

**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> 07/23/2009 - 07/24/2009
	<small>FEI NUMBER</small> 1682009

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Paul W. Kruse, President and CEO

<small>FIRM NAME</small> Blue Bell Creameries Inc	<small>STREET ADDRESS</small> 1101 S Blue Bell Rd
<small>CITY, STATE, ZIP CODE, COUNTRY</small> Brenham, TX 77833-4413	<small>TYPE ESTABLISHMENT INSPECTED</small> 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

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

Specifically, on 7/23/09 a stainless steel pipe conveying liquid caramel was located directly over the 3 gallon filler station for Triple Caramel ice cream lot '072311A'. Condensate had collected on the pipe and about 1 drop of condensate per minute was observed falling into the empty 3 gallon cartons just prior to filling and packaging.

In addition, condensate was observed on the fillers above (b) (4) ice cream sandwich machines. A drop of condensate was observed falling onto a sandwich wafer on one of the machines from the filler pipe located directly above it just prior to filling and packaging lot '072311G'.

SEE REVERSE OF THIS PAGE	<small>EMPLOYEE(S) SIGNATURE</small> R. Todd Lorenz, Investigator <i>R. Todd Lorenz</i> Paul E. Frazier, Investigator <i>Paul E. Frazier</i>	<small>DATE ISSUED</small> 07/24/2009
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