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		03/16/2015 - 05/01/2015* FEI NUMBER 1682009
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED		
TO: Paul W. Kruse, CEO		
FIRM NAME	STREET ADDRESS	
Blue Bell Creameries, L.P.	1101 S Blue Bell Rd	
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED	
Brenham, TX 77833-4413	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 foods under conditions and controls necessary to minimize the potential for growth of microorganisms.

Specifically,

The following lots of products, which were manufactured on (b) (4) line (b) (4) between 8/29/14 and 1/21/15 and subsequently distributed into commerce, were sampled by your firm and found positive for *Listeria monocytogenes*.

- Great Divide Bar (Bulk packaging), manufactured on 1/12/15, lot 011217A, and distributed between 1/13/15 - 2/10/15.
- Chocolate Chip Country Cookie (Bulk Packaging), manufactured on 01/20/15, lot 012017A, and distributed between 1/20/15 - 2/11/15.

Additionally, your firm ceased production on 1/30/15, to undergo routine cleaning and overhauling of (b) (4) line (b) (4) On 2/13/15, your firm received notification from DSHS of your products positive for *Listeria monocytogenes*. Prior to resuming operations on this line, your firm swabbed the (b) (4) Line (b) (4) equipment and found the following listeria positive swabs:

- 2/19/15, inside drain of the freezer tunnel (non-food contact surface) of the (b) (4) line (b) (4)
- 2/21/15, the outside drain of the freezer tunnel (non-food contact surface) of the (b) (4) line (b) (4)

On 2/23/15, your firm resumed operations on the (b) (4) line (b) (4) continuing to manufacture on 3/2/15, 3/3/15, 3/4/15, 3/5/15, 3/6/15, and 3/9/15. After each of these manufacturing days your firm performed routine cleaning and sanitizing. However, on 3/9/15, your firm found Listeria monocytogenes positive swabs in (b) (4) line (b) (4) in the (b) (4) bottom (food contact surface) and in the underside (b) (4) chainsprocket (food contact surface). During 3/9/15, the (b) (4) line (b) (4) was manufacturing Sour Pop Apples (lot# 030917A). However, the Sour Pop Apples (lot # 030917A) were never offered for sale.

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OBSERVATION 2

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

Specifically,

After shutting down (b) (4) line (b) (4) for cleaning and overhauling (b) (4) line (b) (4) on 1/30/15, your firm received notification from DSHS on 2/13/15 (regarding positive findings of Listeria monocytogenes in your products), your firm collected environmental samples of (b) (4) Line (b) (4) and swabs taken at the following two locations were subsequently found positive for Listeria monocytogenes:

Swab collected from the inside drain of the freezer tunnel (non-food contact surface) of the (b) (4) line (b) (4) on 2/19/15.

Swab collected from the outside drain of the freezer tunnel (non-food contact surface) of the (b) (4) line (b) (4) on 2/21/15.

Your firm then resumed manufacturing, cleaning and sanitizing operations for (b) (4) line (b) (4) on 2/23/15, 3/2/15, 3/3/15, 3/4/15, 3/5/15, 3/6/15, and 3/9/15. However, on 3/9/15, your firm found Listeria monocytogenes positive swabs in (b) (4) line (b) (4) in the (b) (4) bottom (food contact surface) and in the underside (b) (4) chainsprocket (food contact surface). During 3/9/15, the (b) (4) line (b) (4) was manufacturing Sour Pop Apples (lot# 030917A). However, the Sour Pop Apples (lot # 030917A) were never offered for sale.

OBSERVATION 3

The plant is not constructed in such a manner as to prevent condensate from contaminating food and food-contact surfaces.

Specifically,

During the inspection, we observed condensate and drip throughout the facility. The following are examples of condensate

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that we observed dripping directly into ice cream products:

On 3/17/15, we observed condensate drip on line (b) (4) located on the 3rd floor in production area (b) (4) of the firm. The drip was falling from each of the (b) (4) blue hoses into the stainless steel mold. After the drip would fall on the molds, the molds containing the drip were filled with mix berry ice cream (lot 031717M).

On 3/18/15, we observed condensate above the filler on Pint line (b) (4) located on the 1st floor in production area (b) (4) The condensate was dripping directly into pints of mint chocolate ice cream (lot 031817D).

On 3/18/15, we observed condensate on the filler on 1/2 Gallon line (b) (4) located on the first floor in production area (b) (4) The condensate was dripping directly into 1/2 gallons of Cookies 'n Cream (lot 031817H).

On 4/21/15, we observed condensate drip on top of closed boxes of ice cream sandwich lids. The boxes containing ice cream sandwich lids were staged in the sandwich mezzanine room on the second floor of the firm, under stainless steel ice cream lines which feed ice cream into sandwich production lines (b) (4) The lids are an ingredient used in the manufacture of ice cream sandwiches. Lines (b) (4), manufacture Vanilla Sandwiches, Mini Sandwiches (vanilla), and double vanilla sandwiches.

OBSERVATION 4

Failure to clean food-contact surfaces as frequently as necessary to protect against contamination of food.

Specifically,

On 3/16/15, we observed all (b) (4) of the ingredient hoppers in blending room (b) (4) were not kept clean. The underside of the hopper lids were caked with emulsifiers and stabilizers which had mixed with the humidity found in the room. These ingredients are added to blender (b) (4) along with other ingredients, such as cocoa powder, and blended with raw milk, prior to entering the High Temperature Short Time pasteurizer. Blender (b) (4) room is found on the first floor of the facility.

OBSERVATION 5

Failure to wear beard covers in an effective manner.

Specifically,

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On 3/16/15, we observed 6 employees with beards wear protective beardnets without covering the mustache portion of their beards. The employees were in various areas of the facility, including the HTST area, and in areas where the firm was actively producing products.

OBSERVATION 6

Failure to maintain buildings in repair sufficient to prevent food from becoming adulterated.

Specifically,

On 3/16/15, we observed paint on the ceiling vent directly above blender (b)(4) in the Blender (b)(4) and (b)(4) Room was chipped and cracking. Blender (b)(4) is used to add liquid ingredients and sugars into the raw milk product before it enters the High Temperature Short Time pasteurizers. We also observed that the door guards on the door at the entrance to the (b) (4) equipment room in production area (b)(4) had deep grooves, preventing the surface of the door guards to be easily cleaned.

*** DATES OF INSPECTION:**
03/16/2015(Mon), 03/17/2015(Tue), 03/18/2015(Wed), 03/19/2015(Thu), 03/20/2015(Fri), 03/30/2015(Mon), 03/31/2015(Tue), 04/02/2015(Thu), 04/06/2015(Mon), 04/08/2015(Wed), 04/13/2015(Mon), 04/21/2015(Tue), 05/01/2015(Fri)

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