

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

DISTRICT ADDRESS AND PHONE NUMBER

404 BNA Dr., Bldg. 200, Ste. 500
Nashville, TN 37217-2597
(615) 366-7801 Fax: (615) 366-7802
Industry Information: www.fda.gov/oc/industry

DATE(S) OF INSPECTION

04/06/2015 - 04/30/2015*

FEI NUMBER

1019788

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Kevin D. Wood, General Manager

FIRM NAME

Blue Bell Creameries Inc

STREET ADDRESS

423 N Norton Ave

CITY, STATE, ZIP CODE, COUNTRY

Sylacauga, AL 35150-2009

TYPE ESTABLISHMENT INSPECTED

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 perform microbial testing where necessary to identify possible food contamination.

Specifically,

You stated the results of your sampling for environmental pathogens on non-food contact surfaces as defined in your (b) (4) written procedure entitled "Plant Environmental Testing" were used as an indicator in determining whether the cleaning and sanitization program was effective. However, this sampling program failed to include the following:

- a. Sampling of food contact surfaces
- b. Determination of any preventive 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.

OBSERVATION 2

Suitable outer garments are not worn that protect against contamination of food and food contact surfaces.

Specifically on 4/20/2015,

An employee's shirt came into direct contact with the interior liner of an ingredient container while the employee was loading the ingredients into Fruit Feeder # (b) (4) on the (b) (4) line during production of Bride's Cake Ice Cream. The employee, who was not dressed in the appropriate Blue Bell outer garment, was wearing a shirt which appeared soiled and with several holes.

**SEE REVERSE
OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Patrick C. Dooley, Investigator
Lezette M. Earhart, Investigator
Thomas B. Smith, Investigator
Andrew F. Saunders, Investigator
Wilvor K. Butler, Investigator
Justin N. Henson, Investigator

Patrick C. Dooley, Investigator

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OBSERVATION 3

Failure to maintain food contact surfaces to protect food from contamination by any source, including unlawful indirect food additives.

Specifically,

- 1) On 4/20/2015, several pieces of filling equipment including an (b) (4), (b) (4) pipes, and gaskets were observed in an employee hand sink immediately following the disassembly of the (b) (4) line after production. The equipment was stored in the sink while a COP tank was available for adequate cleaning of equipment approximately (b) (4) from the sink.
- 2) On 4/10/2015, the (b) (4), used in the chocolate blending room, was stored in a unclean metal milk can between uses. The hose connecting the (b) (4) and pump was dirty and was located directly over the (b) (4) storage container.

OBSERVATION 4

The design and materials of equipment and utensils does not allow proper cleaning.

Specifically on 4/20/2015,

- 1) A folded piece of (b) (4) was observed to be wrapped with masking tape covering approximately half of the tool. The tool was being used to (b) (4) on Cone Line # (b) (4) directly adjacent to exposed Nutzo Ice Cream Cones.
- 2) A space heater was observed fastened to the production equipment with duct tape directly under the chocolate tray which (b) (4) during production of Mooo Bars.

OBSERVATION 5

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

Specifically on 4/20/2015,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Patrick C. Dooley, Investigator <i>PCS</i> Lezette M. Earhart, Investigator Thomas B. Smith, Investigator Andrew F. Saunders, Investigator Wilvor K. Butler, Investigator Justin N. Henson, Investigator	04/30/2015

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A maintenance employee, with visibly soiled arms and shirt, was observed leaning on a package machine during production of Nutzo Ice Cream Cones. The employee's arms were resting on the packaging equipment and extending over exposed product and open packaging.

OBSERVATION 6

Employees did not wash and sanitize hands thoroughly in an adequate hand-washing facility at any time their hands may have become soiled or contaminated.

Specifically on 4/20/2015,

An employee was observed touching their visibly damp pant leg while wearing single-use gloves. The employee then proceeded to load sleeves of lids on (b) (4) Line during production of vanilla and chocolate ice cream without washing hands or changing gloves.

OBSERVATION 7

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

Specifically on 4/10/2015,

- 1) The drop ceiling in the mixing room was damaged and in poor repair. Tiles appeared to be stained and broken throughout the mixing room.
- 2) Light fixture above mixing tank (b) (4) had condensate on it.

OBSERVATION 8

Non food-contact equipment in manufacturing areas is not constructed so that it can be kept in a clean condition.

Specifically on 4/10/2015,

- 1) (b) (4) motor mount was rusty and had peeling/flaking paint.
- 2) Gasket for (b) (4) was cracked, with cracks extending from (b) (4) to outer edge of gasket.

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*** DATES OF INSPECTION:**

04/06/2015(Mon), 04/07/2015(Tue), 04/08/2015(Wed), 04/09/2015(Thu), 04/10/2015(Fri), 04/20/2015(Mon), 04/21/2015(Tue),
04/29/2015(Wed), 04/30/2015(Thu)

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."