

Establishment Inspection Report

Blue Bell Creameries Inc
Brenham, TX 77833-4413

FEI: 1682009
EI Start: 07/23/2009
EI End: 07/24/2009

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SUMMARY

This GMP inspection of a food manufacturer was conducted per FACTS assignment #975103 and DAL-DO FY 2009 PG High Risk Food Inspections in accordance with CP 7303.803 & CP 7321.005 and covered PAC's 03803 and 21005.

The previous inspection conducted on 5/5/2005 by DSHS under FDA contract was classified as NAI.

FDA credentials were shown by R. Todd Lorenz, CSO and Paul E. Frazier, CSO and a FDA-482 was issued to Paul W. Kruse, President and CEO on 7/23/09. The current inspection found the firm operating as a manufacturer of various ice creams and ice cream novelties. During the inspection, Triple caramel ice cream was covered. A field exam was conducted on Triple Caramel ice cream and reported separately into FACTS without deviations. At the conclusion of the inspection, a 1-item FDA 483 was issued concerning condensation from an overhead caramel pipe dripping into 3 gallon tubs prior to filling and filler heads dripping condensate onto wafers for ice cream sandwiches prior to filling. Some corrections were made and verified. There were no refusals. No samples

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were collected during this inspection. FDA correspondence should be addressed to Paul W. Kruse, President and CEO, at the address below.

ADMINISTRATIVE DATA

Inspected firm: Blue Bell Creameries Inc
Location: 1101 S Blue Bell Rd
Brenham, TX 77833-4413
Phone: 979-836-7977
FAX:
Mailing address: 1101 S Blue Bell Rd
Brenham, TX 77833-4413

Dates of inspection: 7/23/2009, 7/24/2009
Days in the facility: 2
Participants: R. Todd Lorenz, Investigator
Paul E. Frazier, Investigator

HISTORY

The firm has been in business since 1907 and is a private corporation. The inspected facility was first constructed in 1972. Operating hours are generally (b) (4). There are about (b) (4) production employees at this location. Sales are (b) (4) wholesale and annual volume is about (b) (4) gallons at this plant and (b) (4) at all plants combined. Two other Blue Bell ice cream plants are located in Broken Arrow, OK and Sylacauga, AL. A smaller plant is located nearby that manufactures primarily ice cream novelties (802 Creamery St., Brenham, TX 77833). The firm has a webpage at www.bluebell.com.

The previous inspection was conducted on 5/5/2005 by DSHS under FDA contract was classified as NAI.

INTERSTATE COMMERCE

Interstate ingredients account for less than (b) (4) % of finished products. Milk is about (b) (4) % of most ice creams and is purchased from (b) (4) within a (b) (4) mile radius of the facility. Other ingredients such as sugar, corn syrup, cocoa, colors, & flavors originate from interstate commerce. About (b) (4) of the finished product ice creams are shipped into (b) (4) surrounding states from this plant.

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Shipping documents and certificates of analysis for sugar from (b) (4) fructose from (b) (4) vanilla extract chocolate liquor and cocoa powder from (b) (4) were collected as **Exhibit 1**.

JURISDICTION

The firm operates as a food manufacturer where ingredients are from interstate commerce and finished products are shipped into interstate commerce. Thus, the firm is subject to 21 CFR Part 110 as well as other applicable regulations.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

FDA credentials were shown by R. Todd Lorenz, CSO and Paul E. Frazier, CSO and a FDA-482 was issued to Paul W. Kruse, President and CEO on 7/23/09 (**Attachments 1**).

Mr. Kruse identified himself as the most responsible person at the firm. Mr. Kruse is normally present on a day-to-day basis, oversees management of production, manufacturing, and quality control unit and has overall authority to detect, prevent and correct problems at the facility. This site is also the corporate headquarters for Blue Bell Creameries, Inc. Mr. Kruse has been President & CEO for about 5 years and reports to the Board of Directors.

Present at the discussions, accompanying us during the inspections and at the closing meeting were Andrew (Andy) F. Kollman, Quality Control Manager and Thomas (Tommy) J. Supak, Director Quality Control and Mix Operations. Mr. Kollman has been at his present position for 4 years and with the company for 12 years. Mr. Supak and Mr. Kollman answered questions and provided copies of requested documents. Mr. Supak has been with the firm for 35 years. Both report directly to Mr. Kruse. Organizational charts and contacts were collected as **Exhibit 2**.

FIRM'S TRAINING PROGRAM

All new employees undergo training in GMP, hand washing and sanitation, and food handling via classroom instruction and videos. New refresher videos and coursework are provided on a periodic, at least (b) (4) basis.

MANUFACTURING/OPERATIONS

The firm operates as a manufacturer of numerous ice cream flavors and sizes as well as and ice cream novelties such as cones and ice cream sandwiches. This facility manufactures about (b) (4) (b) (4) gallons annually. The other two Blue Bell facilities located in Broken Arrow, OK and

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Sylacauga, AL produce about (b) (4) gallons. A list of all products manufactured at this site was collected as **Exhibit 3**.

The facility occupies about (b) (4) square feet of manufacturing, staging, storage, warehousing, and freezer space in a single freestanding building. Floors are concrete with drains within the manufacturing areas. There are load-out docks for shipping out finished products and receiving raw materials. A floor plan of the facility was collected as **Exhibit 4**.

A basic flow chart of the manufacturing process for ice cream was collected as **Exhibit 5**. Milk comprises about (b) (4)% of most ice cream products. Milk is purchased by contract from (b) (4) (b) (4) coop dairies located within a (b) (4) mile radius of the firm. Milk is delivered (b) (4). Tankers arrive at the firm scale station weighed, and samples are taken and tested for (b) (4) and (b) (4). Texas DSHS oversees (b) (4) testing at the firm (b) (4).

After acceptance, tankers are unloaded into one of (b) (4) gallon refrigerated silos dedicated for milk storage. Total milk storage capacity is about (b) (4) gallons. Milk tankers are dedicated and washed out at the firm after unloading.

Milk is conveyed to (b) (4) and (b) (4) to about (b) (4) total solids from (b) (4). A separator is used to remove cream and obtain (b) (4) cream. Cream is routed to a (b) (4) and (b) (4) to (b) (4) in one of (b) (4) gallon tanks. The skimmed milk is (b) (4) cream and stored in one of (b) (4) tanks with capacities of (b) (4) gallons, or (b) (4) gallons. The cream, skimmed (b) (4) milk, corn syrup and (b) (4) are drawn from tanks into a (b) (4) gallon (b) (4) blender and taken to (b) (4) gallon holding tanks. The mixture is taken through a (b) (4) and (b) (4) at (b) (4) for (b) (4) seconds to pasteurize. Texas DSHS Milk and Dairy Division oversee the HTST (High Temperature Short Time) equipment tests and pasteurization at the firm (b) (4).

The (b) (4) and pasteurized mixture is drawn to (b) (4) gallon hold tanks and drawn into (b) (4) gallon (b) (4) vats where colors, flavors and juices are added. The flavored mixture is pumped to freezer units in the production room and chilled to (b) (4) and (b) (4). The final mixture is then pumped to fillers where solid ingredients (i.e. ribbons, fruits, nuts, chocolate chips, candies, marshmallows) are added with (b) (4) just prior to filling various size packages. Finished products are tested for weight, fill height, correct lot codes, and taste.

The firm is aware of allergen issues and utilizes sequencing as well as full clean outs after nut allergens. Mini Country Cones contain peanuts. Egg yolks are ingredients for French Vanilla ice cream and Chocolate Moo-Ilenium Crunch. Nuts used in ice creams include; pecans, almonds, walnuts, peanuts and macadamia nuts. Nuts are received from (b) (4) (b) (4) and (b) (4). Certificates of Analysis are required for nut acceptance with tests conducted for (b) (4).

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(b) (4) An example Certificate of Analysis and Bill of Lading for a recent shipment of roasted almond from (b) (4) was collected as **Exhibit 10**. All ingredients are inventoried and used on a FIFO (first in first out) basis. Chocolate wafers for ice cream sandwiches are made in a separate kitchen area and consist of primarily flour, sugar, and chocolate powder.

The firm utilizes HACCP concepts with CCP's at (b) (4) pasteurization time and temperature. The (b) (4) are have monitoring, verification/validation and recordkeeping.

There are (b) (4) employees in Quality Control who oversee testing, certificates of analysis and incoming product evaluations. Milk is tested for (b) (4) (b) (4) and (b) (4). Samples are taken at (b) (4) and tested for (b) (4) using the (b) (4). About (b) (4) tests are conducted (b) (4) Environmental swabs are taken with (b) (4) on a (b) (4) basis in (b) (4) to (b) (4) random areas of the production plant.

The three largest volume ice creams are (b) (4) and (b) (4) Popsicles are also manufactured on separate dedicated lines. During the inspection on 7/23/09 production of the following ice creams was observed; Pecan Pralines n cream, Strawberry, Banana Nut; Groom's Cake, Vanilla, Cookie Cones, Nutty Chocolate, Rocky Road, low fat vanilla ice cream, Triple Caramel and Ice Cream Sandwiches.

During the inspection on 7/23/09, a stainless steel pipe conveying liquid caramel was observed 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 (**Exhibit 6**).

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' (**Exhibit 7**). These observations were noted on the FDA 483 issued at the closing meeting on 7/24/09.

Employees were observed wearing hairnets or hats, gloves, uniform shirts and aprons where appropriate. Hand wash stations in production rooms as well as employee rest rooms were inspected and had adequate hot water, soap and towels. The firm utilizes Brenham City sewer services and Brenham City water. (b) (4) are tested (b) (4) and used for outdoor cleaning and milk truck washouts.

Sanitation chemicals and training for their use is supplied by (b) (4) The firm has a sanitation manual with SOP's for clean in place (CIP) and clean out of place (COP) operations of the various equipment. Chemicals include; (b) (4) a general (b) (4) cleaner for manual cleaning, (b) (4) used

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for the HTST pasteurizer in CIP, (b) (4) sanitizer for COP, (b) (4) liquid (b) (4) cleaner for CIP and COP, (b) (4) a (b) (4) detergent (b) (4) for exteriors, (b) (4) (b) (4) and (b) (4) detergent (b) (4) for exteriors, (b) (4) a (b) (4) detergent for manual cleaning, (b) (4) an (b) (4) for painted surfaces, (b) (4) an (b) (4) sanitizer for CIP, (b) (4) and environmental sanitizer (b) (4) a (b) (4) sanitizer for floors and doorways, (b) (4) a sanitizer for fruit buckets, (b) (4) a liquid (b) (4) sanitizer for pre-op CIP systems, freezer circuits, and draw lines.

CIP cleaning is generally conducted with an initial hot water flush out followed by a (b) (4) ppm solution of (b) (4) at (b) (4) F, a water flush out and CIP with sanitizer (b) (4) until start-up. COP cleaning is generally conducted with take down of the parts and rinse off in warm water. Parts are placed into (b) (4) long stainless steel tanks with a (b) (4) ppm (b) (4) solution with circulation at (b) (4) (b) (4) F. The tank is drained, parts are rinsed and reassembled and sanitized (b) (4) with (b) (4) solutions. COP cleaning was observed during the inspection. There were no observations noted for cleaning and sanitation.

Pest control is contracted to (b) (4) and administered by (b) (4) on (b) (4). Pest control records were reviewed for the previous 6 months. Tin cats, insect light traps and insectacutors, bait stations and catchalls with glue boards were observed in various areas of the plant and perimeter of the building. There were no observations noted for pests.

A field exam was conducted on Triple Caramel ice cream and reported separately into FACTS without deviations. An ingredient list for Triple Caramel ice cream was collected as **Exhibit 9**.

MANUFACTURING CODES

Manufacturing codes are ink printed or heat branded onto the bottom of containers. The lot codes are changed on a (b) (4) basis by the floor Production Manager and are verified by Quality Control personnel. On 7/23/09, the lot code of a quart container of ice cream was '072311A' where '07' designates July, '23' designates the 23rd day of the month, '11' designates (b) (4) (b) (4) and 'A' designates that the ice cream was packaged (b) (4) (b) (4). This plant uses (b) (4) for various package sizes.

The Broken Arrow, OK plant uses letters 'Q, R, S, and T' exclusively as the last digit of the lot code. The Sylacauga, AL plant uses letters 'W, X, Y and Z' exclusively as the last digit of the lot code.

COMPLAINTS

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There were no recent complaints in FACTS to follow-up. The firm has a procedure for documenting and investigating complaints.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

Present at the closing meeting on 7/24/09 with myself and Paul E. Frazier, CSO were; Paul W. Kruse, President and CEO, Andrew F. Kollman, QC Manager, Thomas J. Supak, Director QC and Mix Supervisor, Stacy L. Thiel, QC Supervisor, Kim Greiffenstein, Production Supervisor, and Eugene C. Supak, Vice President-Operations.

A 1-item FDA 483 was issued to Paul W. Kruse, President and CEO and discussed in detail. I informed management that the written item was our inspectional observations and upon further review by the Agency, the conditions listed may or may not be considered violations of the FD&C Act. The legal sanctions available to FDA were explained should the conditions be considered violations and remain uncorrected.

I also informed Mr. Kruse and management that my inspection may not have encompassed all processes or area of the plant. It was explained that their firm was responsible for maintaining the proper GMP requirements appropriate for their operations.

I explained that the firm could direct a response letter of the observations directly to the District Director of DAL-DO, preferably within 10 days. Mr. Kruse stated that they intended to correct all observations noted and would send a response letter documenting the modifications that were made. [A CC response letter from Mr. Kruse was received at AUS-RP on 8/4/09].

Observations listed on form FDA 483

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'.

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Reference: 21 CFR 110.80

Supporting Evidence and Relevance: **Exhibits 7-8**, condensation falling into a food product or container is adulteration.

Discussion with Management: Mr. Kruse agreed with the observations and gave assurances that the line to the 3 gallon filler would be rerouted such that condensate could not drip into containers.

Additionally, Mr. Kruse noted that the firm's mechanics installed stainless steel shrouds with sanitary welds around the fillers of all ice cream sandwich machines the evening of 7/23/09. This correction was verified on 7/24/09 prior to closing.

Mr. Kruse stated that the firm was firmly committed to following GMP's and these observations were helpful to the QC team to improve their systems and means of detection of other problems that might occur.

It was also discussed at the closing meeting that the drop down plastic curtain at the entrance to the production room was a possible source of contamination and not easily cleanable. Mr. Kruse agreed and stated another solution such as a quick-open door would be incorporated immediately.

Employee practices were discussed; it was emphasized that employees may occasionally need reminders and retraining concerning good handling practices at ice cream filling stations. Mr. Supak stated that employee practices were a constant struggle but on the job training was consistently emphasized. There were no further comments or questions and the inspection was closed.

REFUSALS/SAMPLES

There were no refusals. No samples were collected during this inspection.

ADDITIONAL INFORMATION

(b) (3) (A)

Paul E. Frazier, CSO participated in the entire inspection and took the photographs for this report.

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VOLUNTARY CORRECTIONS

The firm installed stainless steel shrouds with sanitary welds around the fillers of all ice cream sandwich machines the evening of 7/23/09. This correction was verified on 7/24/09 prior to closing.

EXHIBITS COLLECTED

1. Interstate shipping documents (14 pages).
2. Org charts (8 pages).
3. Product listing (9 pages).
4. Floor plan of facility (1 page).
5. Ice cream flow process diagram (1 page).
6. Photos of caramel pipe with condensation over empty 3 gallon tubs prior to filling (2 pages).
7. Photos of condensation above ice cream sandwich filler (b) (4) (2 pages).
8. Photo of SS shroud on filler of ice cream sandwich filler (1 page).
9. Ingredient list for Triple Caramel Ice Cream (1 page).
10. C of A and B/L from (b) (4) (2 pages).
11. FDA 525 with CD of photos taken during inspection (1 page).

ATTACHMENTS

1. FDA 482 issued to Paul W. Kruse, President and CEO on 7/23/09.
2. One item FDA 483 issued to Paul W. Kruse, President and CEO on 7/24/09.

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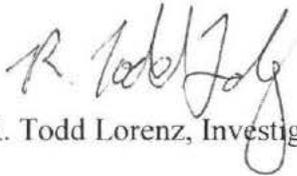
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R. Todd Lorenz, Investigator



Paul E. Frazier, Investigator