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FDA Investigates Listeria monocytogenes in Ice Cream Products from Blue Bell Creameries

June 10, 2015

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The U.S. Food and Drug Administration along with the Centers for Disease Control and Prevention (CDC) and state and local officials are investigating an outbreak of listeriosis potentially linked to certain Blue Bell Creameries single serving ice cream products. Listeriosis is caused by the bacterium Listeria monocytogenes.

Update: June 10, 2015

The [FDA has released information](#) ([//7993/20170404202435/https://www.fda.gov/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORAElectronicReadingRoom/ucm446102.htm](https://www.fda.gov/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORAElectronicReadingRoom/ucm446102.htm)) on inspections conducted at Blue Bell Creameries facilities including the laboratory results for the environmental and product samples collected by the FDA during its inspections of the Blue Bell Creameries production facilities in Brenham, Texas, Broken Arrow, Okla. and Sylacauga, Ala. in 2015.

What is the Problem and What is Being Done About It?

CDC reports (<https://wayback.archive-it.org/7993/20170404202435/http://www.cdc.gov/listeria/outbreaks/ice-cream-03-15/index.html>) that as of April 20, 2015, a total of ten patients infected with several strains of *Listeria monocytogenes* were reported from four states: Arizona (1), Kansas (5), Oklahoma (1), and Texas (3). Illness onset dates ranged from January 2010 through January 2015. All ten patients were hospitalized. Three deaths were reported from Kansas.

The **CDC (<https://wayback.archive-it.org/7993/20170404202435/http://www.cdc.gov/listeria/outbreaks/ice-cream-03-15/index.html>)** and the Kansas Department of Health and Environment report that there are five patients who were treated in a single hospital in Kansas and who were infected with one of four rare strains of *Listeria monocytogenes*. Three of these strains, which are highly similar, have also been found in products manufactured at the Blue Bell Creameries production facility in Brenham, Texas. The most recent illness onset date was January 2015.

FDA was notified that the three strains related to the illnesses reported in Kansas and four other rare strains of *Listeria monocytogenes* were found in samples of Blue Bell Creameries single serving Chocolate Chip Country Cookie Sandwich and the Great Divide Bar ice cream products collected by the South Carolina Department of Health & Environmental Control during routine product sampling at a South Carolina distribution center, on February 12, 2015. These products are manufactured at Blue Bell Creameries' Brenham facility.

The Texas Department of State Health Services subsequently collected product samples from the Blue Bell Creameries Brenham facility. These samples yielded *Listeria monocytogenes* from the same products tested by South Carolina and a third, single-serving ice cream product, Scoops, which is also made on the same production line.

According to the Kansas Department of Health and Environment, hospital records available for four patients show that all were served ice cream from Blue Bell Creameries' prepackaged, single-serving products and milkshakes made from these products. The hospital receives ice cream manufactured by Blue Bell Creameries, although it is not confirmed that the hospital receives ice cream only from the Brenham facility.

On March 13, 2015, Blue Bell Creameries reported that it had removed the affected ice cream products from the market by picking it up directly from the retailers and hospital settings it serves. The company has also shut down the production line where the products were made.

As part of the investigation, the Kansas Department of Health and Environment (KDHE), and the Kansas Department of Agriculture (KDA), collected environmental samples, which are swabs from surfaces likely to come in contact with food, from the hospital kitchen.

They also collected samples of containers of Blue Bell ice cream still on hand at the hospital. Analysis of the environmental samples did not detect the presence of *Listeria monocytogenes*. However, one sample taken from a Blue Bell 3-ounce single serving chocolate ice cream cup manufactured in Blue Bell's Broken Arrow, Okla., plant did show the presence of *Listeria monocytogenes*. On March 22, 2015, state and federal authorities notified Blue Bell of this finding.

The CDC reported that three patients reported from Texas had a *Listeria monocytogenes* strain that is highly related to the strains found in a sample taken from a Blue Bell 3-ounce single serving chocolate ice cream cup made at the company's facility in Broken Arrow, Okla. Two additional patients, one from Arizona and one from Oklahoma, were confirmed by CDC to be part of the outbreak through whole genome sequencing which showed their strains of *Listeria monocytogenes* to be highly related to strains found in the Broken Arrow facility.

On March 23, 2015, Blue Bell Creameries issued a second recall, recalling three flavors of 3 oz. institutional/food service ice cream cups—chocolate (SKU #453), strawberry (SKU #452) and vanilla (SKU #451)—with tab lids because they have the potential to be contaminated with *Listeria monocytogenes*.

These products were distributed in Alabama, Arizona, Arkansas, Colorado, Florida, Georgia, Illinois, Indiana, Kansas, Kentucky, Louisiana, Mississippi, Missouri, Nevada, New Mexico, North Carolina, Ohio, Oklahoma, South Carolina, Tennessee, Texas, Virginia and Wyoming via food service accounts. The company reports that these products are not sold via retail outlets such as convenience stores and supermarkets, and this initial recall did not include Blue Bell Ice Cream half gallons, pints, quarts, 3 gallons or other 3 oz. cups. The product was sold to schools, nursing homes, and hospitals.

On April 3, 2015, Blue Bell Creameries **announced** (https://wayback.archive-it.org/7993/20170404202435/http://cdn.bluebell.com/BB_withdrawal) (<https://wayback.archive-it.org/7993/20170404202435/http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm>) that the firm had voluntarily suspended operations at its Broken Arrow, Okla., plant.

On April 7, 2015, FDA notified Blue Bell Creameries of Brenham, Texas, that *Listeria monocytogenes* was present in samples of Blue Bell Banana Pudding Ice Cream pints. FDA collected the samples as part of a joint inspection with the Oklahoma Department of Agriculture, Food and Forestry (ODAFF) of the Broken Arrow plant which began on March 23, 2015. During the inspection, the ODAFF collected a sample showing the presence of *Listeria monocytogenes* from a 3 oz. Blue Bell chocolate ice cream cup with a tab lid, which was part of an earlier recall by Blue Bell Creameries.

On April 7, 2015, Blue Bell Creameries expanded the recall of ice cream manufactured in its Broken Arrow, Okla., plant to include additional products that have the potential to be contaminated with *Listeria monocytogenes*. The company has reported that the recalled products were manufactured on the same production line that produced the ice cream that showed the presence of *Listeria monocytogenes* and that the products were manufactured between February 12, 2015, and March 27, 2015.

The products being recalled are distributed to retail outlets, including food service accounts, convenience stores and supermarkets in Alabama, Arizona, Arkansas, Colorado, Florida, Georgia, Illinois, Indiana, Kansas, Kentucky, Louisiana, Mississippi, Missouri, Nevada, New Mexico, North Carolina, Ohio, Oklahoma, South Carolina, Tennessee, Texas, Virginia, and Wyoming.

Additionally, Blue Bell Creameries has reported that on April 4, 2015, the firm began working with retail outlets to remove all products produced in Broken Arrow, Okla., from their service area. These products are identified with a code date ending in O, P, Q, R, S or T located on the bottom of the carton.

On April 20, 2015, Blue Bell Creameries of Brenham, Texas, voluntarily expanded its recall to include all of its products currently on the market because they have the potential to be contaminated with *Listeria monocytogenes*. Samples taken by the firm showed the presence of *Listeria monocytogenes* in Chocolate Chip Cookie Dough Ice Cream half gallons produced on March 17 and March 27, 2015. Although FDA environmental sampling has not shown the presence of *Listeria monocytogenes* on food contact surfaces in any Blue Bell facilities, sampling identified the presence of *Listeria monocytogenes* in other areas of the Blue Bell production facilities in Broken Arrow, Okla., and in Sylacauga, Ala.

Blue Bell Creameries has announced that on Monday, April 27, the firm would carry out an intensive cleaning and training program at all of its production facilities.

The inspectional observations of the most recent completed FDA inspections at the Blue Bell production facilities in Brenham, Texas, Broken Arrow, Okla., and Sylacauga, Ala. are available:

- [Blue Bell Creameries Inc, Sylacauga, AL 483 Issued 04/30/15 \(PDF - 1MB\)](https://wayback.archive-it.org/7993/20170404202435/http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM445810.pdf) (<https://wayback.archive-it.org/7993/20170404202435/http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM445810.pdf>)
- [Blue Bell Creameries, L.P. Brenham, TX, 483 Issued 05/01/15 \(PDF - 1023KB\)](https://wayback.archive-it.org/7993/20170404202435/http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM446107.pdf) (<https://wayback.archive-it.org/7993/20170404202435/http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM446107.pdf>)
- [Blue Bell Creameries, LP, Broken Arrow, OK 483 Issued 04/23/15 \(PDF - 2.6MB\)](https://wayback.archive-it.org/7993/20170404202435/http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM445811.pdf) (<https://wayback.archive-it.org/7993/20170404202435/http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM445811.pdf>)

The FDA has moved quickly to investigate this issue and learn as much as possible to prevent additional people from becoming ill. We recognize that people will be concerned about these illnesses, and we will continue to provide updates and advice.

On May 14, 2015, [Blue Bell Creameries announced](https://wayback.archive-it.org/7993/20170404202435/http://cdn.bluebell.com/the_little_creamery/press_releases/tx-ok-agreement) (https://wayback.archive-it.org/7993/20170404202435/http://cdn.bluebell.com/the_little_creamery/press_releases/tx-ok-agreement) (<https://wayback.archive-it.org/7993/20170404202435/http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm>) that it has entered into voluntary agreements with the Texas Department of State Health Services and the Oklahoma Department of Agriculture, Food, and Forestry outlining a series of steps and actions Blue Bell will take as part of its efforts to bring Blue Bell ice cream products back to market. According to Blue Bell "the actions include rigorous facility cleaning and sanitizing, revised testing protocols, revised production policies and procedures designed to prevent future contamination, and upgraded employee training initiatives." The firm also states that the agreements include provisions specific to addressing Listeria, including:

- Conducting root cause analyses to identify its potential or actual sources;
- Retaining an independent microbiology expert to establish and review controls to prevent the future introduction of Listeria;
- Notifying the Texas and Oklahoma health agencies promptly of any presumptive positive test result for Listeria monocytogenes found in ingredients or finished product samples, and providing the state agencies full access to all testing;
- Ensuring that the company's Pathogen Monitoring Program (PMP) for Listeria in the plant environment outlines how the company will respond to presumptive positive tests for Listeria species; and, Instituting a "test and hold" program to assure that products are safe before they are shipped or sold.

On May 20, 2015, the Food and Drug Administration released inspectional observations of FDA inspections at Blue Bell Creameries facilities in [Brenham, Texas in 2009](https://wayback.archive-it.org/7993/20170404202435/https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM447617.pdf) (PDF - 170KB) ([/7993/20170404202435/https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM447617.pdf](https://wayback.archive-it.org/7993/20170404202435/https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM447617.pdf)), [Broken Arrow, Okla., in 2012](https://wayback.archive-it.org/7993/20170404202435/https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM447618.pdf) (PDF - 328KB) ([/7993/20170404202435/https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM447618.pdf](https://wayback.archive-it.org/7993/20170404202435/https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM447618.pdf)), [Houston, Texas in 2007](https://wayback.archive-it.org/7993/20170404202435/https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM447619.pdf) (PDF - 196KB) ([/7993/20170404202435/https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM447619.pdf](https://wayback.archive-it.org/7993/20170404202435/https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM447619.pdf)), and [San Antonio, Texas](https://wayback.archive-it.org/7993/20170404202435/https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM447619.pdf)

[in 2014 \(PDF - 159\) \(/7993/20170404202435/https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM447620.pdf\)](https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM447620.pdf).

On June 1, 2015, [Blue Bell Creameries announced \(https://wayback.archive-it.org/7993/20170404202435/http://cdn.bluebell.com/the_little_creamery/press_releases/alabama-agreement\)](https://wayback.archive-it.org/7993/20170404202435/http://cdn.bluebell.com/the_little_creamery/press_releases/alabama-agreement); [\(https://wayback.archive-it.org/7993/20170404202435/http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm\)](https://wayback.archive-it.org/7993/20170404202435/http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm) that it had entered into voluntary agreements with the Alabama Department of Public Health outlining a series of steps and actions Blue Bell will take as part of its efforts to bring Blue Bell ice cream products back to market. According to Blue Bell Creameries, the agreement contains provisions similar to those that Blue Bell agreed to with the Texas Department of State Health Services and the Oklahoma Department of Agriculture, Food, and Forestry on May 21, 2015.

On June 10, 2015, the [FDA released information \(/7993/20170404202435/https://www.fda.gov/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/ucm446102.htm\)](https://www.fda.gov/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/ucm446102.htm) on inspections conducted at Blue Bell Creameries facilities including the laboratory results for the environmental and product samples collected by the FDA during its inspections of the Blue Bell Creameries production facilities in Brenham, Texas, Broken Arrow, Okla. and Sylacauga, Ala. in 2015.

Integration between federal, state, local, territorial and tribal agencies is key to the success of our U.S. food safety system. The FDA has been working with its partners in Texas, Oklahoma and Alabama throughout the investigation and supports agreements like the ones signed between Blue Bell Creameries and the states of Oklahoma, Texas and Alabama. This collaboration will continue. The FDA will be working with Blue Bell and our state and local partners to review corrective actions taken at the Blue Bell facilities and will be engaged in discussions and decisions on when Blue Bell can safely resume shipment of product.

The FDA has moved quickly to investigate this issue and learn as much as possible to prevent additional people from becoming ill. We recognize that people will be concerned about these illnesses, and we will continue to provide updates and advice.

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What are the Symptoms of Listeriosis?

Listeriosis is a rare but serious illness caused by eating food contaminated with the bacteria called *Listeria monocytogenes*. Anyone who experiences fever and muscle aches, sometimes preceded by diarrhea or other gastrointestinal symptoms, or develops fever and chills after eating the ice cream should seek medical care and tell their health care provider about any history of eating the ice cream. Symptoms can appear from a few days up to a few weeks after consumption of the contaminated food.

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Who is at Risk?

Listeriosis can be fatal, especially in certain high-risk groups. These groups include the elderly, and people with weakened immune systems and certain chronic medical conditions (such as cancer). In pregnant women, listeriosis can cause miscarriage, stillbirth, premature labor, and serious illness or death in newborn babies.

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What Products Are Involved?

On April 20, 2015, Blue Bell Creameries of Brenham, Texas, voluntarily expanded its recall to include all of its products currently on the market. This expanded recall includes ice cream, frozen yogurt, sherbet and frozen snacks made at all Blue Bell facilities. Blue Bell has facilities in Brenham, in Broken Arrow, Okla., and in Sylacauga, Ala.

According to Blue Bell, the products being recalled are distributed to retail outlets, including food service accounts, convenience stores and supermarkets in Alabama, Arizona, Arkansas, Colorado, Florida, Georgia, Illinois, Indiana, Kansas, Kentucky, Louisiana, Mississippi, Missouri, Nevada, New Mexico, North Carolina, Ohio, Oklahoma, South Carolina, Tennessee, Texas, Virginia, Wyoming and international locations.

What Do Consumers Need To Do?

Consumers should not eat any Blue Bell products. Recalled products may still be in people's homes. Consumers unaware of the recalls could continue to eat the products and get sick. Additionally, institutions should not serve and retailers should not sell recalled products. These products are frozen, so consumers, institutions, and retailers should check their freezers.

Recommendations for preventing listeriosis are available at the CDC *Listeria* website: <http://www.cdc.gov/listeria/prevention.html> (<https://wayback.archive-it.org/7993/20170404202435/http://www.cdc.gov/listeria/prevention.html>).

Listeria monocytogenes can grow at refrigerator temperatures, as low as 40 degrees Fahrenheit (4 degrees Celsius). The longer ready-to-eat refrigerated foods are stored in the refrigerator, the more opportunity *Listeria* has to grow.

For refrigerators and other food preparation surfaces and food cutting utensils that may have come in contact with the potentially contaminated ice cream, it is very important that the consumers thoroughly clean these areas

- Wash the inside walls and shelves of the refrigerator, cutting boards and countertops; then sanitize them with a solution of one tablespoon of chlorine bleach to one gallon of hot water; dry with a clean cloth or paper towel that has not been previously used.
- Consumers should follow these simple steps:
- Wash hands with warm water and soap for at least 20 seconds before and after handling food.
- Wipe up spills in the refrigerator immediately and clean the refrigerator regularly.
- Always wash hands with warm water and soap following the cleaning and sanitization process.

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What Do Institutions and Retailers Need To Do?

Institutions and retailers should not sell or serve any Blue Bell products. They should also take the following steps:

- Wash and sanitize display cases and refrigerators where potentially contaminated products were stored.
- Wash and sanitize cutting boards, surfaces, and utensils used to cut, serve, or store potentially contaminated products.
- Wash hands with warm water and soap following the cleaning and sanitation process.
- Retailers, restaurants, and other food service operators who have processed and packaged any potentially contaminated products need to be concerned about cross contamination of cutting surfaces and utensils through contact with the potentially contaminated products.

- Regular frequent cleaning and sanitizing of cutting boards and utensils used in processing may help to minimize the likelihood of cross-contamination.

Listeria can grow at refrigeration temperatures. Retailers, restaurants, and other food service operators may wish to consider whether other foods available for sale could have been cross-contaminated from the potentially contaminated products, and should be discarded.

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Who Should be Contacted?

Blue Bell urges consumers who have purchased these items to return them to the place of purchase for a full refund. For more information consumers with questions may call 1-866-608-3940 Monday – Friday 8 a.m. – 8 p.m., Saturday 10 a.m. – 2 p.m. CST or go to bluebell.com.

The FDA encourages consumers with questions about food safety to call 1-888-SAFEFOOD Monday through Friday between 10 a.m. and 4 p.m. Eastern time, or to consult <http://www.fda.gov> (<https://wayback.archive-it.org/7993/20170404202435/http://www.fda.gov/>).

Additional Information

- [CDC Vital Signs *Listeria*](https://wayback.archive-it.org/7993/20170404202435/http://www.cdc.gov/vitalsigns/listeria/index.html) (<https://wayback.archive-it.org/7993/20170404202435/http://www.cdc.gov/vitalsigns/listeria/index.html>)
- [FoodSafety.gov on *Listeria*](https://wayback.archive-it.org/7993/20170404202435/http://www.foodsafety.gov/poisoning/causes/bacteriaviruses/listeria/index.html) (<https://wayback.archive-it.org/7993/20170404202435/http://www.foodsafety.gov/poisoning/causes/bacteriaviruses/listeria/index.html>)

The information in this posting reflects the FDA's best efforts to communicate what it has learned from the manufacturer, the CDC, and the state and local public health agencies involved in the investigation. The agency will update this page as more information becomes available.

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