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LEGISLATION, REGULATIONS AND STANDARDS

FDA Announces Plans to Curtail Antibiotic Use in Farm Animals

The U.S. Food and Drug Administration (FDA) has <u>announced</u> plans to phase out the use of certain antibiotics in food animals as part of its effort to reserve medically important drugs for the treatment of human infection. Noting that voluntary participation "is the fastest, most efficient way to make these changes," the agency will partner with industry to discontinue the practice of adding these drugs to animal feed and drinking water as a growth promoter. To this end, FDA has <u>issued final guidance</u> that urges animal pharmaceutical companies "to voluntarily revise the FDA-approved conditions on the labels of these products to remove production indications," in addition to <u>proposing</u> an updated veterinary feed directive (VFD) "to facilitate expanded veterinary oversight by clarifying and increasing the flexibility of the administrative requirements for the distribution and use of VFD drugs."

"The plan also calls for changing the current over-the-counter (OTC) status to bring the remaining appropriate therapeutic uses under veterinary oversight," states FDA in a December 11, 2013, press release. "Once a manufacturer voluntarily makes these changes, its medically important antimicrobial drugs can no longer be used for production purposes, and their use to treat, control, or prevent disease in animals will require veterinary oversight."

The agency has asked animal pharmaceutical companies to notify FDA "within the next three months of their intent to voluntarily make the changes recommended in the guidance." Participants would then have three years to implement these changes. FDA will also accept comments on the VFD proposed rule until March 12, 2013. See Federal Register, December 12, 2013.

USDA Terminates National Leafy Green Marketing Agreement

The U.S. Department of Agriculture (USDA) has <u>terminated</u> proceedings on a proposed marketing agreement that sought to regulate the handling of fresh leafy green vegetables in the United States. Modeled after a 2006 initiative pioneered by California growers in the wake of an *E. coli* outbreak linked to fresh spinach, the National Leafy Green Marketing Agreement (NLGMA) would have authorized "the development and implementation of handling regula-



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SHB 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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tions (audit metrics) to reflect the United States Food and Drug Administration's (FDA) Good Agricultural Practices [], Good Handling Practices [], and Good Manufacturing Practices []."

According to the California LGMA, which participated in the NLGMA effort, the proposed program became redundant under the Food Safety Modernization Act (FSMA), which requires FDA to regulate produce farmers "to ensure their products are safe." To this end, the California LGMA recently submitted comments on FSMA's proposed Produce Safety Rule, asking the FDA to consider certified LGMA members as compliant with new food safety laws.

"Through the LGMA programs in California and Arizona, 90 percent of the leafy greens grown in the U.S. are already being produced in [a] manner that meets or exceeds proposed new food safety regulations," states the California LGMA blog. "The LGMA programs utilize mandatory government auditors, funding is provided by industry and doesn't require additional tax dollars and these programs have been in place for over six years." Additional details about the NLGMA appear in Issue 393 of this *Update*. See California LGMA Blog, December 4, 2013; Federal Register, December 5, 2013.

HHS/USDA Postpone Dietary Guidelines Advisory Committee Meeting

Due to the recent government shutdown, the U.S. Department of Health and Human Services (HHS) and U.S. Department of Agriculture (USDA) have rescheduled the second meeting of the 2015 Dietary Guidelines Advisory Committee for January 13-14, 2014. Among those on the agenda are HHS, USDA and Institute of Medicine representatives, committee members and Food Systems Consultant Kate Clancy, who will address "Dietary Guidelines and Sustainability." The public will have an opportunity to speak, and those who registered to do so before the originally scheduled October 3-4, 2013, meeting "will retain their designation." Those choosing to participate by Webcast or in person must register by January 6, 2014. Comments are requested either by December 31, 2013, or throughout the committee's deliberative process. See Federal Register, December 9, 2013.

FTC Holds Workshop on Native Advertising in Digital Media

The Federal Trade Commission (FTC) recently **hosted** a workshop on digital native advertising as part its effort to ensure that "consumers can identify advertisements as advertising wherever they appear." Titled "Blurred Lines: Advertising or Content?," the workshop examined "the practice of blending advertisements with news, entertainment, and other content in digital media," bringing together publishers, marketers, consumer advocates, academics, and self-regulatory organizations to discuss: (i) "the ways in which sponsored content is presented to consumers online and in mobile apps"; (ii) "consumers' recognition and understanding of it"; (iii) "the contexts in which it should be



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identifiable as advertising"; and (iv) "effective ways of differentiating it from editorial content."

Building on recent updates to FTC's guidance on search engine advertising, dot com disclosures, and endorsements and testimonials, the workshop is reportedly the latest step in the commission's efforts to ensure that digital advertisers conform to rules intended to help consumers distinguish between marketing and editorial content. See FTC News Release, December 3, 2013; The New York Times and Adweek, December 4, 2013.

EFSA Finds Aspartame Safe at Current Exposure Levels

The European Food Safety Authority's (EFSA's) Panel on Food Additives and Nutrient Sources Added to Food (ANS) has **published** its full risk assessment on aspartame, concluding that the food additive is safe at current levels of exposure. In addition to noting that aspartame's breakdown products—phenylalanine, methanol and aspartic acid—occur naturally in other foods, EFSA's experts found that aspartame's acceptable daily intake (ADI) of 40 mg/kg bw/day "is protective for the general population," with the exception of those individuals with phenylketonuria, a medical condition that necessitates a diet low in phenylalanine.

At the request of the European Commission, the ANS Panel analyzed "all available information" in an effort to resolve uncertainties related to the re-evaluation of aspartame as a food additive. In particular, the panel's final **scientific opinion** assessed both human and animal studies submitted in response to public calls for data; previous evaluations; and additional literature that became available during and after the initial public consultation and release of a draft scientific opinion in February 2013.

"The Panel noted that although many of the studies were old and were not performed according to current standards (e.g. Good Laboratory Practice (GLP) and Organization for Economic Co-operation and Development (OECD) guidelines), they should be considered in the re-evaluation of the sweetener as long as the design of such studies and the reporting of the data were considered appropriate," explains the scientific opinion. "In its re-evaluation of aspartame, the Panel also considered the safety of its gut hydrolysis metabolites methanol, phenylalanine and aspartic acid and of its degradation products 5-benzyl-3,6-dioxo-2-piperazine acetic acid (DKP) and β -aspartame, which may be present in the sweetener as impurities."

After reviewing these data as well as 200 comments replying to its draft opinion, the ANS Panel ruled out "a potential risk of aspartame causing damage to genes and inducing cancer," and concluded that the food additive "does not



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harm the brain, the nervous system or affect behavior or cognitive function in children or adults." It also reported "no risk to the developing fetus from exposure to phenylalanine derived from aspartame at the current ADI."

"This opinion represents one of the most comprehensive risk assessments of aspartame ever undertaken," said ANS Panel Chair Alicja Mortensen. "It's a step forward in strengthening consumer confidence in the scientific underpinning of the EU food safety system and the regulation of food additives." See EFSA Press Release, December 10, 2013.

Meanwhile, the Center for Science in the Public Interest (CSPI) has already criticized the risk assessment as flawed, claiming that the scientific opinion failed to properly consider animal studies conducted by the Ramazzini Institute that purportedly linked aspartame to rare kidney tumors in rats. Although EFSA panels ultimately identified methodological problems with these reports, CSPI faulted the agency for disputing the laboratory's diagnosis of lymphoma or leukemia in two animal studies.

"Three large, independent studies that found a link between aspartame and cancer are far more reliable than inferior industry-funded studies that do not even meet current standards and did not find a link," opined CSPI Senior Scientist Lisa Lefferts. "Yet the EFSA dismissed the independent studies, effectively whitewashing valid safety concerns. Aspartame just isn't worth the risk it poses to consumers." See CSPI News Release, December 10, 2013.

Connecticut Governor Holds Ceremonial GM Labeling Bill Signing

While Connecticut enacted legislation (H.B. 6527) in June 2013 requiring that foods containing genetically modified (GM) ingredients be labeled as such, once neighboring states have adopted similar laws, Governor Daniel Malloy (D) held a ceremonial bill signing in a health-food café in Fairfield on December 11, 2013. Now known as Public Act 13-183, the bill's provisions are summarized in Issue 486 of this *Update*. The governor said, "I am proud that leaders from each of the legislative caucuses can come together to make our state the first in the nation to require the labeling of GMOs. The end result is a law that shows our commitment to consumers' right to know while catalyzing other states to take similar action." See Press Release of Governor Daniel Malloy, December 11, 2013.

LITIGATION

Court Dismisses Claims Against WhiteWave with Prejudice

Citing the settlement of similar class claims in a Florida court and plausibility issues, a federal court in California has dismissed with prejudice a putative class action alleging that companies misbrand products with an evaporated



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cane juice (ECJ) designation and sell products not meeting the standard of identity for yogurt and milk, including soymilk and almond milk. *Ang v. WhiteWave Foods Co.*, No. 13-1953 (U.S. Dist. Ct., N.D. Cal., decided December 10, 2013). According to the court, the California plaintiffs, who filed their complaint after the class action was filed in Florida, were members of the class, knew about that settlement and had an opportunity to, but did not, object to it. Thus, the court found their ECJ and yogurt claims barred by res judicata.

As for claims that consumers are confused by use of the terms "soymilk," "almond milk," and "coconut milk" in the names of Silk® products, an alleged violation of the standard of identify for milk, the court found that (i) the Food and Drug Administration may not have yet arrived at a consistent interpretation of its milk description as to milk substitutes; and (ii) these names accurately describe the products and "clearly convey the basic nature and content of the beverages, while clearly distinguishing them from milk that is derived from dairy cows." Analogizing the plaintiffs' claims to those raised in unsuccessful litigation alleging that "Cap'n Crunch's Crunch Berry" cereal label misled consumers to believe the product contained real fruit, the court said consumer confusion was "highly improbable."

The court further stated, "Plaintiffs essentially allege that a reasonable consumer would view the terms 'soymilk' and 'almond milk,' disregard the first words in the name, and assume that the beverages came from cows. The claim stretches the bounds of credulity. Under Plaintiffs' logic, a reasonable consumer might also believe that veggie bacon contains pork, that flourless chocolate cake contains flour, or that e-books are made out of paper."

Meanwhile, WhiteWave Foods Co. has announced that it will acquire Earthbound Farm, "one of the country's leading organic food brands." The \$600-million cash deal will expand WhiteWave's dairy product offerings to an extensive line of organic produce, both raw and frozen. Subject to regulatory approvals and closing conditions, the agreement is expected to be completed in the first quarter of 2014. See WhiteWave Foods Co. News Release, December 9, 2013.

Court Approves Class Certification in Fraud Suit Against Olive Oil Co.

A federal court in New York has certified a consumer-fraud class action against Kangadis Food Inc., d/b/a The Gourmet Factory, alleging that the company falsely labels its products as "100% Pure Olive Oil" when they actually contain the industrially processed substance "olive-pomace oil," "olive-residue oil" or "Pomace." Ebin v. Kangadis Food Inc. d/b/a The Gourmet Factory, No. 13-2311 (U.S. Dist. Ct., S.D.N.Y., order entered December 11, 2013). The court approved the named plaintiffs as class representatives and indicated that a memorandum stating the reasons for its ruling "will issue in due course." Additional information about the lawsuit appears in Issue 492 of this *Update*.



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On the day the order issued, the court also filed a memorandum explaining its reasons for dismissing certain claims and allowing others to proceed in an order entered in July 2013. The court dismissed for insufficient pleading the plaintiffs' New York breach of warranty claims, express and implied; breach of implied warranty of fitness for a particular purpose under New Jersey law; and unjust enrichment under New York and New Jersey law.

The court refused to dismiss claims relating to labeling a product as "100%" Pure Olive Oil" because it "is a written warranty sufficient to survive a motion to dismiss" and because every relevant labeling standard regards the defendant's products as mislabeled. According to the court, the plaintiffs adequately pleaded "that Kangadis's label breaches the implied warranty of merchantability under New Jersey law." The court also found sufficiently pleaded claims that the company violated the deceptive acts and practices statutes of both states and claims alleging negligent misrepresentation and fraud under New York and New Jersey law. In the court's view, "the Complaint fully specifies who made the false statement (here, Kangadis), what the false statement was (the labeling describing the product as '100% Pure Olive Oil'), when the statement was made (in late 2012 or early 2013), where the statement was made (on the Capatriti containers plaintiffs purchased from the local grocery store), and how that statement was false (the product was Pomace rather than pure olive oil)."

False ECJ Claims Against Amy's Kitchen Narrowed

A federal court in Florida has dismissed putative class claims in a consumerfraud lawsuit to the extent they involve allegedly false "evaporated cane juice" (ECJ) labeling on Amy's Kitchen food products that the named plaintiff did not purchase, but has otherwise allowed the remaining claims to proceed. Reilly v. Amy's Kitchen, Inc., No. 13-21525 (U.S. Dist. Ct., S.D. Fla., order entered December 9, 2013).

According to the court, in the Eleventh Circuit, plaintiffs have standing to assert claims based only on products they actually purchase thus rejecting the plaintiff's argument that (i) she could bring claims involving products nearly identical to the purchased product and (ii) the issue was one of typicality and representation best resolved at the class certification stage. Because the plaintiff purchased just three Amy's Kitchen products with ECJ listed as an ingredient on the label, she will be unable to pursue claims as to 57 other products.

The court rejected the company's arguments that (i) the plaintiff failed to state a claim for per se violation of the Florida Deceptive and Unfair Trade Practices Act (FDUTPA); (ii) the court should dismiss the action and defer to the Food and Drug Administration under the primary jurisdiction doctrine; (iii) the plaintiff failed to plead any facts supporting the claim that use of ECJ on a product label is misleading, finding that whether consumers were misled is a question of fact that cannot be resolved in a motion to dismiss; (iv) the plaintiff's allegations about monetary losses and price inflation are too speculative to constitute an injury in



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fact; (v) ECJ is an ingredient's common or usual name, noting that "the mere fact that the term ECJ was trademarked also fails to establish that Defendant's use of this name was not false and misleading"; and (vi) the plaintiff's unjust enrichment claim fails because it is based on the same conduct as her FDUTPA claim.

Court Further Trims "Healthy" and "Wholesome" Claims for Snacks

A federal court in California has dismissed a number of claims with prejudice in the second amended complaint filed on behalf of a putative class alleging that the promotion of various snack products made by Procter & Gamble Co. and Kellogg Co. is false and misleading. Samet v. Procter & Gamble Co., No. 12-1891 (U.S. Dist. Ct., N.D. Cal., San Jose Div., order entered December 10, 2013). The complaint challenges "0g Trans Fat," "evaporated cane juice (ECJ)," "healthy and wholesome," and "fortification" claims for snack chips, riblets and mixed berry snacks. The plaintiffs also bring slack-fill claims that survive.

The court will allow "0g Trans Fat" claims to proceed, finding the allegations sufficient, but dismissed them with prejudice as to Pringles chip products that are "reduced fat" or sold in 100-calorie packs, finding that they have "insufficient fat content to require the disclosure in question." The court also dismissed with prejudice causes of action based on "healthy" and "wholesome" statements relating to Pringles for twice failing to meet "even the simplest 8(a) pleading standard." The plaintiffs apparently relied on Website statements but failed to provide screen shots or information about where on the Websites the statements are made. And the court dismissed with prejudice claims relating to the vitamin fortification of Kellogg's Fruity Snacks, finding that applicable federal regulations merely "urge" companies to follow certain guidelines and thus that more stringent state law requirements are preempted.

Still, the court will allow all remaining claims to proceed, disagreeing with the defendants that they were otherwise preempted and finding that certain matters, such as reasonable consumer reliance, were inappropriate for resolution on a motion to dismiss.

Ruby Tuesday to Pay \$575,000 to Settle EEOC Age-Bias Suit

Some four years after the U.S. Equal Employment Opportunity Commission (EEOC) accused several Ruby Tuesday, Inc. restaurants in Pennsylvania and Ohio of engaging in a pattern or practice of age discrimination against 40-year-old or older job applicants, Ruby Tuesday agreed to settle the claims, without admitting any liability. EEOC v. Ruby Tuesday, Inc., No. 09-1330 (U.S. Dist. Ct., W.D. Pa., consent decree approved December 9, 2013).

The company will pay \$575,000 into a qualified settlement fund account to provide back pay and statutory damages to eligible claimants, designate a decree compliance monitor to ensure compliance with the terms of the agreement, establish hiring and recruitment goals for individuals in the protected age group,



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adopt and maintain an electronic applicant tracking system, audit compliance, and report to EEOC. The company has also agreed to provide sufficient training regarding the decree, will report age-discrimination complaints to EEOC and retain certain records to resolve claims that it failed to maintain employment records as required by law.

Court Agrees to Postpone Criminal Trial Against Peanut Co. Owner/Employees

A federal court in Georgia has called for the prosecutors and defendants in a criminal action arising from the 2009 nationwide *Salmonella* outbreak linked to the peanut products made by the Blakely, Georgia, Peanut Corp. of America to propose a scheduling order and trial dates between July 7, 2014, and August 2014. *United States v. Parnell*, No. 13cr12 (U.S. Dist. Ct., M.D. Ga., order entered December 11, 2013). The case had been set for trial in February. The court also agreed to review *in camera* affidavits and other supporting documents "to demonstrate why [the defendants'] defenses are antagonistic and mutually exclusive." Former Peanut Corp. owner Stewart Parnell has requested that the court sever the proceedings which have been brought jointly against him and several company employees. The court further reserved ruling on pending discovery motions and the government's motion for a competency hearing as to Stewart Parnell.

Suit Filed in Israeli Court Against McDonald's

Mafrash Attias has reportedly filed a putative class action against McDonald Israel alleging that the company cheats consumers by putting less ice cream into its ice cream cups. According to the complaint, Attias found that the contents of two sizes of the company's "Ice Blast" product, with an NIS 2 shekel price (US 50 cents) difference, are nearly always barely distinguishable in weight or volume. He has also apparently alleged that the large size sometimes holds less ice cream than the less expensive smaller alternative and that the McDonald's marketing pitch is to encourage customers to "size-up" for "only" 2 additional shekels. The named plaintiff reportedly submitted samples from several McDonald's stores to the independent, Jerusalem-based Forensic Science Institute for testing. According to a news source, its report is attached to the complaint. The plaintiff seeks NIS 24.5 million (about US\$7 million). See Jewish Business News, December 9, 2013.

OTHER DEVELOPMENTS

FWW Report Suggests That Choice at the Grocery Store Is a Mirage

A December 2013 Food & Water Watch (FWW) <u>report</u> titled "Grocery Goliaths: How Food Monopolies Impact Consumers" examines consolidation in the food industry and how this affects "every link in the food chain, from farm to fork." Analyzing 100 types of grocery products from cereals and soft drinks to frozen meals and crackers, the report suggests that the top four or fewer food compa-



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nies control a "substantial majority of the sales of each item." It further contends that the largest food manufacturers often offer multiple brands of the same food product, "giving consumers the false impression that they are choosing between competing products when in fact all the sales can go to the same parent company."

Noting that during the past few years as food companies and supermarket chains have consolidated, the illusion of choice has coincided with higher grocery bills, FWW Executive Director Wenonah Hauter said, "you might think you're a savvy shopper, supporting independent businesses when you buy a product from the organic foods aisle of your grocery store, but chances are you're really being duped by a small handful of grocery industry Goliaths hiding behind an array of brands and pretty packaging."

The report suggests that "intense consolidation throughout the grocery industry" limits not just where consumers can shop, but what they can buy, and claims that mergers and acquisitions have increased as the economy emerges from the recession. Concluding that consumers have "little chance to make informed decisions and comparison shop in a grocery industry that is dominated by big supermarket retailers and manufacturers," FWW suggests that government regulators "step in and level the playing field to make sure that there is some semblance of competition and a chance for innovative, small or local food companies to get on store shelves." To that end, the nonprofit has asked Congress and the Federal Trade Commission to, among other things, (i) enact a moratorium on grocery chain mergers; (ii) reject sales of food companies that increase consolidation; and (iii) launch a federal investigation into the impact of consolidation on price and consumer choice. See FWW News Release, December 5, 2013.

Nestle Presentation to Target Role of SSBs in Escalating Obesity Rates

New York University Nutrition Professor Marion Nestle will join other speakers at Cornell University's "Festschrift in Honor of Per Pinstrup-Andersen: New Directions in the Fight Against Hunger and Malnutrition," **slated** for December 13-14, 2013, in Ithaca, New York. She and Cornell's Malden Nesheim will present their paper, "The Internationalization of the Obesity Epidemic: The Case of Sugar Sweetened Sodas." Contending that obesity rates have increased in tandem with the consumption of sugar-sweetened beverages (SSBs) and that "many researchers are confident that the evidence justifies public health efforts to reduce children's soda intake," the co-authors report that efforts are underway globally to curtail SSB consumption despite pushback and purportedly aggressive foreign-marketing campaigns by U.S. SSB companies. Those efforts include taxes on SSBs, restrictions on marketing them in schools, advocacy, and education.



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SCIENTIFIC/TECHNICAL ITEMS

New Study Asserts That Organic Milk Contains More Healthy Fatty Acids

A recent <u>study</u> has reportedly revealed that organic milk contains a healthier balance of omega-6 and omega-3 fatty acids compared with milk from cows raised on conventionally managed dairy farms. Benbrook, et al., "Organic Production Enhances Milk Nutritional Quality by Shifting Fatty Acid Composition: A United States–Wide, 18-Month Study," *PLOS One*, December 9, 2013. The finding, writes *New York Times* writer Kenneth Chang, is the "most clearcut instance of an organic food's offering a nutritional advantage over its conventional counterpart," as "studies looking at organic fruits and vegetables have been less conclusive."

According to the researchers, who note that the ratio of omega-6 to omega-3 fatty acids in the U.S. diet have risen to "nutritionally undesirable levels," the healthier fatty acid profile of organic milk is likely a result of cows foraging on grass. By comparison, cows fed a corn-based diet apparently produce milk that contains higher levels of omega-6 fatty acids, which previous studies have associated with cardiovascular disease, metabolic syndrome and diabetes. "There's really no debate []," said study author Charles Benbrook, a research professor at the Center for Sustaining Agriculture and Natural Resources at Washington State University. "When you feed dairy cows more grass, you improve the fatty acid profile of the milk."

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FOOD & BEVERAGE LITIGATION UPDATE

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.

SHB 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.

SHB lawyers have served as general counsel for feed, grain, chemical, and fertilizer associations and have testified before state and federal legislative committees on agribusiness issues.



