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Re: **Demand Letter Concerning the Safety and Marketing of Monster Beverages**

Dear Counsel:

I write to follow-up on your letter, and to explain my office's continuing concerns about the safety and marketing of Monster Energy drinks.

Although we are pleased that Monster Beverage Corp. ("Monster") recently decided to properly label its products as conventional beverages rather than as dietary supplements, we continue to believe that the caffeine levels in Monster fail to comply with the safety requirements for beverages under California and federal law. As discussed further below, the March 19, 2013 letter from eighteen scientists and clinical experts across the country establishes that there is insufficient evidence that the amount of caffeine in Monster Energy drinks is Generally Recognized as Safe ("GRAS") as required by law. The high caffeine levels in Monster are especially troubling given that the product is aggressively marketed to youth and in a manner that encourages over-consumption of the product. For these reasons, the City demands that Monster take immediate steps to reformulate its products to safe caffeine levels, provide adequate warning labels, and cease promoting over-consumption.

I. MISLABELING AS A DIETARY SUPPLEMENT

As explained in our October 31, 2012 letter, Monster was, until recently, mislabeled as a dietary supplement in violation of federal and state law.

As the FDA's draft guidance on factors that distinguish dietary supplements from beverages explains, "a liquid product's name, packaging, serving size, and recommended conditions of use, as well as other representations about the product," determine whether a product is a conventional food or a dietary supplement.¹ Monster's packaging, labeling, serving size, recommended conditions of use, and advertising statements have consistently represented the product as a conventional beverage. Monster is packaged in a 16-ounce pop-top can resembling a soda, as well as a 24-ounce can with a resealable cap resembling other conventional

¹ Federal Food and Drug Administration, Draft Guidance for Industry: Factors that Distinguish Liquid Dietary Supplements from Beverages, Considerations Regarding Novel Ingredients, and Labeling for Beverages and Other Conventional Foods, December 2009.

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beverages on the market. The listed serving size on the can label is 8.0 fl oz or 240 ml, which is similar to recommended serving sizes for many beverages. And statements on the product's labels and website² represent the product as a beverage:

- **Zero Ultra:** Customers have "been asking for a new Monster drink."
- **Tea-Lemonade:** "We need a new drink. One that can do it all: a triple threat the quenches thirst...."
- **Vanilla Light:** Monster is "[m]aking a low calorie coffee + energy drink that tastes good and works...."
- **Green Tea:** "Naturally loaded with EGCG from the green tea, infused with coconut water...Monster Rehab® Green Tea + Energy delivers a triple threat that quenches thirst...."

Additionally, in your October 23, 2012 press release, you referred to "Monster Energy drinks," and around June 5, 2012, Monster Army asked members to indicate their "favorite drinks" on their profile pages.³ While we are pleased that Monster recently decided to correct its mislabeling and label its product as a conventional beverage, we remain troubled by Monster's longstanding practice of selling a mislabeled product.

II. SAFETY OF LEVEL OF ADDED CAFFEINE

As a conventional beverage, Monster Energy is subject to the regulations for food additives under California's Sherman Food, Drug and Cosmetic Law ("Sherman Law"), as well as federal law, which require that Monster's beverages be Generally Recognized As Safe ("GRAS") under the conditions of its intended use. We believe the March 19, 2013 letter signed by 18 scientific experts attached hereto as Exhibit A establishes that Monster's products are not GRAS because there is no scientific consensus concerning the safety of the caffeine levels in the products. Accordingly, Monster's products as currently formulated are adulterated and unlawful for sale under California law.

Under California and federal law, a food additive like caffeine is presumed "unsafe" unless its particular use has been approved by governmental regulations, or it is GRAS under the conditions of its intended use.⁴ To be considered GRAS, there must be "a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use." 21 C.F.R. 170.3(i). The burden is on the manufacturer to prove that (1) an additive is safe for its intended use based on published scientific literature, and (2) there is a consensus of scientific opinion regarding the safety of the use of the substance. 21 C.F.R. §§ 170.3, 170.30. The levels of added caffeine in Monster Energy drinks do not satisfy the GRAS standard. As the 18 distinguished experts concluded in their March 19, 2013 letter:

[T]here is no general consensus among qualified experts that the addition of caffeine in the amounts used in energy drinks is safe under its conditions of intended use as required by the GRAS standard, particularly for vulnerable populations such as adolescents. On the contrary, there is evidence in the

² Monster Energy, <http://www.monsterenergy.com/us/en/products/monster-energy#!/products>

³ See, e.g., Kempsey Alexandre, *Profile*, Monster Army, <http://web.archive.org/web/20120605025656/http://www.monsterarmy.com/members/skaterkay95/>

⁴ See <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/IngredientsAdditivesGRASPackaging/ucm061846.htm>

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published scientific literature that the caffeine levels in energy drinks pose serious potential health risks, including increased risk of serious injury or even death.

Specifically, the scientists found the following risks:

- “The consumption of highly caffeinated energy drinks has been associated with elevated blood pressure, altered heart rates, and severe cardiac events in children and young adults.” Findings from multiple studies “show how acute effects of caffeine administration on heart rate may result in cardiovascular events requiring hospitalization, especially in differentially susceptible and at-risk youth.”
- A number of cases have “been reported of new-onset seizures attributed to energy drink consumption among adolescents and young adults ages 15 to 28.” This age group is also the one which Monster’s advertising heavily targets.
- Energy drinks like Monster “have also been shown to contribute to youth obesity due to their high calorie and sugar content. . . . The American Academy of Pediatrics’ Committee on Nutrition reports findings that the consumption of excessive carbohydrate calories from energy drinks increases risk of pediatric overweight.”
- It is well established that “[y]outh with higher caffeine intake commonly report troubling neurological symptoms, including nervousness and anxiety, jitteriness, dizziness, headache, muscle twitching, and tremors.” These symptoms “may undermine students’ ability to stay on task, focus, and perform well.”
- Energy drinks also pose unique dangers when combined with alcohol. Indeed, the FDA and CDC have concluded that the combination of alcohol and energy drinks is unsafe and poses serious health risks.

The safety concerns are especially great in the context of adolescent consumption. Indeed, the American Academy of Pediatrics recommends that energy drinks should not be a part of the adolescent diet.⁵ Experts have recommended that adolescents should consume no more than 100 mg of caffeine daily, which is less than the amount in a single 16-ounce can of Monster.⁶ A new article in *Pediatrics in Review* concluded that the high levels of caffeine in energy drinks “may lead to significant morbidity in adolescents (cardiovascular effects, withdrawal symptoms, mixing with alcohol, association with substance dependence).”⁷

Energy drinks also pose dangers for athletes. Although Monster’s marketing features extreme sports and athletics, and claims that its product “hydrates like a sports drink,” *Pediatrics in Review* recently concluded:

Cardiovascular effects as a result of heavy caffeine use can be a significant source of morbidity in athletes. Hypertension and palpitations in the adolescent athlete often lead to extensive medical evaluations. The diuretic

⁵ Committee on Nutrition and the Council on Sports Medicine and Fitness, *Sports drinks and energy drinks for children and adolescents: Are they appropriate?* *Pediatrics*. 2011;127(6):1182-1189.

⁶ Seifert *et al.*, *Health Effects of Energy Drinks on Children, Adolescents and Young Adults*, *Pediatrics*, Vol. 127, No. 3, at p. 519 (2011).

⁷ Blankson *et al.*, *Energy Drinks: What Teenagers (and Their Doctors) Should Know*, *Pediatrics in Review* 2013;34:55.

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effect of high levels of caffeine could lead to dehydration in athletes who do not drink enough fluids to compensate.⁸

We have reviewed the studies cited in your letter and they do not establish that the level of added caffeine in your product is GRAS, particularly with respect to consumption by adolescents. Many of the studies cited in your letter analyzed the body's caffeine intake mechanism rather than the potential health consequences posed by the absorption of high quantities of caffeine.⁹ Among those studies that did analyze health consequences, the focus was usually on short-term or behavioral effects.¹⁰ The Chou study, for example, found that coffee had only a small effect on blood pressure, but was also careful to note that this effect may become quite "significant with prolonged exposure."¹¹

Even among the studies cited by your letter, the general consensus is that elevated levels of caffeine consumption can lead to serious health consequences.¹² The study prepared by the Institute of Medicine ("IOM"), "Caffeine for the Sustainment of Military Operations," notes that "[a] number of studies have demonstrated that caffeine consumption produces a transient elevation in blood pressure. . . . Thus, high caffeine intake may be an additional risk factor for hypertension at the individual level due to long-lasting stress or genetic susceptibility to hypertension."¹³

Moreover, the mode of caffeine delivery is an important consideration in determining consumer safety, especially given that drinks such as coffee and tea are served hot and are therefore less likely to be consumed quickly than a chilled beverage such as Monster. The OECD report on which you rely is notable for its admission that most of the studies in this field look only at coffee consumption, rather than the effects of caffeine per se.¹⁴ Indeed, many of the studies upon which you rely did not address energy drinks at all.

Finally, the vast majority of studies cited in your letter discussed adults rather than children or adolescents, whose reactions to caffeine are often more pronounced.¹⁵ Moreover,

⁸ Blankson, *supra* note 7, at 57.

⁹ See, e.g., Maurice Arnaud, *Pharmacokinetics and Metabolism of Natural Methylxanthines in Animal and Man*, 200 *Handbook of Experimental Pharmacology* 33 (2011); European Food Safety Authority, *The Use of Taurine and D-Glucosamine-γ-Lactone As Constituents of the So-Called "Energy" Drinks*, 935 *The EFSA Journal* 1, 1 (2009) [hereinafter EFSA] (noting that the panel did not "evaluate the 'safety' of energy" drinks as such"); Laszlo P. Somogyi, *Caffeine Intake by the US Population*. Silver Spring, MD: Food and Drug Administration (2010).

¹⁰ See, e.g., Tony M. Chou *et al.*, *Caffeine and Coffee: Effects on Health and Cardiovascular Disease*, 109 *Comparative Biochemistry and Physiology* 173 (1994); Judith L. Rapoport *et al.*, *Behavior and Nutrition: A Mini Review*, 51 *J. Dentistry for Children* 451, 453 (1984) (analyzing behavioral effects); Judith L. Rapoport *et al.*, *Behavioral and Autonomic Effects of Caffeine in Normal Boys*, 3 *Dev. Pharmacological Therapy* 74, 74-84 (1984) (also analyzing behavioral effects). Others studies focused only on caffeine's physiological impact only during exercise, which does nothing to establish that Monster's caffeine levels are GRAS for the ordinary consumer. See Erica R. Goldstein *et al.*, *International Society of Sports Nutrition Position Stand: Caffeine and Performance*, 7 *J. of the Int'l Society of Sports Nutrition* 5 (2010).

¹¹ Chou, *supra* note 10, at 178.

¹² Institute of Medicine, *Caffeine for the Sustainment of Mental Task Performance: Formulations for Military Operations* (2001); Organisation for Economic Co-Operation and Development (OECD), *Caffeine*, UNEP Publications (2003).

¹³ Institute of Medicine, *supra* note 12, at 8.

¹⁴ OECD, *supra* note 12, at 14.

¹⁵ Chou, *supra* note 10; see also Institute of Medicine, *supra* note 12, at 3 ("It is important to emphasize that the responses to the questions and recommendations in this report are specific to military operations and are not necessarily applicable to the needs of the civilian population.")

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almost all of the studies cited in your letter suggested that further research would be required before the potential effects of caffeine on youth could be fully understood.¹⁶

For these reasons, the caffeine in Monster does not satisfy the GRAS standard and therefore the beverages are adulterated under California and federal law.¹⁷

III. MISLEADING AND UNFAIR MARKETING PRACTICES

In light of the safety risks discussed above, I am further concerned that Monster markets its products in a manner that is designed to appeal to youth, references alcohol and drug use, encourages over-consumption of the product, and suggests special benefits from its "killer energy brew" that likely do not exist.

A. Youth Targeting

Although you claim that "Monster does not target its marketing to adolescents," our review of Monster's website and use of social media outlets compels a different conclusion. As Monster proudly states on its website and Facebook page, its marketing campaign does not employ traditional media outlets such as television, radio, or print.¹⁸ Instead, Monster relies heavily on social media, as well as event and individual sponsorships, popular with youth to promote its products. The Monster website offers links to Monster's Facebook, Twitter, Youtube, Google Plus, Pinterest, and Instagram pages.

Although Monster's can labeling advises that the product is "not recommended for children," Monster markets its product by promoting a "lifestyle" featuring extreme sports, music, gaming, military-themes, and the scantily clad "Monster Girls," all with particular appeal to teenage boys. The Monster "lifestyle" is described on its Facebook page and website as follows:

At Monster, all our guys walk the walk in action sports, punk rock music, partying, hangin' with the girls, and living life on the edge. Monster is way more than an energy drink. Led by our athletes, musicians, employees, distributors, and fans, Monster is a lifestyle in a can!

This fast, loud, extreme vibe does not appear to be an accident; according to CNN, Monster's name came out of a focus group of teenage boys.¹⁹

Although Monster's can labeling advises that the product is "not recommended for children," our investigation has uncovered numerous instances of Monster marketing its products directly to children and teenagers. As just one example, student athletes at some high schools are awarded the "Monster Energy Drink Player of the Game." As part of that honor, minors are photographed with a pack of Monster Energy in each hand.

¹⁶ Castellanos, et al., *Effects of Caffeine on Development and Behavior in Infancy and Childhood: a Review of the Published Literature*, 40 Food & Chem Toxicology 1235-1242, 1242 (2002); EFSA, *supra* note 9.

¹⁷ In addition to caffeine, we note that Monster also contains other food additives such as taurine, ginseng, and guarana. As food additives, these ingredients also must satisfy the GRAS standard. To our knowledge, there is little scientific evidence on the safety of adding these ingredients at these levels to conventional foods and beverages. Of course, to the extent they do not satisfy the GRAS standard, they would also render Monster's products adulterated.

¹⁸ MONSTER ENERGY: ABOUT, <http://www.facebook.com/MonsterEnergy/info> (last visited Mar. 14, 2013).

¹⁹ Matthew Boyle, *An Energy Drink with a Monster of a Shock*, CNN Money, Dec. 15, 2006, http://money.cnn.com/magazines/fortune/fortune_archive/2006/12/25/8396769/index.htm.

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The company also employs a “Monster Army” social networking site, which encourages users (including minors) to post photos and videos of their extreme sports performances and earn perks—including sponsorships—from the company. Monster’s marketing efforts have paid off. It is well established that Monster is popular with youth and is regularly consumed by that demographic.²⁰ Indeed, the “Monster Energy Music” and “Monster Energy Gaming” Facebook pages are most popular with 13-17 year-olds.²¹

B. Alcohol and Drug References

Particularly in light of its popularity among teenagers, it is irresponsible for Monster to market its drinks in a manner that references alcohol and drug use. As you know, energy drinks pose unique dangers when combined with alcohol. Indeed, the FDA and CDC have concluded that the combination of alcohol and energy drinks is unsafe and poses serious health risks.²² This conclusion was based on the agencies’ review of the published scientific literature, which found that the combination of caffeine and alcohol is associated with risky behaviors that may lead to hazardous and life-threatening situations. Because individuals who consume energy drinks with alcohol underestimate their true level of alcohol-related impairment (*i.e.*, a “wide-awake drunk”), the bulk of scientific evidence suggests that individuals who combine energy drinks with alcohol are more likely to engage in risky behavior than if they were only consuming alcohol. As the FDA and CDC’s statements make clear, the safety concerns identified in the scientific literature are not limited to premixed alcoholic energy drinks, but apply equally to the mixing of alcohol with energy drinks.

²⁰ Blankson, *supra* note 7; Pennington *et al.*, *Energy drinks: A new health hazard for adolescents*, *J Sch Nurs*, 2010;26(5):352-359; Seifert *et al.*, *supra* note 6; Somogyi, *supra* note 9.

²¹ MONSTER ENERGY, www.facebook.com/monsterenergy (last visited Mar. 14, 2013).

²² Food and Drug Administration. Warning letter to Phusion Projects Inc. College Park, MD; Food and Drug Administration: 2010; Centers for Disease Control and Prevention. Fact sheets: Caffeinated alcoholic beverages. Atlanta, GA: Centers for Disease Control and Prevention: 2010.

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Despite these dangers, Monster uses drug- and alcohol-references to describe its beverages, which implicitly encourages the mixing of Monster's products with drugs and alcohol, not to mention underage drinking and drug use. In light of Monster's marketing to persons under the legal drinking age, promoting Monster with references to alcohol is an irresponsible and unfair business practice.

C. Overconsumption

Despite the safety risks posed by the high levels of caffeine in its products, Monster's advertising and labeling fails to adequately warn consumers of the risks, and instead encourages overconsumption and rapid consumption of its drinks.

Although Monster's label states in small print that consumers should drink no more than two or three cans per day, its marketing sends a different message altogether. Monster states that "bigger is always better" and "you can never get too much of a good thing." Monster urges consumers to "chug it down," or "throw [it] back." Monster states that its product has a "smooth flavor you can really pound down," and that one of its products has "the biggest chugger friendly wide mouth we could make." Such statements fly in the face of any notion that Monster encourages consumers to exercise restraint in the speed or volume of consumption, or that overconsumption may be unsafe.

And even Monster's warning label suggests a level of consumption that has not been demonstrated to be safe. Monster's labeling recommends that individuals consume no more than three 16 oz. cans or two 24 oz. cans per day, which amounts to a total of 48 oz. of Monster per day. But 48 oz. of Monster contains 480 mg of caffeine, nearly *five times* the caffeine limit recommended for adolescents in an entire day, and more than the 400 mg per day the FDA has indicated is safe for healthy adults.²³

D. Special Benefits of "Killer Energy Brew"

Finally, Monster's marketing also includes unsubstantiated claims about the purported special benefits of its "killer" ingredients and "energy blend," such as boosting energy and enhancing physical performance, particularly athletic performance.

However, recent scientific studies show that there is little if any evidence to support the claim that, apart from caffeine, Monster's other ingredients such as taurine, guarana, ginseng, glucuronolactone, and B-vitamins have benefit for consumers. The International Society of Sports Nutrition recently issued a position paper on the efficacy of energy drinks, and concluded that:

Although [energy drinks] and [energy shots] contain a number of nutrients that are purported to affect mental and/or physical performance, the primary ergogenic nutrients in most [energy drinks] and [energy shots] appear to be carbohydrate and/or caffeine. The ergogenic value of caffeine on mental and physical performance has been well-established but the potential additive benefits of other nutrients contained in [energy drinks] and [energy shots] remains to be determined.²⁴

Another recent study published in *Nutrition Reviews* concluded that "[w]ith the exception of some weak evidence for glucose and guaraná extract, there is an overwhelming lack

²³ Letter from Jeanne Ireland, Assistant Comm'r for Legislation, Food and Drug Admin., to Hon. Richard J. Durbin, U.S. Senate (Aug. 10, 2012).

²⁴ Campbell *et al.*, *International Society of Sports Nutrition position stand: energy drinks*, *Journal of the International Society of Sports Nutrition* 2013, 10:1.

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of evidence to substantiate claims that components of EDs, other than caffeine, contribute to the enhancement of physical or cognitive performance.”²⁵ Another study soon to be published in the *Journal of Strength and Conditioning Research* similarly concludes that the secondary ingredients (i.e., non-caffeine ingredients) in energy drinks do not augment aerobic metabolism during or subsequent to heavy exercise.²⁶

With regard to taurine in particular, the European Food Safety Authority has concluded that a cause and effect relationship has not been established between the consumption of taurine and contribution to normal cognitive function, maintenance of normal cardiac function, and a delay in the onset of physical fatigue during exercise.²⁷

For these reasons, experts have concluded that drinks like Monster are little more than “caffeine delivery systems” that offer no special benefits that would not be available through less expensive products such as coffee or NoDoz.²⁸

Without adequate substantiation, these marketing claims are misleading. In addition, as a conventional beverage, any health claims or structure-function claims must comply with the requirements of FDA regulations and California law.

IV. CONCLUSION

For the reasons set forth above, I am confident that the City would prevail in claims against Monster under the Sherman Law, and California’s consumer protection laws. To avoid litigation, the City demands that Monster immediately agree to take the following steps:

- Reformulate its product to lower the caffeine content to safe levels
- Provide adequate warning labels
- Cease promoting over-consumption in marketing
- Cease use of alcohol and drug references in marketing
- Cease targeting minors

Please let me know when you are available to discuss these changes to your product and marketing practices. If we do not receive an adequate response, the City will proceed to file suit forthwith.

Very truly yours,

DENNIS J. HERRERA
City Attorney

Attachments: Exhibit A (March 19, 2013 letter to Commissioner Hamburg)

²⁵ Tom M McLellan, Harris R Lieberman. *Do energy drinks contain active components other than caffeine?* *Nutrition Reviews*. Volume 70. Issue 12, pages 730–744. December 2012.

²⁶ Pettitt *et al.*. *Do the non-caffeine ingredients of energy drinks affect metabolic responses to heavy exercise?* *Journal of Strength and Conditioning Research* Publish Ahead of Print DOI: 10.1519/JSC.0b013e3182736e31.

²⁷ Scientific Opinion, European Food Safety Authority. *EFSA Journal* 2011; 9(4):2035.

²⁸ Barry Meier. *Energy Drinks Promise Edge, but Experts Say Proof Is Scant*. *New York Times* (January 1, 2013).