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Blue Bell Creameries Agrees to Plead Guilty and Pay \$19.35 Million for Ice Cream Listeria Contamination – Former Company President Charged

Texas-based ice cream manufacturer Blue Bell Creameries L.P. agreed to plead guilty to charges it shipped contaminated products linked to a 2015 listeriosis outbreak, and the company's former president was charged in connection with a scheme to cover up the incident, the Justice Department announced today.

In a plea agreement filed with a criminal information in federal court in Austin, Texas, Blue Bell agreed to plead guilty to two misdemeanor counts of distributing adulterated ice cream products and pay a criminal fine and forfeiture amount totaling \$17.25 million. Blue Bell also agreed to pay an additional \$2.1 million to resolve civil False Claims Act allegations regarding ice cream products manufactured under insanitary conditions and sold to federal facilities. The total \$19.35 million in fine, forfeiture, and civil settlement payments constitutes the second largest-ever amount paid in resolution of a food-safety matter.

In a related case, Blue Bell's former president, Paul Kruse, also was charged with seven felony counts related to his alleged efforts to conceal from customers what the company knew about the *listeria* contamination.

"American consumers rely on food manufacturers to take necessary steps to provide products that are safe to eat," said Assistant Attorney General Jody Hunt of the Department of Justice's Civil Division. "The Department of Justice will take appropriate action where food manufacturers ignore poor factory conditions or fail to abide by required recall procedures when problems are discovered."

The plea agreement and criminal information filed today against Blue Bell in the U.S. District Court for the Western District of Texas alleges that the company distributed ice cream products that were manufactured under insanitary conditions and contaminated with *Listeria monocytogenes*, in violation of the Food, Drug and Cosmetic Act. According to the plea agreement, Texas state officials notified Blue Bell in February 2015 that two ice cream products from the company's Brenham, Texas factory tested positive for *Listeria monocytogenes*, a dangerous pathogen that can lead to serious illness or death in vulnerable populations such as pregnant women, newborns, the elderly, and those with compromised immune systems. Blue Bell directed its delivery route drivers to remove remaining stock of the two products from store shelves, but the company did not recall the products or issue any formal communication to inform customers about the potential *listeria* contamination. Two weeks after receiving notification of the first positive *listeria* tests, Texas state officials informed Blue Bell that additional testing confirmed *listeria* in a third product. Blue Bell again chose not to issue any formal notification to customers regarding the positive tests.

In March 2015, tests conducted by the Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) linked the strain of *listeria* in one of the Blue Bell ice cream products to a strain that sickened five patients at a Kansas hospital with listeriosis, the severe illness caused by ingestion of *listeria*-contaminated food. The FDA, CDC, and Blue Bell all issued public recall notifications on March 13, 2015. Subsequent tests confirmed *listeria* contamination in a product made at another Blue Bell facility in Broken Arrow, Oklahoma, which led to a second recall announcement on March 23, 2015.

"The health of American consumers and the safety of our food are too important to be thwarted by the criminal acts of any individual or company," said Judith A. McMeekin, Pharm.D., Associate Commissioner for Regulatory Affairs, FDA. "Americans expect and deserve the highest standards of food safety and integrity and we will continue to pursue and bring to justice those who put the public health at risk by distributing contaminated foods in the U.S. marketplace."

"This settlement demonstrates the commitment of the Defense Criminal Investigative Service and our law enforcement partners to hold companies accountable for failing to abide by important contract requirements," said Robert E. Craig Jr., Special Agent in Charge of the DCIS Mid-Atlantic Field Office. "This case has been particularly concerning because of the disregard of basic food safety rules and the impact those actions can have on the health and safety of the Defense Department's service members and their families."

"The health and safety of our military members and their families is critical to the Department of Defense and mission readiness," said Michael C. Mentavlos, Special Agent in Charge of the DCIS Southwest Field Office. "We take all criminal acts, including those that raise grave health concerns, seriously, and DCIS will always place a premium on the well-being of our service members, their dependents, and our veterans."

According to the plea agreement with the company, FDA inspections in March and April 2015 revealed sanitation issues at the Brenham and Broken Arrow facilities, including problems with the hot water supply needed to properly clean equipment and deteriorating factory conditions that could lead to insanitary circumstances. Blue Bell temporarily closed all of its plants in late April 2015 to clean and update the facilities. Since re-opening its facilities in late 2015, Blue Bell has taken significant steps to enhance sanitation processes and enact a program to test products for *listeria* prior to shipment.

According to the allegations filed against Kruse, Blue Bell's former president allegedly 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*. Kruse specifically is asserted to have directed other Blue Bell employees to remove potentially contaminated products from store freezers without notifying retailers or consumers about the real reason for the withdrawal. Kruse also is alleged to have directed employees to tell customers who asked why products were removed that there had been an unspecified issue with a manufacturing machine instead of that samples of the products had tested positive for listeria.

The civil False Claims Act settlement with the company resolves allegations that Blue Bell shipped ice cream products manufactured in insanitary conditions to U.S. facilities, and later failed to abide by contractually required recall procedures when its employees removed products from federal purchasers' freezers without properly disclosing details about the potentially contaminated ice cream to the appropriate federal officials.

The allegations filed against Kruse merely assert that crimes have been committed. All defendants are presumed innocent until proven guilty beyond a reasonable doubt.

Except as admitted in the plea agreement, the False Claims Act claims resolved by the settlement with the company are allegations only and there has been no determination of liability.

Trial Attorneys Patrick Hearn and Matt Lash of the Civil Division's Consumer Protection Branch prosecuted the case with assistance from Shannon Singleton and Michael Varrone of the FDA's Office of Chief Counsel. The criminal investigation was conducted by the FDA's Office of Criminal Investigations and the Department of Defense's DCIS. The U.S. Attorney's Office for the Western District of Texas provided substantial assistance.

The civil False Claims Act investigation was led by Trial Attorney Michael Podberesky of the Civil Division's Commercial Litigation Branch, with investigative support from the Department of Defense's DCIS.

For more information about the enforcement efforts of the Consumer Protection Branch and the Fraud Section of the Commercial Litigation Branch, visit their websites at <http://www.justice.gov/civil/consumer-protection-branch> and <https://www.justice.gov/civil/fraud-section>.

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