Shook, Hardy & Bacon L.L.P.

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FOOD & BEVERAGE LITIGATION UPDATE

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LEGISLATION, REGULATIONS AND STANDARDS

Illinois Lawmaker Calls on FDA to Address Caffeine Levels in Energy Drinks

U.S. Senator Dick Durbin (D-Ill.) has **urged** the Food and Drug Administration (FDA) to "take regulatory action to address the rising health concerns around energy drinks" in an April 3, 2012, letter to FDA Commissioner Margaret Hamburg.

Durbin's action follows the December 2011 death of a 14-year-old girl that the lawmaker attributed to "caffeine toxicity after drinking two 24-ounce Monster Energy drinks in a 24-hour period." Noting that FDA has the authority to regulate caffeine levels in soft drinks and additives in beverages, Durbin asked FDA to clarify whether energy drinks should be regulated as beverages or dietary supplements. "Most energy drinks are currently marketed as dietary supplements, therefore they do not need to establish evidence of their products' safety or adhere to a limit on the level of caffeine," he wrote. "At the same time, many energy drinks come in single-use containers ranging from 8 ounces to 32 ounces and are marketed like beverages."

Durbin also asked FDA to require manufactures to "provide scientific evidence that ingredients, such as guarana, tuarine and ginseng, are safe for their intended use and when used in combination with other ingredients and caffeine." The lawmaker noted, "Consuming large quantities of caffeine can have serious health consequences, including caffeine toxicity, stroke, anxiety, arrhythmia, and in some cases death. Young people are especially susceptible to suffering adverse effects because energy drinks market to youth, their bodies are not accustomed to caffeine, and energy drinks contain high levels of caffeine and stimulating additives that may interact when used in combination."

FDA Takes Further Action to Reduce Antibiotic Use in Livestock

The Food and Drug Administration (FDA) has **released** industry guidance and a draft regulation about a new voluntary initiative intended to decrease the use of antimicrobials in agricultural animals. According to an April 11, 2012,

Mark Anstoetter
816-474-6550
manstoetter@shb.com

or

Madeleine McDonough
816-474-6550
202-783-8400
mmcdonough@shb.com

press release, FDA has issued **final guidance** for industry titled "The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals," which "recommends phasing out the agricultural production use of medically important drugs and phasing in veterinary oversight of therapeutic uses of these drugs." The agency has also published **draft guidance** that urges animal pharmaceutical companies to voluntarily remove "production uses of antibiotics from their FDA-approved product labels" and "add, where appropriate, scientifically-supported disease prevention, control, and treatment uses." These two sets of guidance are supplemented with a proposed **veterinary feed directive** outlining "ways that veterinarians can authorize the use of certain animal drugs in feed, which is important to make the needed veterinary oversight feasible and efficient."

The move follows FDA's recent decision to curb the extra-label use of cephalosporin in livestock due to concerns over increased antibiotic resistance in both humans and animals. "It is critical that we take action to protect public health," said FDA Commissioner Margaret Hamburg. "The new strategy will ensure farmers and veterinarians can care for animals while ensuring the medicines people need remain safe and effective. We are also reaching out to animal producers who operate on a smaller scale or in remote locations to help ensure the drugs they need to protect the health of their animals are still available."

Meanwhile, FDA's announcement has drawn praise from the Center for Food Safety (CFS), which described the "3 year phase-out" strategy "a win for consumers, food safety advocates, and medical community." The Center for Science in the Public Interest (CSPI), however, was less sanguine, concluding that FDA's plan is already "tragically flawed" insofar as it relies on voluntary industry compliance. "The problem of antimicrobial resistance, and the contribution of animal agriculture to that problem, is urgent and global," said CSPI Food Safety Director Caroline Smith DeWaal in an April 11 statement. "The United States needs to take a leadership role in bringing comprehensive, effective action, in both the agricultural and medical spheres, to bear. The time for half-measures and voluntary steps has passed." *See CFS Press Release,* April 11, 2012.

Codex Meeting to Target Food Labeling

The U.S. Department of Agriculture's Food Safety and Inspection Service and the Food and Drug Administration have **announced** an April 18, 2012, public meeting in Washington, D.C., to provide information and receive public comments on draft U.S. positions to be discussed at the 40th Session of the Codex Committee on Food Labeling (CCFL) on May 15-18, 2012, in Ottawa, Ontario, Canada. Agenda items include additional conditions for nutrient health claims and comparative claims. *See Federal Register,* April 9, 2012.

Canada Proposes Amendments to Meat-Inspection Regulations

The Canadian Food Inspection Agency (CFIA) has proposed **amendments** to its federal meat-inspection rules to better align them with the regulations and policies

of major trading partners such as the United States and the European Union. According to CFIA, the plan updates a 1990 rule but does not lower food-safety standards. Instead, among other things, it would "repeal certain redundant requirements" to make it easier for small- to medium-sized slaughterhouses and meat-processing plants to achieve federal registration so that they could expand trade opportunities both in and outside Canada.

Under current law, Canadian plants that are provincially registered cannot sell or export their meat products outside their home province unless they are also federally registered. According to CFIA, 730 establishments are federally registered and approximately 4,000 are not, most notably because "becoming federally registered is expensive, with costs varying greatly from establishment to establishment in relation to the volume and nature of product." The agency asserts that the proposed rules could save establishments seeking federal registration approximately $50,000.

Other proposed amendments include (i) streamlining packaging and labeling registration; (ii) providing greater flexibility in the activities within a registered establishment; (iii) allowing an inspector, not an official government veterinarian, to sign export certificates; and (iv) establishing a register of allowable materials and coatings for food packaging to remove multiple checks and requirements. "There are already adequate safeguards to ensure that material is safe and suitable for use," CFIA noted.

LITIGATION

Chipotle Claims Kroger Chicken Product Infringes and Dilutes Its Trademark

Chipotle Mexican Grill, Inc., which operates 1,250 "fast-casual" restaurants throughout the United States, has sued The Kroger Co. in Colorado federal court, alleging that the grocery store chain has infringed the CHIPOTLE® trademark by using the descriptor on its spicy fried chicken take-out products. *Chipotle Mexican Grill, Inc. v. The Kroger Co,* CV00930 (U.S. Dist. Ct., D. Colo., filed April 5, 2012). According to the complaint, Chipotle has invested "tens of millions of dollars" "to create and maintain the goodwill of its CHIPOTLE® national brand," which evidently includes a commitment to sourcing ingredients "in the most ethical and sustainable manner possible." In addition to claiming monetary damages, Chipotle argues that Kroger's use of the word "Chipotle" on its chicken entrée packaging has caused "irreparable harm to the value and goodwill of Plaintiff's CHIPOTLE® Marks, as well as irreparable harm to Chipotle's business, goodwill and reputation."

"Kroger's use of CHIPOTLE… can only be explained by an intention to wrongfully profit from and trade off of Chipotle's valuable goodwill and reputation," states the complaint, which ultimately alleges trademark infringement under 15 U.S.C. § 1114, trademark dilution under 15 U.S.C. § 1125(c), false designation of origin under 15 U.S.C. § 1125(a), and violation of Colorado's Consumer Protection Act.

The company seeks unspecified damages as well as temporary and permanent injunctions enjoining Kroger from using the mark CHIPOTLE or "otherwise competing unfairly or committing any acts likely to confuse the public into believing that Kroger or any of Kroger's products are associated, affiliated or sponsored by Chipotle or are authorized by Chipotle, in whole or in part, in any way."

OTHER DEVELOPMENTS

ASA UK Chides Budweiser for Linking Beer to Sexual Success

The U.K. Advertising Standards Authority (ASA) has **upheld** a complaint alleging that a radio advertisement for Budweiser® beer violated rule 19.6 of the Broadcast Committee of Advertising Practice code by linking the consumption of alcohol to sexual success. According to ASA, the ad produced by AB InBev UK Ltd. featured a male speaker modeled after "the typical American football coach" giving "a motivational-style speech" to other male characters preparing for the evening ahead, which would likely include meeting new people. Although InBev argued that the commercial did not explicitly link consumption of its product to sexual prowess but instead "drew upon the commonly attributed American values of optimism, free-spiritedness and a positive attitude," ASA interpreted the message as implying that "on such nights [] unexpected and significant events, including conception, could take place."

"We considered the ad was likely to be understood as suggesting the group was preparing for an evening where alcohol would be drunk and during which the participants would have a great time, including the possibility of meeting a potential sexual partner," stated ASA's April 11, 2012, adjudication notice. "We considered the ad linked alcohol to sexual success and therefore concluded that it breached the Code."

SCIENTIFIC/TECHNICAL ITEMS

Maternal Metabolic Conditions Allegedly Tied to Increased Autism Risk

Researchers with the Medical Investigation of Neurodevelopmental Disorders (MIND) Institute at the University of California, Davis, have published a **study** claiming that maternal metabolic conditions (MCs) during pregnancy "may be broadly associated" with neurodevelopment problems, including autism spectrum disorder (ASD), in children. Paula Krakowiak, et al., "Maternal Metabolic Conditions and Risk for Autism and Other Neurodevelopmental Disorders," *Pediatrics,* April 2012. The authors apparently analyzed data from children ages 2-5 years enrolled in the Childhood Autism Risks from Genetics and the Environment (CHARGE) study, focusing on 517 children diagnosed with ASD, 172 with developmental delays (DD) and 315 controls.

The results evidently suggested that not only were diabetes, hypertension and obesity "more common among mothers of children with ASD and DD compared with controls," but mothers with obesity "were 67 percent more likely to have a child with ASD than normal-weight mothers without diabetes or hypertension, and were more than twice as likely to have a child with another developmental disorder," according to an April 8, 2012, MIND Institute press release. In addition, the authors noted that "[a]mong children without ASD, MCs collectively were associated with impairments in visual reception, motor skills, and receptive and expressive language, as well as adaptive communication and socialization."

"Over a third of U.S. women in their childbearing years are obese, and nearly one-tenth have gestational or type 2 diabetes during pregnancy. Our finding that these maternal conditions may be linked with neurodevelopmental problems in children raises concerns and therefore may have serious public-health implications," said lead author Paula Krakowiak. "And while the study does not conclude that diabetes and obesity cause ASD and developmental delays, it suggests that fetal exposure to elevated glucose and maternal inflammation levels adversely affect fetal development."

New Study Claims Sugary Drink Intake Linked to Retinal Vascular Changes in Kids

A recent study has allegedly linked sugary drink consumption to narrowed retinal blood vessels in children as young as age 12, raising concerns about the youths' long-term cardiovascular health. Bamini Gopinath, et al., "Carbohydrate nutrition is associated with changes in the retinal vascular structure and branching pattern in children," *American Journal of Clinical Nutrition,* May 2012. Designed to determine whether high-glycemic index (high-GI), high-glycemic load (high-GL) or carbohydrate-laden diets could lead to small vessel dysfunction, the study selected 12-year-old students from 21 schools to undergo "detailed eye examinations" measuring retinal vessel caliber and fractal dimension, that is, "the single 'global' measure of the branching pattern of retinal blood vessels as a whole." In particular, the study noted that narrower arteriolar caliber and wider venular caliber have been associated with incident hypertension and CVD [cardiovascular disease], whereas fractal dimension has been associated with higher blood pressure, acute lacunar stroke and coronary artery disease mortality.

Children who reported consuming soft drinks once or more per day apparently "had significantly narrower mean retinal arterioles… than did those who never or rarely consumed soft drinks." In addition, for girls only, "a higher-GI diet was associated with narrower retinal arterioles," while "carbohydrate intake and a high-GL diet were associated with greater retinal fractal dimension." As the study thus concluded, "Because these subtle retinal microvascular signs have shown to be markers of future CVD risk, the presence of this risk factor in children could support the need for health dietary patterns that include less consumption of high-GI foods and soft drinks."

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Study Finds No Link Between Coffee Consumption and Chronic Disease

A recent study has purportedly found that "neither caffeinated nor decaffeinated coffee was associated with an increased risk of total chronic disease, CVD [cardiovascular disease], or cancer," according to a concurrent editorial published in the *American Journal of Clinical Nutrition.* Anna Floegel, "Coffee Consumption and Risk of Chronic Disease in the European Prospective Investigation into Cancer and Nutrition (EPIC)-Germany Study," *American Journal of Clinical Nutrition,* April 2012. Researchers analyzed data from medical follow-ups and food frequency questionnaires gathered from 42,659 participants in the European Prospective Investigation into Cancer and Nutrition (EPIC)-Germany, reporting the effects of coffee on overall health. The results not only failed to reveal a link between coffee and chronic disease, but suggested that the beverage may be associated with a lower risk of type 2 diabetes.

"The association between coffee consumption and risk of chronic disease is of considerable relevance because coffee is consumed worldwide and any effect on health that it may cause will have public health consequences," notes the editorial, which stresses the need for further research into non-filtered coffee as well as its effects on those with preexisting conditions such as high blood pressure, diabetes, cancer or CVD. In addition, the study apparently did not address whether coffee drinkers tend to be healthier than non-consumers because the beverage itself has beneficial qualities or because coffee consumption in some cultures "is a marker of social interaction" generally synonymous with a higher quality of life. Nevertheless, the editorial concludes, the Floegel research "adds to the evidence on the null association between habitual coffee consumption and CVD, cancer and total mortality" and "suggests that coffee is not as bad as we were told."

OFFICE LOCATIONS

Geneva, Switzerland
+41-22-787-2000
Houston, Texas
+1-713-227-8008
Irvine, California
+1-949-475-1500
Kansas City, Missouri
+1-816-474-6550
London, England
+44-207-332-4500
Miami, Florida
+1-305-358-5171
San Francisco, California
+1-415-544-1900
Tampa, Florida
+1-813-202-7100
Washington, D.C.
+1-202-783-8400