effects of consuming caffeinated alcohol beverages such as Moonshot.

We have further been advised that the Food and Drug Administration ("FDA") has warned you that caffeine, as used in your product, Moonshot, is an "unsafe food additive" under the Federal Food, Drug, and Cosmetic Act.<sup>4</sup> As a result, your product is deemed adulterated.

The FDA's warning that caffeine is an "unsafe food additive," as used in Moonshot, is a relevant consideration in the FTC's analysis of whether the marketing of caffeinated alcohol products such as Moonshot is deceptive or unfair under the Federal Trade Commission Act.<sup>5</sup> In

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.nwsource.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 pushe.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-d anger/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).

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

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

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the past, the FTC has accorded significant weight to FDA findings regarding product safety and efficacy.<sup>6</sup>

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. In addition, the non-disclosure of rare but serious safety risks may constitute an unfair practice. But the protect of the prote

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

http://www.ftc.gov/os/2001/06/aaronanalysis.htm, noting discussions with FDA).

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).

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).

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