



February 28, 2008

Mr. Tom Long
President and Chief Executive Officer
Miller Brewing Company
3939 West Highland Boulevard
Milwaukee WI 53201-0482

Dear Mr. Long:

The Center for Science in the Public Interest (“CSPI”) intends to file a lawsuit against Miller Brewing Corporation (“Miller”), the manufacturer of Sparks Original, Sparks Plus, and Sparks Light (collectively “Sparks”). The lawsuit will allege that Sparks is an adulterated product and that Miller engages in acts and practices that are both unfair and deceptive with respect to the marketing and sale of Sparks. This letter details Miller’s illegal practices and offers settlement before CSPI files a lawsuit.

CSPI will seek an injunction prohibiting Miller from manufacturing and offering for sale any alcoholic beverage that contains caffeine, guarana, or any other stimulant, or taurine, ginseng, or any other ingredient that is not generally recognized as safe for use in alcoholic beverages. CSPI will also seek an injunction prohibiting Miller from (1) representing that Sparks products or the ingredients in the products give the consumer energy or counteract the effects of alcohol, or (2) making any other misleading statements. CSPI also may seek restitution, damages, disgorgement, and attorneys’ fees.

Facts Giving Rise to Liability of Miller

Alcoholic beverages, including the entire Sparks product line, that are pre-mixed with the stimulants caffeine and guarana and with other substances (such as taurine and ginseng) are of unique concern. The harm to consumers is multiple:

- 1) No studies ensure the safety of – and new evidence demonstrates the risk of – consuming stimulants and alcohol together;
- 2) None of these ingredients has been approved by the FDA as Generally Recognized as Safe (GRAS) for use in alcoholic beverages.
- 3) Miller promotes taurine and ginseng for their stimulant effect, when in fact there is no adequate substantiation that either has a stimulant effect.
- 4) There is a physiological effect – and marketing message – that consuming alcohol and caffeine together allows one to drink more alcohol without feeling as intoxicated as would otherwise be the case.

This last effect is the most dangerous — the presence of the stimulants may lead drinkers to engage in risky behavior such as driving, because they do not feel drunk, even though their behavior/skills might be degraded. A study on the interaction be-

tween alcohol and energy drinks found that stimulants did nothing to reduce alcohol's negative effects on motor coordination skills and visual reaction times, but did reduce subjective perception of alcohol intoxication.¹

Last August, a task force of 30 state attorneys general wrote a letter to the Alcohol and Tobacco Tax and Trade Bureau (TTB) expressing serious concerns about the marketing of alcoholic energy drinks. In addition to the grave statistics about youth and alcohol in general,² including the approximation that 5,000 people under the age of 21 die each year from alcohol-related injuries,³ the AGs in the Task Force highlighted their concerns about youth and alcoholic energy drinks. The letter warned that “[a]dding caffeine and other stimulants to alcohol may increase the risk to young consumers because those additives tend to reduce the perception of intoxication and make greater quantities of alcohol palatable.”⁴

Most disturbing, theoretical concerns are becoming manifest as actual problems. A recent study of thousands of college students found that the students who drank alcohol mixed with energy drinks were more likely to experience alcohol-related consequences than were those students who drank only alcohol.⁵ It found students who drank alcohol mixed with energy drinks were twice as likely as students who drank only alcohol to ride with a driver under the influence; get hurt or injured; require medical treatment; take advantage of another person sexually; or be taken advantage of sexually.⁶

Miller's website has this to say about its Sparks portfolio:

Sparks created the caffeinated malt beverage segment. . . . Everything from its packaging, to point-of-sale signage, to its name echoes the brand's high-fun positioning. Event sponsorship, on-premise sampling, and viral campaigns are a part of the brand's discovery marketing model, helping to

¹ Sionaldo Eduardo Ferreira, et al., *Effects of Energy Drink Ingestion on Alcohol Intoxication*, 30 ALCOHOLISM: CLINICAL AND EXPERIMENTAL RES. 598 (April 2006).

² As the AG letter to TTB advised, alcohol is the top drug problem of American youth and is involved in the three leading causes of teen death: car accidents, homicides, and suicides. Letter from Attorneys General to the Alcohol and Tobacco Tax and Trade Bureau 2 (Aug. 20, 2007), available at www.marininstitute.org/alcopops/resources/TTB_Letter_Final_Sigs_08172007.pdf.

³ OFFICE OF THE SURGEON GEN., U.S. DEP'T OF HEALTH AND HUMAN SERV., THE SURGEON GENERAL'S CALL TO ACTION TO PREVENT AND REDUCE UNDERAGE DRINKING 10-12 (U.S. Dep't of Health and Human Serv. 2007), available at <http://www.surgeongeneral.gov/topics/underagedrinking/calltoaction.pdf>.

⁴ The AGs in the Task Force are also concerned about alcoholic energy drink's categorization as a malt beverage instead of a distilled spirit, even though alcoholic energy drinks' content of alcohol by volume is significantly greater than that of beer. They wrote: “This classification renders alcoholic energy drinks more readily available to young people, because malt beverages can be purchased in many more places, and at significantly lower prices, than distilled spirits.” Letter from Attorneys General, *supra* note 2.

⁵ Mary Claire O'Brien, et al., Abstract, Caffeinated Cocktails: Get Wired, Get Drunk, Get Injured (Nov. 2007) available at http://apha.confex.com/apha/135am/techprogram/paper_166629.htm.

⁶ Mary Claire O'Brien, et al., Poster, Caffeinated Cocktails: Get Wired, Get Drunk, Get Injured (Nov. 2007), presented at Annual Meeting of the American Public Health Association in Washington, D.C. (Nov. 4, 2007).

extend Sparks irreverent tone while avoiding traditional mainstream marketing.⁷

Miller's viral marketing plan for Sparks is deliberately untraditional to appeal to young consumers. This tactic includes using a chaotic, interactive website (www.sparks.com), which offers a local store and venue locator for the drink. This feature certainly makes it easier for young consumers to pinpoint where to obtain the drink. Also, Miller reportedly gives away Sparks at house parties and other gatherings.⁸ Private gatherings do not have the same level of licensing requirements, strict regulations, or other safety nets that prevent minors from accessing alcohol in public establishments.

Miller's illegal practices

The FDA regulates ingredients added to foods, pursuant to the Federal Food, Drug, and Cosmetic Act (FDCA). In 2001, the FDA issued its "Letter to Manufacturers Regarding Botanicals and Other Novel Ingredients in Conventional Foods."⁹ The Letter provides a good summary of the law relating to food additives:

Many ingredients intentionally added to a conventional food are food additives. Food additives require pre-market approval based on data demonstrating safety submitted to the agency in a food additive petition, ordinarily by the producer. The agency issues food additive regulations specifying the conditions under which an additive has been demonstrated to be safe and, therefore, may be lawfully used.

A substance is exempt from the definition of a food additive and thus, from pre-market approval, if, among other reasons, it is generally recognized as safe (GRAS) by qualified experts under the conditions of intended use. Accordingly, for a particular use of a substance to be GRAS, there must be both technical evidence of safety and a basis to conclude that this evidence is generally known and accepted by qualified experts. The technical element of the GRAS standard requires that the information about the substance establish that the intended use of the substance is safe, i.e., that there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under its intended conditions of use. In addition, the data and information to establish the technical element must be generally available, and there must be a basis to conclude that there is consensus among qualified experts about the safety of the substance for its intended use. Any substance added to food that is an unapproved food additive (e.g., because it is not GRAS for its intended use)

⁷ Miller Brewing Co., *Our Brands*, <http://www.millerbrewing.com/brandsBreweries/brands.asp>, (last visited Feb. 15, 2008).

⁸ Tom Dayki, *Miller's Guerilla Marketing Effort Targets Gen Y*, MILWAUKEE J. SENTINEL, Jan. 1, 2008, available at <http://www.lohud.com/apps/pbcs.dll/article?AID=/20080101/BUSINESS01/801010332>.

⁹ CTR. FOR FOOD SAFETY AND APPLIED NUTRITION, U. S. FOOD AND DRUG ADMIN., LETTER TO MANUFACTURERS REGARDING BOTANICALS AND OTHER NOVEL INGREDIENTS IN CONVENTIONAL FOODS (U.S. Food and Drug Admin. Jan. 30, 2001), available at www.cfsan.fda.gov/~dms/ds-ltr15.html.

causes the food to be adulterated (Section 402(a)(2)(C) of the Act), and the food cannot be legally imported or marketed in the United States.

The FDA is concerned that some of the herbal and other botanical ingredients that are being added to conventional foods may cause the food to be adulterated because these added ingredients are not being used in accordance with an approved food additive regulation and may not be GRAS for their intended use.

CSPI also corresponded on this issue with a top official at the Alcohol and Tobacco Tax and Trade Bureau (TTB), the Treasury Department bureau whose mission is to ensure that alcoholic beverages are labeled, advertised, and marketed in accordance with the law.

The official wrote to CSPI in April 2007, stating that "TTB follows the guidance of FDA who has the authority under Federal Food, Drugs, and Cosmetics Act as outlined in 21 CFR 170.3(n)(2). Per section 409 of the Federal Food, Drugs, and Cosmetics Act, any food additive that is to be added to food must first be approved as Generally Recognized as Safe (GRAS) by the FDA. TTB only allows ingredients that FDA has determined GRAS, for alcohol beverages."

In other words, TTB does not permit Miller to use any ingredient that FDA has not affirmatively determined to be GRAS for use in alcoholic beverages.

FDA has issued food additive regulations for caffeine (21 CFR 182.1180), guarana (21 C.F.R. 172.510), and taurine (21 C.F.R. 573.980). However, the regulation provides for limited use of these food additives.

- Caffeine is only approved as an additive to cola-type beverages in concentrations no greater than 0.02 percent. 21 CFR 182.1180.
- Guarana is only approved as an additive to be used as a flavoring or adjunct, in the minimum quantity required to produce the intended physical or technical flavoring effect. 21 C.F.R. 172.510.
- Taurine is not approved as an additive to human food, but only to chicken feed. 21 C.F.R. 573.980.
- Ginseng is not an approved food additive at all.

In addition, *not a single one of these products has been approved as GRAS* (for alcoholic beverages or any other food or beverage) by the FDA, which the TTB official authoritatively stated must be done before an ingredient is added to an alcoholic beverage.

Because these beverages contain ingredients (caffeine, guarana, taurine, and ginseng) that are neither approved additives for use in alcoholic beverages nor generally recognized as safe for use in alcoholic beverages, these beverages are both "adulterated" and "misbranded" in violation of both the FDCA, and state food and drug laws, such as the California Food, Drug, and Cosmetic Act, California Health and Safety Code § 110660.

We have also concluded that the labeling and marketing efforts for these beverages are both unfair and deceptive under state consumer protections laws such as Massachusetts G.L. c. 93A, Texas Business & Professions Code § 17.41 *et seq.*, District of Columbia Code § 28-3905 *et seq.*, New Jersey Statutes Ann. 56:8-1 *et seq.*, and California Business & Professions Code Section 17200 (jointly, "UDAP" laws).

As the manufacturer and distributor of these beverages, Miller is responsible for the injury caused by its actions. Consumer injury occurs each time a consumer purchases one of these beverages. Each occurrence is a separate injury. E.g., *Aspinall v. Philip Morris Companies, Inc.*, 442 Mass. 381, 813 N.E.2d 476 (Mass. 2004).

Settlement Demand

In light of the foregoing, CSPI demands the following forms of relief to settle this matter at this time before filing suit:

- Entry of a permanent injunction that prohibits Miller from (1) manufacturing and offering for sale any alcoholic beverage that contains caffeine, guarana, taurine, ginseng, or any other ingredient that is not determined by FDA as GRAS for use in alcoholic beverages; (2) including any ingredient that does not serve a functional purpose in the product; (3) representing (either expressly or implicitly) that Sparks products or the ingredients in the products give the consumer energy or counteract the effects of alcohol; and (4) making any other misleading statements.
- Disgorgement by Miller of its profits from the sale of this product from the time it acquired Sparks in 2006 into a *cy pres* fund to be used for charitable purposes.

This offer of settlement will remain open for 30 days from the date of this letter, after which it shall be automatically withdrawn and become null and void.

Please have your own counsel contact CSPI's Litigation Director Stephen Gardner if Miller is willing to discuss settlement or needs additional information about this lawsuit.

Yours truly,



Stephen Gardner
Litigation Director

cc: Michael F. Jacobson, Ph.D.
Executive Director

George Hacker
Alcohol Policy Director

Katherine Campbell
Staff Attorney