

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214) 253-5200 Fax: (214) 253-5314 Industry Information: www.fda.gov/oc/industry	03/23/2015 - 04/23/2015*
	FEI NUMBER
	1000118167

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Marty L Kilgore, General Manager

FIRM NAME	STREET ADDRESS
Blue Bell Creameries, LP	8201 E Highway 51
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Broken Arrow, OK 74014-2900	Frozen Dairy Dessert Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Failure to manufacture and package foods under conditions and controls necessary to minimize the potential for growth of microorganisms and contamination.

Specifically, you manufactured ready-to-eat, frozen, dairy desserts which tested positive for *Listeria monocytogenes*. The following finished product manufactured by your firm tested positive for *Listeria monocytogenes*.

- A. Institutional Chocolate Ice Cream in a 3oz cup with a pull tab lid, Lot code 041516Q, produced on 04/15/2014, tested positive for *Listeria monocytogenes* by the Kansas Department of Health and Environment. Your firm distributed all (b) (4) 3oz cups of this lot between 04/15/2014 and 03/23/2015.
- B. (b) (4), produced on 03/23/2015, tested positive for *Listeria monocytogenes* by a third party laboratory selected by your firm. You reported you did not distribute any of the (b) (4), to your customers.
- C. Banana Pudding Ice Cream, Lot code 021217S, produced on 02/12/2015, tested positive for *Listeria monocytogenes* by the FDA. Your firm distributed (b) (4) pints of the Banana Pudding Ice Cream, Lot code 021217S, to your customers between 02/12/2015 and 03/26/2015.

Subsequently, your firm initiated a voluntarily recall of all institutional ice cream products in a 3oz cup with a pull tab lid on 03/23/2015. On 04/07/2015, your firm expanded the voluntary recall to include all products manufactured on Slot (b) (4) after 02/12/2015. Then on 04/20/2015, your firm expanded the voluntary recall to include all products manufactured by your firm.

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	Lloyd D. Payne, Investigator Adam C. Hipko, Investigator Jennifer Owens Dowdy, Investigator Franklin R. Harris, Investigator Travis D. Brown, Investigator	04/23/2015

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OBSERVATION 2

Failure to perform microbial testing where necessary to identify sanitation failures and possible food contamination.

Specifically,

- A. You stated the results of your sampling for environmental pathogens on non-food contact surfaces as defined in your 04/22/2014 written procedure entitled "Plant Environmental Testing" were used as an indicator in determining whether the cleaning and sanitizing program was effective. However, this sampling program failed to include the following:
 - a. Sampling of food contact surfaces.
 - b. Determination of any preventative action needed in response to the possible contamination.
 - c. Determination of the impact on the products produced on the affected date.
 - d. Determination of the *Listeria spp.* associated with the presumptive positive results.
 - e. Root Cause Analysis of why the cleaning and sanitizing treatments were inadequate in controlling the occurrences of microbiological contaminations.
- B. You also stated the results of your daily total coliform sampling on finished product, in-process product, and raw ingredients added post pasteurization were used as an indicator in determining whether the cleaning and sanitizing program was effective. However, this sampling program failed to include the following:
 - a. Determination of any corrective or preventative action needed in response to the possible contamination.
 - b. Determination of the impact on the products produced on the affected date.
 - c. Determination of the pathogenicity of the coliform isolates.
 - d. Root Cause Analysis of why the cleaning and sanitizing were inadequate in controlling the occurrences of microbiological contaminations.
 - e. Establishment of alert and action limits.

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OBSERVATION 3

The procedure used for cleaning and sanitizing of equipment and utensils has not been shown to provide adequate cleaning and sanitizing treatment.

Specifically, you failed to demonstrate your cleaning and sanitizing program is effective in controlling recurring microbiological contaminations. You continued to have presumptive positive environmental test results for *Listeria spp.* and elevated total coliform results following the daily cleaning and sanitizing treatments of your equipment and facilities. You reported the results of the sampling program were used as an indicator in determining whether the cleaning and sanitation program was effective. In response to presumptive positive environmental test results for *Listeria spp.* and the elevated total coliform counts, you reported the usual cleaning and sanitation procedures were followed and verified as being performed more thoroughly during the next cleaning and sanitizing cycle after notification of the results; which may be (b) (4) days for *Listeria spp.* and (b) (4) for in-house total coliform. Examples of microbiological contamination of production equipment and finished product are as follows.

- A. *Listeria spp.* was isolated from non-food contact areas within the processing room and kitchen and from non-food contact surfaces of production equipment. These included 5 samples in 2013, 10 samples in 2014, 1 sample in January, and 1 sample in February of 2015. In addition, environmental samples collected by the FDA on 03/24/2015 and 03/25/2015 tested positive for *Listeria monocytogenes*.

Date	Sample Location	Slot
3/19/2013	Floor in front of Freezer # (b) (4)	(b) (4)
4/19/2013	Pallet Jack in Kitchen	
8/13/2013	Catwalk behind Flavor Tank # (b) (4)	
10/18/2013	Floor in front of Freezer # (b) (4)	
11/12/2013	COP tub in Kitchen	
1/13/2014	(b) (4)	
1/20/2014	(b) (4)	
1/20/2014	(b) (4)	
4/15/2014	(b) (4) at 1/2 Gallon Filler	
4/22/2014	(b) (4) at 1/2 Gallon Filler	
4/22/2014	(b) (4) at 1/2 Gallon Filler	
4/22/2014	(b) (4) at 1/2 Gallon Filler	
8/11/2014	Drain behind Flavor Tank # (b) (4)	
8/11/2014	Catwalk behind Flavor Tank # (b) (4)	
11/12/2014	Water hose in front of (b) (4) Pint Filler	
1/13/2015	Floor between Freezer # (b) (4) & (b) (4) Pint Filler	

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2/12/2015

Floor in front of Freezer (b) (4)

(b) (4)

On 01/13/2014, the (b) (4) was sampled, and the sample was sent to your 3rd party laboratory who received the samples on 01/14/2014. The laboratory reported the sample from the (b) (4) as presumptive positive for *Listeria spp.* on 01/16/2014. (b) (4) was re-sampled on 01/20/2014 and the samples were reported by the laboratory as presumptive positive for a second time on 01/23/2014. The (b) (4) was documented as being cleaned and sanitized after the (b) (4) between 01/13/2015 and 01/17/2014, however, it failed to be cleaned and sanitized adequately and showed evidence of *Listeria spp.* on two consecutive samples.

On 04/15/2014, (b) (4) at 1/2 Gallon Filler was sampled, and the sample was sent to your 3rd party laboratory who received the samples on 04/16/2014. The laboratory reported the sample from the (b) (4) at 1/2 Gallon Filler as presumptive positive for *Listeria spp.* on 04/19/2014. The (b) (4) at 1/2 Gallon Filler was re-sampled on 04/22/2014 and the samples were reported by the laboratory as presumptive positive for a second time on 04/25/2014. The (b) (4) at 1/2 Gallon Filler was documented as being cleaned and sanitized after the (b) (4) between 04/15/2015 and 04/21/2014, however, it failed to be cleaned and sanitized adequately and showed evidence of *Listeria spp.* on two consecutive samples.

B. Total coliform greater than 20 Colony Forming Units (CFUs)/mL was identified in finished product, in-process product batches, and raw ingredients in 6 samples during April 2014, 8 samples during January 2015, 23 samples during February 2015, and 10 samples during March 2015. You reported the Oklahoma Department of Agriculture, Food, and Forestry had a regulatory requirement of 20 CFUs/mL or less in finished products of frozen dairy desserts.

a. Your total coliform sample results greater than 20 CFUs/mL, and as high as 105 CFUs/mL, during April 2014 included the following:

- i. On 04/15/2014, the finished product Pineapple Sherbet, Batch 117993, Lot code 041516S, produced on Slot # (b) (4) had 33 CFUs/mL.
- ii. On 04/22/2014, the finished product Homemade Vanilla Ice Cream, Batch 119386, Lot code 042216O, produced on Slot # (b) (4) had 34 CFUs/mL.
- iii. On 04/25/2014, the in-process product of BBIC Vanilla in Flavor Tank # (b) (4) had 105 CFUs/mL; This mix was used to produce the 3oz cups of Institutional Vanilla Ice Cream, Batch 119317, Lot code 042516Q, on Slot # (b) (4).

b. Your total coliform sample results greater than 20 CFUs/mL, and as high as 124 CFUs/mL during January 2015 included the following:

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- i. On 01/12/2015, the finished product Homemade Vanilla Ice Cream, Batch 127856, Lot code 011217O, produced on Slot # [REDACTED] had 48 CFUs/mL.
- ii. On 01/21/2015, the finished product Dutch Chocolate Ice Cream, Batch 129350, Lot code 012117R, produced on Slot # [REDACTED] had 124 CFUs/mL.
- c. Your total coliform sample results greater than [REDACTED] CFUs/mL, and as high as 840 CFUs/mL during February 2015 included the following:
- i. On 02/09/2015, the finished product Dutch Chocolate Ice Cream, Batch 128824, Lot code 020917O, produced on Slot # [REDACTED] had 275 CFUs/mL.
- ii. On 02/24/2015, the in-process product of Homemade Vanilla in Flavor Tank # [REDACTED] had 228 CFUs/mL; the finished product Homemade Vanilla Ice Cream, Batch 131087, Lot code 022417O, produced on Slot # [REDACTED] had 151 CFUs/mL.
- iii. On 02/24/2015, the in-process product of Homemade Vanilla in Flavor Tank # [REDACTED] had [REDACTED] CFUs/mL; the finished product Homemade Vanilla Ice Cream, Batch 131087, Lot code 022417O, produced on Slot # [REDACTED] had 174 CFUs/mL.
- iv. On 02/26/2015, the in-process product of Homemade Vanilla in Flavor Tank # [REDACTED] had 796 CFUs/mL; the finished product Homemade Vanilla Ice Cream, Batch 129403, Lot code 022617O, produced on Slot # [REDACTED] Side [REDACTED] had 840 CFUs/mL in the morning and 223 CFUs/mL in the afternoon. On 02/27/2015, the finished product Homemade Vanilla Ice Cream, Lot code 022617O, produced on Slot # [REDACTED] Side [REDACTED] was resampled. The three samples had 25 CFUs/mL, 46 CFUs/mL, and Too Many to Count (TMC) CFUs/mL.
- v. On 02/26/2015, the in-process product of Homemade Vanilla in Flavor Tank # [REDACTED] had 392 CFUs/mL; the finished product Homemade Vanilla Ice Cream, Batch 129403, Lot code 022617O, produced on Slot # [REDACTED] Side [REDACTED] had 377 CFUs/mL in the morning and [REDACTED] CFUs/mL in the afternoon. On 02/27/2015, the finished product Homemade Vanilla Ice Cream, Lot code 022617O, produced on Slot # [REDACTED] Side [REDACTED] was resampled. The two samples had 88 CFUs/mL and 142 CFUs/mL.
- d. Your total coliform sample results greater than 20 CFUs/mL, and as high as 121 CFUs/mL during March 2015 included the following:
- i. On 03/06/2015, the finished product Sundae Ice Cream, Batch 129531, Lot code 030617R, produced on Slot # [REDACTED] had 67 CFUs/mL.



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<div style="margin-left: 150px;"> ii. On 03/09/2015, the finished product Homemade Vanilla Ice Cream, Batch 129779, Lot code 030917T, produced on Slot # (b) (4) had 121 CFUs/mL. </div> <div style="margin-left: 150px; margin-top: 20px;"> iii. On 03/16/2015, the in-process product of Homemade Vanilla in Flavor Tank # (b) (4) had 107 CFUs/mL; the finished product Homemade Vanilla Ice Cream, Batch 130037, Lot code 031617T, produced on Slot # (b) (4) had 24 CFUs/mL. </div>			
OBSERVATION 4 <p>Failure to provide running water at a suitable temperature for cleaning of equipment, utensils and food-packaging materials.</p> <p>Specifically, you reported the water temperature for the washing and rinsing of the exterior surfaces of the equipment and COP was not continuously monitored, verified, or documented. You also reported the water temperature for the CIP system used to clean and sanitize the food contact surfaces of the mix tanks, flavor tanks, freezers, fillers, and connecting pipes was not continuously monitored, verified, or documented. However, you stated the water heater was set to heat the water to a temperature between (b) (4) °F and (b) (4) °F.</p> <p>The labeling on the (b) (4) sanitizer, which you use in CIP and COP procedures, states in part, "****To CIP product lines, use (b) (4) ounces of (b) (4) per one gallon of (b) (4) °F water for (b) (4) minutes (minimum of (b) (4) minutes at temperature (b) (4) °F. To CIP cold product storage tanks, use (b) (4) ounces per one gallon of (b) (4) °F water** (b) (4) should be used at a concentration of up to (b) (4) in water at (b) (4) °F for (b) (4) minutes in a soak tank, or less time if (b) (4) ****".</p> <p>On 03/30/2015, you were asked to perform a check on the start-up and final water temperatures during the usual cleaning and sanitizing procedures. Following the (b) (4), you reported the CIP temperature ranged from 122°F at start-up to 118°F at final. You also reported the COP water temperature was 128°F. These temperatures failed to meet the usage instructions on the (b) (4) label.</p>			
OBSERVATION 5 <p>The plant is not constructed in such a manner as to prevent drip and condensate from contaminating food, food-contact surfaces, and food-packaging materials.</p> <p>Specifically, on 03/26/2015 condensation was observed in the following areas:</p> <p>A. A continual line of condensate droplets were observed along the bottom of stainless steel Product Supply Lines (b) (4) and (b) (4). These approximately (b) (4) inch diameter product lines are installed horizontally above all (b) (4) Flavor Tanks and supply the product mixes from the basement mixing tanks. The condensate was observed dripping down onto the tops of the enclosed Flavor Tanks, however, the (b) (4) of the (b) (4) enter the tanks through a hole in the top of each tank and the gaskets between the tanks and the (b) (4).</p>			
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are not tight fitting and do not prevent the entry of the condensate. Additionally, the Mix Tank Operators at Flavor Tank #s (b) (4) and (b) (4) which contained Dutch Chocolate Supreme Ice Cream, Batch 130321, Lot code 032617Q, Slot # (b) (4) and Flavor Tank # (b) (4) which contained Caramel Sundae Crunch Ice Cream, Batch 131906, Lot code 032617S, Slot # (b) (4) were observed spraying the tops of the tanks with a water hose which washed the condensate into and around the gaskets and (b) (4) potentially contaminating the ice cream mixes in the Flavor Tanks. The ice cream mixes were post-pasteurization and "in line" to the (b) (4) freezers and packaging. The Mix Tank Operators were also observed hanging an ingredient mixing pitcher from one of the Product Supply Lines and storing other pitchers on the tops of the Flavor Tanks; potentially contaminating the pitchers with condensate.

- B. At Flavor Tank #s (b) (4) and (b) (4) the Mix Draw Operator was observed removing the round tank lids and placing them directly on the top of the Flavor Tanks with the underside of the lids directly contacting condensate droplets which were dripping from Product Supply Line #s (b) (4) and (b) (4). The Flavor Tanks were being used to mix Dutch Chocolate Supreme Ice Cream, Batch 130321, Lot code 032617Q, Slot # (b) (4). After ingredients were added to the Flavor Tanks, the Mix Draw Operator placed the lids back over the openings of the tanks potentially contaminating the post-pasteurized ice cream mix with condensate from the lids.
- C. Condensate was observed dripping from the Slot (b) (4) Filler Head into quart containers of Orange Sherbet, Batch 131444, Lot code 032617S, while the product was being filled and packaged between (b) (4) and (b) (4). The production of the Orange Sherbet started at (b) (4) and ended at (b) (4) producing (b) (4) quarts.
- D. Condensate was observed dripping from Product Supply Lines (b) (4) and (b) (4) onto the top of cardboard cases of (b) (4), ½ Gallon, Caramel Sundae Crunch Ice Cream containers which were stored directly below the lines and adjacent to Flavor Tank # (b) (4). The cases of containers were staged below the dripping product supply lines until needed at Slot (b) (4), which was filling and packaging Caramel Sundae Crunch Ice Cream, Batch 131906, Lot code 032617S.

OBSERVATION 6

Employees did not wash and sanitize hands thoroughly in an adequate hand-washing facility after each absence from the work station and at any time their hands may have become soiled or contaminated.

Specifically, the following instances of failure to change gloves and wash hands were observed on 03/26/2015:

- A. At Flavor Tank # (b) (4) the Mix Draw Operator was observed touching non-food contact and food contact surfaces with the same pair of gloved hands. The Mix Draw Operator was also observed checking the volume in Flavor Tank # (b) (4) which contained Caramel Sundae Crunch Ice Cream, Batch 131906, Lot code 032617S, Slot # (b) (4) by directly wiping product off the metal dipstick with his gloved hand, while the product drained back into the tank, and then he returned the dipstick back into the Flavor Tank. The Mix Draw Operator did not perform a hand wash or glove change prior to touching the product on the dipstick.

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- B. At Flavor Tank # (b) (4) the Mix Draw Operator and Freight Puller were observed lifting and pouring orange puree from plastic buckets into the Flavor Tank which contained Orange Sherbet, Batch 131444, Lot code 032617S, Slot # (b) (4). The Mix Draw Operator and Freight Puller used gloved hands to pick up the buckets by the sides and bottoms while transferring from one to the other. The buckets on the bottom row were stored directly on the wet, wood pallets which had black mold-like residue and red stains. The Freight Puller was observed alternating hands while picking up the buckets by the bottom and occasionally his fingers would contact the top rim and the inside of the puree buckets; possibly contaminating the food contact surface with the gloved fingers which directly touched the bottom of the buckets.
- C. At the (b) (4) Freezer # (b) (4), the Machine Operator was observed rubbing the product line of Freezer # (b) (4) scraping (b) (4) product off the (b) (4) of the filler, turning the product line valve to divert product to a (b) (4), adding chocolate chips into the fruit feeder, making adjustments to the filler equipment, and adjusting his hairnet and hat. All of the tasks, including directly touching product to be (b) (4), were performed with the same pair of gloves while pints of Chocolate Chip Cookie Dough Ice Cream, Batch 132149, Lot code 032617O, Slot # (b) (4) were being packaged.

This is a repeat violation from the 2012 FDA inspection.

OBSERVATION 7

Failure to store cleaned and sanitized portable equipment in a location and manner which protects food-contact surfaces from contamination.

Specifically, on 03/23/2015, food contact equipment used in processing and packaging including (b) (4) 3oz cup fillers, packaging chutes, conveyors, and tables were observed in the basement. The area where the equipment was being stored was hot and humid due to the adjacent (b) (4). All of the equipment was observed uncovered and unprotected with condensate dripping directly onto random sections and surfaces. You reported the equipment was cleaned and sanitized after its last production run and then relocated into the basement area. You also reported the area was classified as non-sanitary and after the pieces of equipment are moved back to the production slot and installed, the equipment is sanitized prior to usage.

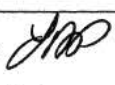

OBSERVATION 8

All reasonable precautions are not taken to ensure that production procedures do not contribute contamination from any source.

Specifically, you do not have cleaning and sanitizing procedures for employee shoes worn into the sanitary food production areas of the firm to ensure that any possible contamination risks are minimized. Shoes are worn out of

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<p>the firm to employee's vehicles and homes and then back into the sanitary food production areas each day without any cleaning and sanitizing requirements. In addition, employees were observed traveling from sanitary food production areas to non-sanitary areas including dry goods storage, maintenance shop, offices, break room, outside smoking areas, and milk truck delivery bays without cleaning and sanitizing prior to re-entry into the sanitary food production areas between 03/23/2015 and 03/27/2015. The only (b) (4) are located at the swinging doors of the Kitchen leading into the processing area and into the garbage collection area and in the HTST area leading into the garbage collection area. The (b) (4) are on (b) (4) (b) (4) and do not cover the entire distance of the entryways.</p>		
OBSERVATION 9 <p>The design of equipment does not allow proper cleaning and maintenance.</p> <p>Specifically, wood pallets which are porous and not easily cleanable are used throughout your firm to store and transport raw ingredients, finished product, and packaging materials. The wood pallets were observed in different stages of damage and disrepair while they were being used in the kitchen, warehouse, freezer, production, and mixing areas. The top platform, bottom, and corners of the pallets were broken, discolored, and soiled. The wood pallets were also observed to be saturated from being used in the wet processing areas and were observed as having black mold-like residues and red stains. The following are examples of the pallet usage observed on 03/26/2015:</p> <ul style="list-style-type: none"> A. Plastic buckets containing Orange puree were stored on wood pallets by Flavor Tank # [REDACTED]. The Orange puree was hand added as an ingredient to the pasteurized Orange Sherbet mix in Flavor Tank # [REDACTED] on Slot # [REDACTED]. The finished product was Orange Sherbet, Batch 131444, Lot code 032617S. B. Plastic buckets containing thawed (b) (4) Sliced Strawberries, Lot (b) (4), were stored on wood pallets in the Kitchen awaiting the addition of granulated sugar in the (b) (4). C. Reusable cardboard sleeves used for palletizing finished product and cardboard cases of ½ Gallon ice cream containers were stored on wood pallets located in the production area. 		
OBSERVATION 10 <p>Failure to hold foods which can support the rapid growth of undesirable microorganisms at a temperature that prevents the food from becoming adulterated.</p> <p>Specifically, between 04/11/2014 and 04/13/2014 there were several elevated temperature excursions above 45°F in unpasteurized milk products which are used as raw ingredients. These included the chocolate (b) (4) stored in Raw Tank # [REDACTED] which was used in the Institutional Chocolate Ice Cream, Lot code 041516Q, produced on 04/15/2014. The excursions above 45°F were documented on the (b) (4) Lab Report and the (b) (4) Temperature Recorders. Examples include the following:</p>		
SEE REVERSE OF THIS PAGE	<small>EMPLOYEE(S) SIGNATURE</small> Lloyd D. Payne, Investigator [Signature] Adam C. Hipko, Investigator [Signature] Jennifer Owens Dowdy, Investigator [Signature] Franklin R. Harris, Investigator [Signature] Travis D. Brown, Investigator [Signature]	<small>DATE ISSUED</small> 04/23/2015
<small>FORM FDA 483 (09/08)</small> <small>PREVIOUS EDITION OBSOLETE</small> <small style="text-align: center;">INSPECTIONAL OBSERVATIONS</small> <small style="float: right;">PAGE 9 OF 11 PAGES</small>		

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		
<small>DISTRICT ADDRESS AND PHONE NUMBER</small> 4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214) 253-5200 Fax: (214) 253-5314 Industry Information: www.fda.gov/oc/industry		<small>DATE(S) OF INSPECTION</small> 03/23/2015 - 04/23/2015* <small>FEI NUMBER</small> 1000118167
<small>NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED</small> TO: Marty L Kilgore, General Manager		
<small>FIRM NAME</small> Blue Bell Creameries, LP	<small>STREET ADDRESS</small> 8201 E Highway 51	
<small>CITY, STATE, ZIP CODE, COUNTRY</small> Broken Arrow, OK 74014-2900	<small>TYPE ESTABLISHMENT INSPECTED</small> Frozen Dairy Dessert Manufacturer	
<div style="margin-top: 20px;"> <p>A. On 04/12/2014, Raw Tank # (b) (4) contained chocolate (b) (4). The AM and PM temperatures were documented as being 47°F</p> <p>B. On 04/12/2014, Raw Tank # (b) (4) contained (b) (4) cream. The AM and PM temperatures were documented as being 46°F</p> <p>C. On 04/13/2014, Raw Tank # (b) (4) contained skim milk. The AM temperature was documented as being 48°F and the PM temperature was documented as being 46°F</p> <p>D. On 04/13/2014, Raw Tank # (b) (4) contained cream rinse. The AM and PM temperature were documented as being 50°F</p> </div>		
OBSERVATION 11 <p>Failure to have smoothly bonded or well maintained seams on food contact surfaces, to minimize accumulation of food particles and organic matter and the opportunity for growth of microorganisms.</p> <p>Specifically, the stainless steel (b) (4) mixer, referred to as the (b) (4), had rough welds and non-continuous welds along the back and side splash guards located on top of the tank. The welds, approximately (b) (4) linear feet in length, are hard to clean and create areas where food particles and microorganisms could harbor. On 03/26/2015 the (b) (4) was observed being used in the Kitchen to mix granulated sugar and thawed (b) (4) Sliced Strawberries, Lot code (b) (4), for the eventual addition to batches of pasteurized ice cream mixes.</p>		
OBSERVATION 12 <p>Failure to take apart equipment as necessary to ensure thorough cleaning.</p> <p>Specifically, the front face plate of the (b) (4) Freezer # (b) (4) is not disassembled to thoroughly clean the white gasket which ensures there is no leakage of the ready-to-eat ice cream and sherbet. On 03/22/2015, the faceplate was removed for environmental sampling and the gasket was observed to have black mold-like residual on the flat portions of the gasket which forms the seal against the faceplate and the freezer body. Freezer # (b) (4) was last used in the 03/20/2015 production of the Institutional Vanilla Ice Cream in a 3oz cup with a pull tab lid, Batch 130043, Lot code 032017Q. Freezer # (b) (4) was reported to be "clean" following the CIP, wash, and sanitization performed on 03/20/2015.</p>		
SEE REVERSE OF THIS PAGE	<small>EMPLOYEE(S) SIGNATURE</small> Lloyd D. Payne, Investigator  Adam C. Hipko, Investigator Jennifer Owens Dowdy, Investigator Franklin R. Harris, Investigator Travis D. Brown, Investigator 	<small>DATE ISSUED</small> 04/23/2015

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

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FIRM NAME Blue Bell Creameries, LP	STREET ADDRESS 8201 E Highway 51	
CITY, STATE, ZIP CODE, COUNTRY Broken Arrow, OK 74014-2900	TYPE ESTABLISHMENT INSPECTED Frozen Dairy Dessert Manufacturer	

*** DATES OF INSPECTION:**

03/23/2015(Mon), 03/24/2015(Tue), 03/25/2015(Wed), 03/26/2015(Thu), 03/27/2015(Fri), 03/30/2015(Mon), 03/31/2015(Tue),
04/02/2015(Thu), 04/07/2015(Tue), 04/21/2015(Tue), 04/23/2015(Thu)

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OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Lloyd D. Payne, Investigator *[Signature]*
Adam C. Hipko, Investigator *NOT PRESENT*
Jennifer Owens Dowdy, Investigator *NOT PRESENT*
Franklin R. Harris, Investigator *[Signature]*
Travis D. Brown, Investigator *[Signature]*

DATE ISSUED

04/23/2015