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MEMORANDUM

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RE: Blue Bell Creameries Enters into Negotiated Agreements with the Department of Justice to Resolve Investigations Related to Listeria Contamination in Ice Cream

On May 1, 2020, Blue Bell Creameries L.P. (“Blue Bell”) and the U.S. Department of Justice (“DOJ”) entered into two separate agreements related to the 2015 listeriosis outbreak linked to Blue Bell ice cream. This memorandum provides an overview of the negotiated agreements, the facts giving rise to the agreements, and key takeaways for the food industry. These takeaways include: (1) DOJ continues to actively pursue criminal investigations of companies in the food industry; (2) DOJ places a high interest not just on food safety, but also on the company’s communications with the public and its customers; (3) DOJ will take note of remediation efforts implemented by food manufacturers for the purposes of negotiated agreements; and (4) the False Claims Act is a statute that food manufacturers should become familiar with in short order, particularly if they sell food products to government customers.

In the first agreement with DOJ, Blue Bell agreed to plead guilty to two strict liability misdemeanors under the Federal Food, Drug, and Cosmetic Act (“FFDCA”) and pay a criminal fine and forfeiture totaling \$17.25 million. In the second agreement with DOJ, Blue Bell also agreed to pay \$2.1 million to resolve (without any admissions of liability) civil False Claims Act allegations regarding ice cream product sold to federal government customers. The total of \$19.35 million in fine, forfeiture, and civil settlement payments is the second largest amount ever paid to resolve a food safety matter.

Separately, the former president of Blue Bell was charged with seven felony counts alleging that he orchestrated a scheme to deceive certain Blue Bell customers after he learned that products from the company’s Texas factory tested positive for *Listeria monocytogenes*.

Disclosure: Hogan Lovells represented Blue Bell in connection with these matters. The information contained in this client alert is based strictly on publicly available information. Hogan Lovells does not represent the former president of Blue Bell.

Facts of the Case

In February 2015, Texas state officials notified Blue Bell that two samples of Blue Bell ice cream products tested positive for *Listeria monocytogenes*. The two samples of Blue Bell products that tested positive for *Listeria monocytogenes* were each frozen treats manufactured on a single line at the Brenham, Texas facility. Blue Bell removed those products from the marketplace.

In March 2015, the Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) linked the strain of *Listeria monocytogenes* in one of the Blue Bell ice cream products to a strain that sickened five patients at a Kansas hospital. The FDA, CDC, and Blue Bell all issued public recall notifications on March 13, 2015. In total, testing linked 10 illnesses, including three fatalities, to the consumption of Blue Bell ice cream.

Subsequent tests confirmed *Listeria monocytogenes* contamination in a product made at another Blue Bell facility in Broken Arrow, Oklahoma, which led to a second recall announcement by the company on March 23, 2015. On April 3, 2015, Blue Bell issued a public announcement that it was closing the Broken Arrow facility for cleaning.

In March and April of 2015, FDA inspectors flagged sanitation issues at the Brenham and Broken Arrow facilities, including problems with the hot water supply needed to properly clean equipment and factory conditions that could lead to insanitary conditions. On April 20, 2015, Blue Bell, following additional testing, recalled all remaining ice cream product in the market and temporarily closed all of its plants to clean and update the facilities.

Since re-opening its facilities in July (Sylacauga, AL), September (Broken Arrow, OK) and November (Brenham, TX) of 2015, Blue Bell has taken significant steps to enhance sanitation processes and enact a strict “test and hold” program to test products for *Listeria monocytogenes* prior to shipment.

Key Takeaways

On the heels of Chipotle Mexican Grill’s \$25 million settlement with the DOJ on April 21, 2020, the Blue Bell plea agreement now gives the DOJ its two largest corporate resolutions for food safety matters in the span of only two weeks. The Blue Bell case further underscores that the DOJ continues to actively pursue criminal investigations of companies in the food industry.

Additionally, the Blue Bell settlements make clear that DOJ places a high interest not just on food safety, but also on a company’s communications with the public and its customers during an outbreak or recall process. This case reinforces that DOJ and the FDA expect companies to pay close attention to FDA’s recall procedures and to communicate clearly with the public regarding the reason for removing product from the marketplace.

Moreover, despite the fine and criminal charges, the DOJ noted that it took into consideration the tremendous efforts taken by Blue Bell after the 2015 recalls to modernize and assure a first-in-class sanitation and compliance system.

Finally, the civil investigation by DOJ also marks a novel use of the False Claims Act against a food manufacturer for potential liability – liability relating to allegations of, among other things, insanitary conditions at facilities and failure to follow contractually required recall procedures – resulting from sales to government customers. The False Claims Act is a statute that food manufacturers should become familiar with in short order, particularly if they sell food products to government customers.

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Should you have any questions, please contact us.