



ISSUE 634 | MAY 12, 2017



LEGISLATION, REGULATIONS & STANDARDS

Scott Gottlieb Confirmed, Sworn In as FDA Commissioner

The U.S. Senate has <u>confirmed</u> Scott Gottlieb to lead the Food and Drug Administration (FDA) in a 57-42 vote. Gottlieb previously served as a deputy FDA commissioner and an official at the Centers for Medicare and Medicaid Services during the George W. Bush administration. Among Gottlieb's critics are senators who expressed concern over his connections with the pharmaceutical and medical device industry, but Gottlieb has promised to divest himself from several companies and recuse himself from decisions involving those companies for one year. *See New York Times* and *Washington Post*, May 9, 2017.

EFSA Rejects Study Linking Sucralose to Cancer

The European Food Safety Authority (EFSA) has issued a <u>statement</u> rejecting an Italian study claiming a link between the use of the sweetener sucralose and cancer in mice. The *EFSA Journal*'s review of a 10-year study conducted by the Ramazzini Institute criticized the study's design and methodology, concluding that available data does not support the institute's claim that sucralose may cause lymphoma or leukemia in mice. Among other criticisms, the panel said the design introduced too many variable factors that could make the data difficult to interpret, and there was no demonstrated dose-response relationship between exposure to sucralose and incidence of cancer. EFSA also pointed to the study's

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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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failure to establish a cause-effect relationship in epidemiological studies and said there was no reliable evidence of *in vivo* or *in vitro* genotoxicity.

USDA Postpones Organic Livestock and Poultry Rule

The U.S. Department of Agriculture (USDA) has <u>delayed</u> the effective date of a final rule amending organic livestock and poultry requirements and <u>requests</u> additional public comment. The effective date of the rule has been postponed from May 19, 2017, to November 14, 2017. Interested parties may submit written comments by June 9, 2017.



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NYC Considering Bill Requiring Curbside EPS Container Recycling

New York City is reportedly considering a <u>bill</u> that would require curbside recycling of expanded polystyrene foam (EPS) containers. The city's Sanitation Department is currently under a court mandate to develop a plan to collect and clean EPS containers. New York City previously attempted to ban EPS containers in 2013, but a court invalidated the prohibition after a challenge by several food companies, supermarkets and foodservice businesses. Additional details on the decision and the city's appeal appear in Issues <u>579</u> and <u>583</u> of this *Update*. *See Huffington Post*, May 4, 2017; *New York Post*, May 7, 2017.

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.

LITIGATION

Bumble Bee Pleads Guilty to Felony in Price-Fixing Conspiracy

Bumble Bee Foods, LLC has agreed to plead guilty to one felony count for its role in a conspiracy to fix prices of shelf-stable tuna and will pay a minimum \$25-million fine. *U.S. v. Bumble Bee Foods LLC*, No. 17-CR-249 (N.D. Cal. May 8, 2017). According to the U.S. Department of Justice, Bumble Bee conspired with other seafood companies and their executives to inflate prices for canned and pouch tuna. Two Bumble Bee executives have already pleaded guilty to criminal charges; details appear in Issue <u>625</u> of this *Update*.

"Today's charge is the third to be filed—and the first to be filed against a corporate defendant—in the Antitrust Division's ongoing





investigation into price fixing among some of the largest suppliers of packaged seafood," Acting Assistant Attorney General Andrew Finch said in a May 8, 2017, <u>press release</u>. "The division, along with our law enforcement colleagues, will continue to hold these companies and their executives accountable for conduct that targeted a staple in American households."

Beverage Mislabeling Suit Dismissed After Plaintiffs Admit They Knew ECJ Was Sugar

A California federal court has ruled that plaintiffs who admitted to reading Healthy Beverage's website cannot sue the company for listing evaporated cane juice (ECJ) on the ingredient list rather than sugar. Swearingen v. Healthy Beverage, No. 13-4385 (N.D. Cal., order entered May 5, 2017). The plaintiffs initially filed a putative class action claiming Healthy Beverage misled consumers by listing evaporated cane juice on their product labels, but they later alleged in an amended complaint that the company's website "is incorporated into the label for each of Defendants' products" and that the website states "cane juice is natural sugar." Given those allegations, the court dismissed the suit with prejudice, holding, "An allegation of reliance, which is necessary for all of plaintiffs' claims" under California consumer-protection laws and unjust enrichment, was "impossible . . . [t]he Court will not allow them a third bite at the apple to amend a factual allegation that is squarely inconsistent with a prior allegation."

Mott's Applesauce Sued Over "Natural" Labeling

Consumer-advocacy group Beyond Pesticides has filed suit against the maker of Mott's applesauce products, alleging the term "natural" on its labels misleads consumers because the products contain the pesticide acetamiprid. *Beyond Pesticides v. Dr Pepper Snapple Grp.*, No. 2017 CA 003156 B (D.C. Super. Ct., filed May 5, 2017). The plaintiff asserts that the "natural" and "All Natural Ingredients" labeling on several varieties of Mott's applesauce mislead consumers who would not expect the products to contain a "synthetic, unnatural chemical." Claiming violations of the District of Columbia's Consumer Protection Procedures Act, the plaintiff seeks injunctive and equitable relief—including the establishment of a "community fund" to raise consumer awareness of acetamiprid—and attorney's fees.

Putative Class Action Claims Slack-Fill Violations in Chocolate Packaging

Candy maker Fannie May faces a proposed class action alleging the confectioner underfilled some of its seven-ounce chocolate boxes by as much as 50 percent. *Benson v. Fannie May*, No. 17-3519 (N.D. Ill., filed May 10, 2017). The allegations involve boxes of Hot Fudge Truffles, Mint Meltaways[®], Peanut Butter Buckeyes, milk and dark Sea Salt Caramels, regular and bite-sized Pixies[®], milk and dark Carmarsh[®] and Trinidads[®] sold at the company's retail stores and on its website as well as other retail and online outlets nationwide. The plaintiffs allege that nonfunctional slack-fill in the company's nontransparent boxes violates the federal Food, Drug and Cosmetic Act as well as Illinois consumer-protection statutes and seek class certification, equitable relief, monetary damages and attorney's fees.

Plaintiff Claims Ginger Snaps Marketing Misleads

A consumer has filed a lawsuit alleging Mondelez International misleadingly markets Ginger Snaps cookies as healthy. *Winn v*. *Mondelez Int'l*, No. 17-2524 (N.D. Cal, removed to federal court May 3, 2017). The proposed class action claims that Ginger Snaps packages were marketed with the phrases "Made With Real Ginger and Molasses" and "Sensible Solutions," leading consumers to believe the cookies were healthy despite allegedly containing "dangerous levels" of partially hydrogenated oils and high-fructose corn syrup. For alleged violations of California's consumer protection laws, the plaintiff seeks class certification, damages, restitution, injunctive relief and attorney's fees.

Court Approves Publicity Plan for Safeway Tuna Settlement

A California federal court has approved a plan to publicize the settlement of a proposed class action filed against Safeway alleging the supermarket chain underfilled its canned tuna. *In re Safeway Tuna Cases*, No. 15-5078 (N.D. Cal., order entered May 4, 2017). The judge approved the settlement in March 2017 but was concerned that potential class members would be unaware of the dismissal of the case. The publicity plan requires the parties to issue press releases to major news outlets and legal publications in

California and nationwide and post notice on a publicly searchable website. When that plan is complete, the court said, the action will be dismissed. Additional details on the settlement appear in Issue 628 of this *Update*.

Truffle Oil False Labeling Suits Filed

Two proposed class actions have been filed in California claiming false labeling of truffle-flavored olive oil. *Schiffman v. Urbani Truffles*, No. 17-0935 (E.D. Cal., filed May 3, 2017); *Quiroz v. Sabatino Truffles*, No. 17-0783 (C.D. Cal., filed May 3, 2017). The plaintiffs argue that the olive oil producers add 2,4-dithiapentane to flavor their products instead of truffles and sell the "truffle infusions" at markups as high as 1,400 percent over the price of plain olive oils. The actions claim violations of the Magnuson-Moss Warranty Act and state consumer-protection laws. Details on similar lawsuits in New York appear in Issue <u>633</u> of this *Update*.

Court Enters Consent Decree for Animal Feed Maker After FDA Complaint

Syfrett Feed Co., a Florida manufacturer of medicated animal feeds, has entered into a consent decree to control its production process and comply with federal laws before resuming medicated feed operations. *U.S. v. Syfrett Feed Co., Inc.*, No. 17-14038 (S.D. Fla., order entered May 4, 2017). The court entered the decree after the U.S. Food and Drug Administration (FDA) filed a complaint alleging the company failed to adequately identify and store the drugs it used or prevent contamination of drugs and feeds as well as mislabeled and misbranded feeds. According to the complaint, 17 horses had to be euthanized after eating the company's horse-pellet food. Syfrett manufactures feeds for cattle, poultry, pigs, sheep, goats and exotic animals, but has agreed to discontinue production of the horse feed connected to the animal deaths.

"Animal feed manufacturers that fail to comply with labeling and good manufacturing requirements for medicated animal feeds jeopardize the health of animals," Acting Assistant Attorney General Chad A. Readler said in a May 4, 2017, press release. "The Department of Justice and FDA will continue to work together to ensure that animal feed manufacturers produce safe medicated animal feed products."

OTHER DEVELOPMENTS

Glitch Reveals Pizza Co.'s Facial-Recognition Ad Tactics

An apparent glitch in a Peppes Pizza advertisement in Oslo, Norway, reportedly revealed to passersby that the ad determined whether to show pizza or salad to its audience based on gender as perceived by facial-recognition software. The digital billboard used a hidden camera to scan faces of the audience and showed images of sausage pizza for men and salads for women. The glitch revealed that the software scanned for the gender of the viewer, the age segment, the length of time the viewer looked at the ad, and whether the viewer was wearing glasses or smiling. After the glitch gained attention as a purported breach of privacy in Norwegian media, the hidden camera was reportedly removed. *See The Outline*, May 12, 2017.

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