FOOD & BEVERAGE LITIGATION UPDATE

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SHOOK HARDY & BACON

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LEGISLATION, REGULATIONS AND STANDARDS

FDA Proposes Added Sugar Details on Nutrition Labels

The U.S. Food and Drug Administration (FDA) has **issued** proposed revisions to the required information appearing in food and beverage products' Nutrition Facts labels. The changes include a required declaration of the percent daily value for added sugars based on the recommendation that daily intake from added sugars not exceed 10 percent of total calories. The proposal would also revise the footnote appearing on the Nutrition Facts label "to help consumers understand the percent daily value concept." FDA has reopened a 60-day comment period addressing its proposed revisions.

"The FDA has a responsibility to give consumers the information they need to make informed dietary decisions for themselves and their families," Susan Mayne, director of the FDA's Center for Food Safety and Applied Nutrition, was quoted as saying in a July 24, 2015, press release. "For the past decade, consumers have been advised to reduce their intake of added sugars, and the proposed percent daily value for added sugars on the Nutrition Facts label is intended to help consumers follow that advice."

FDA Guidance on ECJ Labeling to Appear in 2016

The U.S. Food and Drug Administration (FDA) has told a California federal court that the agency will not issue guidance until 2016 about the use of "evaporated cane juice" (ECJ)—which plaintiffs nationwide assert is merely sugar—on food and beverage labeling. *Swearingen v. Late July Snacks LLC*, No. 13-4324 (N.D. Cal., agency letter filed July 13, 2015); *Swearingen v. Healthy Beverage LLC*, No. 13-4385 (N.D. Cal., agency letter filed July 13, 2015). The court issued an order in May 2015 requesting FDA to indicate whether the agency would issue guidance within 180 days.

"FDA is actively working on a final guidance to address this issue," Associate Commissioner for Policy Leslie Kux writes. "However, because of competing priorities, FDA cannot commit to issuing a decision within 180 days. . . . We have received a substantial number of comments and extensive amounts of supporting materials. FDA is obligated to review and consider all of this material under its GGP regulation before issuing final guidance . . . . The Agency currently anticipates that a final guidance will issue before the end of 2016."

Labeling Small Amounts of Nutrients, Dietary Ingredients Subject of FDA Draft Guidance

The U.S. Food and Drug Administration (FDA) has **issued** draft **guidance** for industry about the agency's current thinking regarding the disclosure of small amounts of nutrients and dietary ingredients on nutrition labeling. The document focuses on how the agency intends to use its enforcement discretion when a conflict occurs between compliance with § 101.9(c) and § 101.9(g) of Title 21 of the *Code of Federal Regulations* such that compliance with both sections is not possible. FDA is also considering whether to revise both sections and, if so, may reportedly amend or withdraw the draft guidance. Those wishing to submit comments on the draft guidance must do so by September 28, 2015. *See Federal Register*, July 30, 2015.

FDA Extends Comment Period for Risk Assessment of Animal Drug Residues in Milk

Citing stakeholder concerns over insufficient time to develop meaningful submissions, the U.S. Food and Drug Administration (FDA) has **extended** by 90 days the period in which to submit comments about the agency's risk assessment titled, "Multicriteria-Based Ranking Model for Risk Management of Animal Drug Residues in Milk and Milk Products." FDA seeks suggestions for improving the specific criteria, scoring and weighting scheme; selection of animal drugs evaluated; and transparency of the risk assessment. Electronic or written submissions are now due by October 27, 2015. *See Federal Register*, July 30, 2015.

Shook offers expert, efficient and innovative representation to clients targeted by food lawyers and regulators. We know that the successful resolution of food-related matters requires a comprehensive strategy developed in partnership with our clients.

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LITIGATION

Putative "Handmade"-Labeling Class Action Dismissed Against Maker's Mark

A California federal court has dismissed a putative class action against Maker's Mark Distillery, Inc. alleging that its whiskey is mislabeled as "handmade" because it uses machines to produce the product. *Nowrouzi v. Maker's Mark Distillery, Inc.*, No. 14-2885 (S.D. Cal., order entered July 27, 2015). Additional information about the complaint appears in Issue **548** of this *Update*.

The court first denied the distillery's motion to dismiss on safe harbor grounds, finding that the record is unclear as to whether "handmade" claims fall within the purview of the Tobacco Tax and Trade Bureau. The decision then turned to whether the public would likely be deceived by the "handmade" label. Maker's Mark cited a May 2015 decision in a similar lawsuit finding that a reasonable person would understand that "handmade" is not meant to indicate that substantial equipment was not used in production, and the court found the reasoning persuasive. "This Court finds that 'handmade' cannot reasonably be interpreted as meaning literally by hand nor that a reasonable consumer would understand the term to mean no equipment or automated process was used to manufacture the whisky," the court held. Details of the previous dismissal appear in Issue **564** of this *Update*.

California Court Dismisses Labeling Claims from Cup Noodles® *Trans* Fat Dispute

A California federal court has dismissed claims challenging the *trans* fats labeling of Nissin Foods Co. Inc.'s Cup Noodles® but allowed to continue allegations that the use of partially hydrogenated oil (PHO) violates California law. *Guttmann v. Nissin Foods (U.S.A.) Co., Inc.*, No. 15-0567 (N.D. Cal., order entered July 15, 2015). The plaintiff challenged the Cup Noodles label, which indicated that the product contained "Trans Fat: 0g," despite including PHO among its ingredients. Nissin argued that the U.S. Food and Drug Administration (FDA) dictates that the nutritional panel lists an ingredient as zero grams if its actual content is less than one-half of a gram, and Nissin's compliance with that mandate could not create misleading labels.

The court looked to a 2010 case with the same plaintiff challenging Quaker Oats Co.'s label on similar grounds. According to the court, the decision in that case determined that "if the FDA had decided there was 'no nutritional difference' between the rounded and unrounded values in the context of reference claims, use of the unrounded value could not be misleading when used as an express nutrient-content claim. Because that label was not misleading, any state-law claim based on that label would establish requirements that were inconsistent with [federal law]. Such claims were expressly preempted by [the statute]," the court said. "So too here." Accordingly, the court dismissed the plaintiff's claims related to mislabeling.

The court then assessed the plaintiff's allegations "that Nissin violated California law by including such a poisonous ingredient as artificial trans-fat in its noodles." The court found that the plaintiff alleged "in great detail the serious harm artificial trans-fat poses to public health," and further alleged that "the only utility in the use of partially-hydrogenated oils, as opposed to oils that do not contain artificial trans-fat, is that partially-hydrogenated oils are less expensive." These allegations were sufficiently pled, the court found, so it denied Nissin's motions to dismiss the claims related to the use of *trans* fat.

San Francisco SSB Statute Violates First Amendment, Industry Lawsuit Argues

The American Beverage Association (ABA) has partnered with California retail and advertising associations to challenge San Francisco ordinances requiring warning labels on sugar-sweetened beverage (SSB) advertisements and prohibiting advertisements of such products on city property. *Am. Beverage Ass'n v. City of San Francisco*, No. 15-3415 (N.D. Cal., filed July 24, 2015). ABA argues that the ordinances violate the First Amendment, which "forbids the City from conscripting private speakers to convey [the city's viewpoint] while suppressing conflicting viewpoints on this controversial topic."

The complaint first details ad prohibition on city property, including transportation and parks, while it "explicitly permits advertisements that criticize sugar-sweetened beverages or encourage people to stop drinking them. The First Amendment flatly forbids such government-imposed viewpoint discrimination." The second component of the ordinance prohibits all producers of SSBs "from using their *names* on any City

property to promote *any* product or *any non-charitable event*, no matter whether commercial, athletic, musical, or even political in nature," including "local icons like Ghirardelli Chocolate, Peet's Coffee, Jamba Juice, and Swenson's," the complaint notes.

ABA then explains the SSB warning label mandate, describing it as requiring private speakers "to convey, regardless of their own views, the City's controversial and misleading opinion that certain beverages with added sugar are inherently hazardous, more harmful to consumers' health than beverages with natural sugar or foods with added sugar, and uniquely responsible for increasing rates of obesity and diabetes." The mandate singles out SSBs unfairly, the complaint argues, because SSBs are no more hazardous than other foods or beverages that require no warning. Further, "while Americans consume many more calories today than in the past and rates of obesity and diabetes are on the rise, sugar-sweetened beverage consumption has decreased substantially over the last 15 years." The complaint compares the mandated warnings to a 2010 initiative requiring retailers to warn consumers about cell-phone radiation regardless of the retailers' beliefs, which a California federal court enjoined on First Amendment grounds and the Ninth Circuit affirmed.

The plaintiffs seek an injunction preventing enforcement of the ban, which is set to take effect on July 25, 2016.

Kraft "Natural" Fat-Free Cheese Challenged in Puerto Rico Court

A consumer has filed a putative class action against Kraft Foods Group Inc. alleging that the company's fat-free cheese is mislabeled as "natural" because it contains artificial or synthetic ingredients, including "artificial color." *Quiñones-Gonzalez v. Kraft Foods Grp., Inc.*, No. 15-1892 (D.P.R., filed July 27, 2015). The plaintiff asserts that she relied on the "natural" label to mean that the product, "at a minimum, has no *artificial* ingredients or characteristics. The public is further led to believe the Product will be healthier, safer and/or produced to a higher standard." She seeks class certification, an injunction, restitution and damages for allegations of deceptive and unfair marketing and unjust enrichment. A class was certified in June 2015 in a similar lawsuit pending in California federal court; details about the ruling appear in Issue 570 of this *Update*.

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Mentos® Gum Packages Are Slack-Filled, Proposed Class Action Alleges

A group of consumers has filed a putative class action against Perfetti Van Melle USA alleging that the packaging of its Mentos® sugar-free gum contains non-functional slack fill, which amounts to unfair business practices. *Hu v. Perfetti Van Melle USA Inc.*, No. 15-3742 (E.D.N.Y., filed June 26, 2015). The gum is sold as packages of 50 in non-transparent tubes designed to fit into a car's cup-holder. The complaint alleges that the height of the tube is unnecessary because it could hold approximately 70 pieces of Mentos® gum—leaving the 50 pieces to fill just 71 percent of the tube's capacity. The 50-piece product's packaging was "designed by Defendant to give the impression that there is more content than actually packaged," the complaint asserts, noting that a 15-piece Mentos® gum product does use transparent packaging. The complaint lists two named plaintiffs, residents of New York and California, along with four John Doe plaintiffs who reside in Michigan, Illinois, New Jersey and Florida. They seek class certification for consumers of those states along with a nationwide class for unfair trade practices.

OTHER DEVELOPMENTS

U.K. Group Issues Report Critical of Government Action on Sugar

Britain's Institute of Economic Affairs (IEA) has published a **report** condemning government policies aimed at reducing the consumption of sugar. "Just as fat seems to have been given an amnesty, so sugar is now in the dock," according to report co-authors Rob Lyons and Christopher Snowdon. "So what exactly is the evidence that sugar is deadly? Can one substance really be responsible for a plethora of chronic diseases? If so, are the calls for action to reduce sugar consumption – including taxes and regulations – justified?" *See IEA News Release*, July 15, 2015.

ABOUT SHOOK

Shook, Hardy & Bacon is widely recognized as a premier litigation firm in the United States and abroad. For more than a century, the firm has defended clients in some of the most substantial national and international product liability and mass tort litigations.

Shook attorneys are experienced at assisting food industry clients develop early assessment procedures that allow for quick evaluation of potential liability and the most appropriate response in the event of suspected product contamination or an alleged food-borne safety outbreak. The firm also counsels food producers on labeling audits and other compliance issues, ranging from recalls to facility inspections, subject to FDA, USDA and FTC regulation.