

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

DISTRICT ADDRESS AND PHONE NUMBER 4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214) 253-5200 Fax: (214) 253-5314 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 03/28/2012
	FEI NUMBER 1000118167

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Mr. Jeffrey H. Martin, Quality Control Manager

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 ice cream 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 I OBSERVED:

OBSERVATION 1

Failure to manufacture foods under conditions and controls necessary to minimize contamination.

Specifically, during the inspection on 3/28/2012, an employee in the (b) (4) line was observed to take the shipping boxes from the warehouse pallet, open the boxes and the plastic liner bags containing "Nutty Chocolate Pre-Mix" and empty the mix into the fruit feeder (hopper); the employee then proceeded to sweep the remaining contents out of the bag into the feeder with his gloved hand, throw the bag into the trash container, then break down the box and place it into the box stack.

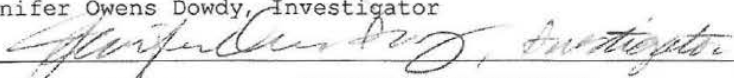
This employee's activity was observed to be repetitive; subsequently, the employee was also observed scratching his head, touching his cap and waistband, and then observed to resume his routine - including touching the pre-mix - as describe above.

"Nutty Chocolate Pre-Mix" is an ingredient in the "Nutty Chocolate Ice Cream." The pre-mix from the feeder goes directly into the filling machine, where it is mixed with ice cream and deposited into 1/2-gallon containers of finished product.

OBSERVATION 2

Failure to handle and maintain equipment, containers and utensils used to hold food in a manner that protects against contamination.

Specifically, during the inspection on 3/28/2012, two partial pallets of bulk "inclusions" and/or ingredients were observed inside the 0-14 degree room (cooler) that were not labeled and with residue on the lids and sides of the five-gallon buckets. "Inclusions" are ingredients added directly into various ice cream products during the final mixing and/or filling process, which are delivered into the production area in lidded, five-gallon buckets.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Jennifer Owens Dowdy, Investigator 	DATE ISSUED 03/28/2012
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Broken Arrow, OK 74014-2900	ice cream manufacturer	

A brown, dried residue was observed on the lids and down the sides of at least 3 of the [REDACTED] unmarked five-gallon buckets on one pallet, and a yellowish, dried residue was observed on the lid of one of the [REDACTED] unmarked five-gallon buckets on the other pallet. A third partial pallet of [REDACTED] five-gallon buckets labeled "Maraschino Cherries" was also observed to have reddish residue on the lids and sides of at least 2 of the buckets.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Jennifer Owens Dowdy, Investigator <i>Jennifer Owens Dowdy, Investigator</i>	03/28/2012
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