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LEGISLATION, REGULATIONS & STANDARDS

FDA Announces First Deputy Commissioner for Human Foods

The U.S. Food and Drug Administration (FDA) has named James Jones as the agency's first Deputy Commissioner for Human Foods. Jones will be tasked with setting and advancing priorities for a proposed unified Human Foods Program (HFP). He comes to the agency with more than 30 years of experience holding various positions in the U.S. Environmental Protection Agency (EPA), stakeholder community and private industry related to chemical safety and sustainability. He will begin September 24.

At EPA, Jones played a key role in the 2016 overhaul of the Toxic Substances Control Act and was responsible for decision-making related to pesticides and commercial chemicals regulations. He was also an integral member of the Reagan-Udall Foundation's Independent Panel for Foods, which submitted a report on the operational evaluation of the HFP to FDA in December 2022.

In a statement, FDA Commissioner Robert Califf, to whom Jones will report, said Jones' "impressive career, extensive leadership experience, and passionate vision for the future of the Human Foods Program make him an ideal selection for this pivotal position."

"Our proposed reorganization is the largest undertaking of its kind in recent history for our agency," Califf said. "I'm confident that under Jim's leadership, we will build a stronger organization that will be integrated with other components of the FDA and focused on keeping the foods we regulate safe and nutritious, while ensuring the agency remains on the cutting edge of the

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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latest advancements in food science and nutrition."

Canada Issues Public Advisory on Caffeinated Energy Drinks

The Canadian Food Inspection Agency has issued a public advisory urging caution when consuming caffeinated energy drinks. "If you choose to consume caffeinated energy drinks, follow the cautionary statements that appear on their label and pay attention to your caffeine consumption," the advisory sates. "Adults 18 years and over should not consume more than 400 mg of caffeine per day. Too much caffeine can have negative impacts on your health, such as insomnia, irritability, headaches and nervousness." In addition to noting that children, those who are pregnant or breastfeeding, and individuals sensitive to caffeine should avoid caffeinated energy drinks, the advisory notes that "[o]thers should also limit their consumption of these products."

Beef Mandatory Country-of-Origin Labeling Law Introduced in U.S. House

Rep. Dusty Johnson (R-SD) has introduced a bill seeking to clarify and reinstate mandatory country-of-origin labeling (MCOOL) for beef products. The Beef Origin Labeling Accountability Act would:

- Direct the U.S. Trade Representative and Secretary of Agriculture to work together to determine a process of reinstating MCOOL for beef compliant with World Trade Organization (WTO) rules;
- Require the two agencies to report to Congress on their progress in determining a trade-compliant means of MCOOL, including legislative recommendations and any engagement with international governments; and
- Direct the U.S. Trade Representative to enter into consultations with the Canadian and Mexican governments to resolve their outstanding MCOOL trade disputes with the United States.

The 2008 Farm Bill implemented MCOOL and labeling for beef products from cattle born, raised and harvested in the United States, but Congress repealed it in 2015 after Canada and Mexico filed disputes with WTO claiming it violated WTO agreements. The United States lost multiple appeals to WTO rulings against MCOOL, and in December 2015, WTO authorized more than $1 billion in tariffs against U.S. products from Canada and Mexico.

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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.

The WTO cases remain active.

FDA Proposes Changes to Canned Tuna Standard Fill of Container

The U.S. Food and Drug Administration (FDA) is proposing to amend the standard of identity and standard fill of container for canned tuna. The action is a partial response to a citizen petition submitted in 2015 by Bumble Bee Foods, LLC, StarKist Co., and Tri Union Seafoods, LLC. Among other things, the proposed rule would replace the pressed cake weight method with the drained weight method to determine the standard fill of container.

FDA said it is proposing the changes because the pressed cake weight method is only required in U.S. canned tuna standards and does not align with current industry practice in the United States. The agency noted that the pressed cake weight method relies upon using a three-piece can, but the current industry practice is to use a two-piece can.

"In comparison, the type of packaging is irrelevant when using the drained weight method. The pressed cake weight method relies on more complex instrumentation and requires more steps than the drained weight method, resulting in a more costly procedure with a wider margin of error than the drained weight method," FDA said. "The pressed cake weight method is therefore more difficult to perform, more prone to human error, and may produce inconsistent results compared with the drained weight method."

FDA will accept comments on the proposed rule until November 24, 2023.

LITIGATION

Sazerac Seeks Sanctions Against Prolific Plaintiff's Attorney

The maker of Fireball liquors is seeking sanctions against a prolific New York plaintiff's attorney, alleging he filed an amended complaint knowing it lacked any factual basis and that the court lacked jurisdiction. *Ortiz v. Sazerac Company, Inc.*, No. 23-0097 (N.D. Ill., filed August 29, 2023).

Sazerac is seeking sanctions against Spencer Sheehan of Sheehan & Associates, P.C. in a case he initially brought on behalf of an Illinois woman alleging Sazerac's malt-beverage Fireball Cinnamon product misleads consumers. According to the company's filing supporting its motion for sanctions, Sazerac

moved to dismiss the woman's complaint because her assertion that she had purchased Fireball Cinnamon multiple times at a grocery store in Illinois could not be true because Fireball Cinnamon is not sold in Illinois.

In response, Sazerac said, plaintiff's counsel filed an amended complaint—which was later voluntarily dismissed in May 2023—removing the plaintiff and asserting claims on behalf of three new plaintiffs, alleging one bought Fireball Cinnamon at a gas station in Calumet City, Illinois.

"In obvious recognition of the fact that Fireball Cinnamon is not sold in Illinois, the Amended Complaint went out of its way to note that the gas station in Calumet City where Plaintiff Ortiz allegedly purchased the product is 'approximately three miles from the Illinois-Indiana border,'" Sazerac said in its filing. "Proximity to Indiana, of course, does not change the fact that Fireball Cinnamon is not sold in Illinois – no matter how close to a border with another state."

Additionally, Sazerac said the amended complaint "attempted to sidestep that inconvenient fact" by alleging the plaintiff had also purchased the product at a store in Indiana, while another plaintiff had bought the product at a store in South Carolina.

"It is obvious even to first-year lawyers that this Court lacks personal jurisdiction over purchases by an Indiana resident in Indiana and by a South Carolina resident in South Carolina," Sazerac said. The company argued that sanctions are warranted because Sheehan has violated Federal Rule of Civil Procedure 11 and 28 U.S.C. 1927. It is seeking attorneys' fees for opposing the amended complaint.

Burger King Whopper Lawsuit to Proceed

A Florida federal court has denied a motion to dismiss some claims in a lawsuit alleging Burger King Corp. "materially overstates" the size of its hamburgers. *Coleman v. Burger King Corp.*, No. 22-20925 (S.D. Fla., entered August 23, 2023). The plaintiffs alleged Burger King's marketing showed the burgers as 35% larger and containing 100% more beef.

Burger King argued that its advertisements are solicitations that could not form the basis of a contract, and the court confirmed but found that the contract formed on other grounds. "[W]e agree with Burger King that a reasonable person wouldn't have interpreted Burger King's TV and online ads as binding offers," the court held. "But the same can't be said of Burger King's *in-store* 'menu ordering boards.' … These in-store ordering boards—

unlike BKC's TV and online ads—*do* list price information and do provide item descriptions. [] Plus, these ordering boards aren't advertisements at all. So far as we can tell, these ordering boards are actually *in the stores* when the customers walk in. Their whole purpose is to present to the potential customer an offering of the available menu items (and their prices). They're thus very different from the advertisements one might see on the Internet or on TV—which cannot constitute offers precisely because they cannot promise that the item will still be available when, at some future date and time, the customer finally elects to walk into the store."

The plaintiffs plausibly pleaded the existence of a valid contract, the court held, and they asserted that they relied on the information on the menu ordering boards. "[W]e'll accept (for now) those ordering boards as offers. … Taking the Plaintiffs' factual allegations as true—and construing them in the light most favorable to the Plaintiffs—we conclude that a reasonable person could have viewed Burger King's in-store depictions of its menu items as offers, and not merely as invitations to bargain."

The court dismissed Burger King's argument that the appearance of the sandwich "isn't an essential term of a contract." "How can that be?" the court asked. "We won't lightly suppose that a proprietor can offer to sell you a certain amount of food at a specified price only to provide you with less food for the same price. Nor will we simply assume that most reasonable people would take lying down this incongruity between the amount of sustenance they were promised and the amount of sustenance they got. We'll agree with Burger King (of course) that most reasonable people would be unfazed by, say, a one-percent disparity between the amount of food they were offered and the amount they ultimately received—just as (we would think) Burger King would concede that a fifty-percent delta between what was promised and what was sold would probably vex most reasonable consumers."

"Who are we to decide whether such a seemingly substantial difference between what was promised and what was sold was (or was not) enough to alter the purchasing preferences of reasonable American consumers?" the court noted. "Far better, it seems to us, to leave that determination to the consumers themselves, who—if the case survives that far—will get to sit in the jury box and tell us what reasonable people think on the subject."

Dole Agrees to Settle 100% Juice Claims for $7.8M

An Illinois court has given preliminary approval to a $7.8 million class action settlement resolving claims that Dole unlawfully advertised, marketed and sold its products as containing “100% Juice” or as packaged “in 100% fruit juice.” *Blankenship v. Dole Packaged Foods, LLC*, No. 23-LA-0361 (Ill. Cir. Ct., entered June 27, 2023). The plaintiff alleged that the products contain trace amounts of added ascorbic acid, citric acid or other ingredients and raised claims under common law and Illinois consumer-protection law.

Dole agreed to claims up to $4,303,125 as well as $3.5 million in injunctive relief. The company agreed to either include explanatory language, remove the added ingredients from the products or remove the statements “in 100% juice” and “in 100% fruit juice.”

Target Water Enhancer Contains Artificial Flavor, Consumer Alleges

A Florida consumer has filed a proposed class action against Target alleging the company misleads consumers about the flavor source of its Market Pantry berry pomegranate water enhancer. *Broodie v. Target Corp.*, No. 23-00955 (M.D. Fla., filed August 14, 2023). The plaintiff alleges that the product purports to get its berry pomegranate taste only from natural flavoring ingredients, arguing that the front label statements of “Berry Pomegranate” and “Natural Flavor With Other Natural Flavor” appeal to the majority of consumers who seek to avoid artificial flavors. She asserted that laboratory analysis of the product, however, shows the product uses artificial DL-Malic Acid, which allegedly is not a “natural flavor” under state and federal regulations and should be identified as an artificial flavor.

“Defendant could have added more berry, such as blueberry and raspberries, and pomegranate ingredients or L-Malic Acid from berries, such as blueberries and raspberries, and pomegranates, but used artificial DL-Malic Acid because it cost less and/or more accurately simulated, resembled, and/or reinforced the taste of berries, such as blueberries and raspberries, and pomegranates,” the complaint asserts. The plaintiff is alleging violations of Florida’s Deceptive and Unfair Trade Practices Act and False and Misleading Advertising Law, as well as breach of express warranty and fraud. She seeks class certification, damages, costs, expenses and attorney's fees.

Listeria Recall Spurs Suit Against Ice Cream Company

A New York woman has filed a proposed class action against Real Kosher Ice Cream Inc. after the company initiated a product recall for *Listeria* in its products. *Gurkov v. Real Kosher Ice Cream Inc.*, No. 23-06128 (E.D.N.Y., filed August 14, 2023). In August, the company recalled ice cream and sorbet cups because they have the potential of being contaminated with *Listeria monocytogenes*. The plaintiff alleges that Real Kosher Ice Cream failed to disclose to consumers on its packaging that consumption of its products may increase the risk of contracting *Listeria*-related infection.

“Defendant is using a marketing and advertising campaign that omits from the ingredients lists that the Products contain *Listeria monocytogenes*,” the plaintiff argues. “This omission leads a reasonable consumer to believe they are not purchasing a product with a known bacterium when in fact they are purchasing a product contaminated with *Listeria monocytogenes*.”

The plaintiff also claimed that the company makes misleading "100% natural" claims on some of its products containing sodium alginate, which the plaintiff asserts is a synthetic ingredient. The plaintiff is asserting violations of New York’s General Business Law and the state’s Agriculture and Markets Law, as well as breach of express warranty and negligence per se. She seeks class certification, an order establishing medical monitoring, damages, costs, expenses and attorney's fees.