Having trouble reading this email? View it in your browser.

ISSUE 649 | OCTOBER 06, 2017

LEGISLATION, REGULATIONS & STANDARDS

OIG Report Suggests Improvements to FSMA Enforcement

A report from the Office of the Inspector General (OIG) of the U.S. Department of Health and Human Services has concluded that the Food and Drug Administration (FDA) fails to adequately conduct or follow up on food-safety inspections required by the 2011 Food Safety Modernization Act (FSMA). OIG reportedly found that while FDA is "on track" to meet inspection timeframes for the initial mandate, future inspection timeframes are two years shorter and FDA may not be able to meet them.

The report also stated that FDA did not always take action when it found significant safety violations and that the agency "commonly relied on facilities to voluntarily correct the violations" instead of taking advantage of FSMA administrative tools. FDA "consistently failed to conduct timely followup inspections" to ensure facilities made the necessary corrections, the report noted. In addition, "inaccuracies" in domestic facility data caused FDA to attempt inspections at the facilities of closed companies. According to the OIG report, FDA concurred with the recommendations to improve inspections and follow-up procedures.

San Francisco Passes Ordinance Requiring Grocers To Report Antibiotics In Meat and Poultry

The San Francisco Board of Supervisors has unanimously approved an ordinance that will require certain grocery stores to report the use of antibiotics in raw meat and poultry. Scheduled to take effect in April 2018, the ordinance requires grocers that own or operate 25 or more stores to submit annual reports that include the purposes for which the antibiotics were used, the number of animals raised, the total volume of antibiotics administered and

SHARE WITH TWITTER | LINKEDIN

SUBSCRIBE

PDF ARCHIVES

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.

For additional information about Shook's capabilities, please contact

Mark Anstoetter
816.474.6550
manstoetter@shb.com

Madeleine McDonough
816.474.6550
202.783.8400
mmcdonough@shb.com

whether the use was "medically important." Grocers who violate the ordinance may be subject to fines or imprisonment.

GAO Criticizes Lack of Oversight of Antibiotic Residue Levels in Imported Seafood

A U.S. Government Accountability Office (GAO) study has criticized the U.S. Food and Drug Administration (FDA) and the Department of Agriculture's Food Safety Inspection Service (FSIS) for their failure to ensure that imported seafood does not contain unsafe levels of antibiotic or other drug residues. According to the GAO, about 90 percent of the seafood eaten in the United States is imported, and about half of imported seafood is raised on fish farms where producers treat fish to prevent infections and foodborne illnesses.

GAO makes five main recommendations: (i) FDA should pursue agreements with exporting countries to test for "drugs of concern" and residue levels; (ii) FSIS should conduct onsite audits of fish farms instead of limiting visits to government offices, commercial food processing facilities and food testing labs; (iii) FSIS should require exporting countries to include residue-monitoring plans in equivalence determinations; (iv) FDA and FSIS should collaborate to develop residue testing methods and maximum levels for imported seafood; and (v) FDA and FSIS should collaborate on testing methods and levels for imported catfish.

According to a GAO highlight report, FDA and FSIS agreed or partially agreed with some of the recommendations, although FSIS argues that it already addresses one; GAO "disagrees and believes the recommendations should be implemented."

FDA Warns Granola Company About Listing "Love" Ingredient

The U.S. Food and Drug Administration (FDA) has warned Nashoba Brook Bakery that it has misbranded its granola by listing "Love" as one of its ingredients. The warning letter informed the company that "'love' is not a common or usual name of an ingredient, and is considered to be intervening material because it is not part of the common or usual name of the ingredient." "Intervening material" refers to information that is not required in FDA labeling and can distract from required content. The letter also cited the bakery for health and sanitary violations as well as misbranding violations for whole-wheat products that contain corn meal.

Delayed Menu Labeling Compliance Date Proposed

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 U.S. Food and Drug Administration (FDA) has proposed an additional extension for compliance with the menu labeling rules required by the Affordable Care Act. Under the proposed rule, the current compliance deadline of July 26, 2018, would be extended to January 1, 2020, for manufacturers with $10 million or more in annual food sales; for manufacturers with less than that amount, the date would be extended to January 1, 2021.

NAD Recommends French's Discontinue "Greatest Tasting Ketchup" Ads

The National Advertising Division (NAD) has recommended that French's Food Company pull Facebook and print advertising claiming that its ketchup and mustard products are "better" than their competitors, preferred by children and free from high-fructose corn syrup.

NAD found that French's was unable to substantiate several claims—"Tastier Meals," "Greatest Tasting Ketchup" and "America's #1 mustard has the greatest tasting ketchup"—and could not support the contention that the absence of GMO ingredients or high-fructose corn syrup made the products "better" than those of competitors. NAD also noted that the Facebook ad did not refer to any improvements or changes in French's products that would make them "better" than previous versions. French's has agreed to discontinue the ads.

LITIGATION

Court Denies Certification in Tito's "Handmade" Suit

A New York federal court has denied class certification to a plaintiff alleging that Fifth Generation, Inc. falsely advertised Tito's Handmade Vodka, ruling that the plaintiff failed to propose a model to measure the alleged price premium. *Singleton v. Fifth Generation, Inc.*, No. 15-474 (N.D.N.Y., entered September 27, 2017). The court noted that the plaintiff had satisfied certification requirements, but because he testified that he did not intend to purchase the product again, he had no standing to seek injunctive relief. In addition, the plaintiff's failure to provide a "suitable model to measure the alleged price premium for Tito's vodka due to the 'handmade representation'" led the court to rule that common issues did not predominate over individual ones. Additional details appear in Issue 590 of this *Update*.

Federal Court Dismisses Energy Cookie Suit

An Illinois federal court has dismissed with prejudice a lawsuit alleging that Mondelez International falsely advertises Belvita breakfast biscuits and cookies as providing "four hours of

nutritious steady energy.” *Spector v. Mondelez Int’l*, No. 15-4298 (E.D. Ill., entered September 27, 2017). The court held that the plaintiff failed to allege plausible facts to support her claim of false advertising and could not “rely on mere allegation of falsity, which is conclusory and thus not entitled to the assumption of truth.” The plaintiff "appears to draw her own conclusions” about daily calorie requirements, the court noted, and her arguments about variability of metabolism that would cause a consumer to receive fewer than four hours of energy “proceed as if the inherent inconsistency is self-evident.”

Putative Class Action Alleges “Ready-to-Eat” Cookie Dough Caused Illnesses

Cookie Do Inc., which sells raw cookie dough desserts, allegedly caused consumers to feel gastrointestinal pain after they ate the products, which are advertised as “ready to eat,” with “NO chance of salmonella” and “NO chance of food-borne illness.” *Canigiani v. Cookie Do, Inc.*, No. 17-7182 (S.D.N.Y., filed September 21, 2017). The complaint cites Yelp posts to argue that other consumers experienced similar symptoms and illnesses. Claiming violations of New York consumer-protection laws, fraudulent concealment, fraudulent inducement, negligent misrepresentation and unjust enrichment, the plaintiffs seek class certification, damages, injunctive relief and attorney’s fees.

Margaritaville Challenges “It’s 1700 Hours Somewhere" Trademark Application

Jimmy Buffett’s Margaritaville Enterprises, which owns trademarks on the phrase “It’s Five O’Clock Somewhere" and several variations, has challenged The Veteran Beverage Company's application to register "It’s 1700 Hours Somewhere.” *Margaritaville Enterprises v. Veteran Beverage Co.*, No. 91236809 (T.T.A.B., filed September 22, 2017). The notice alleges that the trademark application is for beer, which is closely related to Margaritaville’s beverage and bar services marks, and that the only difference is that it shows 5:00 p.m. in military time.

Plaintiff Alleges 80 Percent Slack Fill in Fruit Bliss Packaging

Penguin Trading, Inc., the maker of Fruit Bliss organic dried fruits, faces a putative class action alleging the company’s products contain as much as 80 percent slack fill. *Buso v. Penguin Trading, Inc.*, No. 17-7025 (C.D. Cal., filed September 22, 2017). The plaintiff argues that he would not have bought Fruit Bliss’ Organic Deglet Nour Dates, sold in opaque containers, if he knew the container was “substantially empty.” Asserting violations of California consumer-protection laws, the plaintiff seeks class

certification, compensatory and punitive damages, injunctive relief and attorney's fees.

Gatorade Agrees Not to Assert that Water is Bad For Athletes

In a settlement with California, The Gatorade Co. has agreed to stop suggesting that drinking water harms athletes. *California v. Gatorade Co.*, No. BC676734 (Cal. Super. Ct., Los Angeles Cty., entered September 21, 2017). Gatorade launched a mobile game featuring Usain Bolt that featured the runner speeding up when he ran over the Gatorade logo and slowing down when he touched water droplets. The complaint alleged that players were instructed to "Keep Your Performance Level High By Avoiding Water" and claimed Gatorade violated state unfair competition and false advertising laws.

Under the settlement agreement, Gatorade will no longer make the "Bolt!" app available in any form that "creates the misleading impression" that water will hinder athletic performance or that water should be avoided. Gatorade also agreed not to make "statements that disparage water or the consumption of water" and will include a provision in contracts with endorsers that "clearly and conspicuously disclose" their relationships with the company. Gatorade will also pay $180,000 to the state to be used to defray the cost of enforcement of consumer-protection laws and $120,000 to provide grants to state agencies, schools or nonprofits for "study, research or education" in childhood nutrition or the consumption of non-branded water.

SHB.COM

CHICAGO | DENVER | HOUSTON | KANSAS CITY | LONDON
MIAMI | ORANGE COUNTY | PHILADELPHIA
SAN FRANCISCO | SEATTLE | TAMPA | WASHINGTON, D.C.