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FOOD & BEVERAGE LITIGATION UPDATE

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LEGISLATION, REGULATIONS & STANDARDS

Warning Letter Provides Insight on FDA's Priorities

By Of Counsel John Johnson III

The U.S. Food and Drug Administration's (FDA) Warning Letter to Maribel's Sweets, Inc., provides an important look into how FDA is implementing the Food Safety Modernization Act (FSMA)'s Preventive Control Rule. This is the requirement that a food facility must have and implement a written food safety plan to control known or reasonably foreseeable food safety hazards. Additionally, the warning reflects that FDA continues to prioritize seeking compliance with preventive controls and sanitation practices to avoid undeclared Major Food Allergens (which we discussed in A Taste of FDA's 2021 Food Priorities: Undeclared Major Food Allergens. The list has been expanded to include sesame, which we discussed in Look Beyond the Label: How the FASTER Act Impacts Food Manufacturing).

FDA has been relatively silent about the Preventive Control Rule in 2021, issuing only four Warning Letters directly on that topic. For context, FDA issued at least more than double that number of Preventive Control Rule warnings in 2020. In addition, this year FDA has issued 47 Warning Letters about a different FSMA rule: the Foreign Supplier Verification Program (FSVP), the requirement that importers perform a risk-based foreign supplier approval verification activity.

The numerous FSVP Warning Letters share a similar tune: FDA typically cites that the importer failed to have an FSVP and that they must create a compliant program. Although the FSVP

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process requires conducting a hazard analysis and evaluating the foreign supplier's controls for the identified food safety hazards, FDA's FSVP Warning Letters do not provide much insight into the agency's opinion about which hazards require a preventive control.

In the Maribel's Sweets letter, FDA not only cited the facility for not having a Food Safety Plan (which requires a hazard analysis) but also proceeded to perform a hazard analysis for the facility. This level of specificity provides valuable insight into FDA's expectations given that draft Preventive Control Rule guidance was published in January 2018 and several important chapters have been "coming soon" for three years, including Chapter 11 (Food Allergen Controls).

This warning is a reminder that a facility should expect an FDA inspection after a recall, which also happened in two of the other three 2021 Preventive Control Rule Warning Letters. While FDA's post-recall facility inspection will focus on the underlying issues associated with the recall (such as allergen controls and sanitation practice), FDA will look at the entire food safety and sanitation program for compliance. So while FDA was relatively silent in 2021 about the Preventive Control Rule and allergens in its Warning Letters, this end-of-the-year letter emphasizes that this remains a priority.

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LITIGATION

"Fudge-Covered Oreos" Missing Real Fudge, Alleges Plaintiff

A consumer has alleged that Mondelez Global LLC misleads consumers by marketing its Oreo Fudge Cremes as "fudge covered" because the topping covering the cookies lacks milkfat. *Leonard v. Mondelez Global LLC*, No. 21-10102 (S.D.N.Y., filed November 28, 2021). The complaint lists several recipes for fudge to support its argument that fudge requires the presence of milkfat, while Mondelez produces its "fudge" with palm oils and nonfat milk. "Fudge covered cookies made with fudge ingredients such as dairy components, containing milkfat, are not a rare or pricy delicacy that would make a reasonable consumer 'double check' their presence by scouring the packaging," the plaintiff argues. "The front label creates an erroneous impression that essential fudge ingredients are present." The complaint compares the "fudge" ingredients to the "truthful and non-misleading 'Mint' representations, through

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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

words and pictures of peppermint leaf," which are accurate because the product contains peppermint oil, the plaintiff explains.

The plaintiff alleges violations of New York's consumer-protection statutes and the Magnuson-Moss Warranty Act as well as negligent misrepresentation, fraud and unjust enrichment and seeks class certification, injunctive relief, damages and attorney's fees.

Baby Formula Comparison To Breast Milk Confuses Consumers, Lawsuit Alleges

A plaintiff has filed a putative class action alleging Abbott Laboratories Inc.'s Similac Pro-Advance infant formula is advertised as the company's "closest formula to breastmilk," allegedly misleading consumers into believing that the formula can convey the same benefits as breast milk. *Conner v. Abbott Labs. Inc.*, No. 21-1463 (S.D. Ill., Benton Div., filed November 20, 2021). "Infant formula is critical for children whose mothers are unable to breastfeed or produce enough milk," the complaint asserts. "Marketing of infant formula sometimes goes beyond meeting those limited needs, to tout itself as an equivalent to breast milk. The representations that the Product contains lutein, vitamin E, DHA, and HMO—Human Milk Oligosaccharide, and the claim, 'Our Closest Formula to Breast Milk,' imply the inclusion of these constituents can approach the benefits from breast milk."

The plaintiff seeks class certification, injunctive relief, damages and fees for allegations of fraud, unjust enrichment, negligent misrepresentation and violations of the Magnuson-Moss Warranty Act and Illinois consumer-protection statutes.

inspections, subject to FDA, USDA and FTC regulation.

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