

Establishment Inspection Report

Blue Bell Creameries, LP
Broken Arrow, OK 74014-2900

FEI: 1000118167
EI Start: 03/28/2012
EI End: 03/28/2012

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SUMMARY

This comprehensive inspection of a commercial ice cream manufacturer was initiated by FACTS assignment 1372041, Operation ID 5914725 for Non-FSMA Food Inspection FY-12, and conducted under CPGM 7303.803 Domestic Food Safety Program Inspections for PAC 03803. The firm manufactures ice cream and sherbet in a variety of flavors, packaged for sale to consumers in half-gallon, quart, pint, and 3-oz size containers.

No observations were noted during the previous FDA inspection on 3/30/2011 so no FDA 483 was issued. The only objectionable condition observed was no soap at the hand sink in the (b) (4) room. All product in this area is enclosed. During the current inspection, this condition was verified to be corrected.

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The firm has not had any recall activity since the last inspection, and there is no consumer complaint history associated with the firm.

The current inspection covered the firm's receiving, storage, production, and distribution practices, and revealed two inspectional observations: 1) a production employee was observed touching non-food-contact surfaces and then touching ingredients that were being added directly into finished product; and 2) multiple bulk containers in the cooler were not labeled, and an unknown residue was observed on the lids of some of these containers, as well as on lids of labeled ingredients. Management corrected the employee after the objectionable activity was observed, and management promised to label the containers and initiate cleaning off the lids before and after opening containers.

The firm is registered under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

No samples were collected during this inspection.

No refusals were encountered during the current inspection.

ADMINISTRATIVE DATA

Inspected firm: Blue Bell Creameries, LP
Location: 8201 E Highway 51
Broken Arrow, OK 74014-2900
Phone: 918-258-5100
FAX:
Mailing address: 8201 E Hwy 51
Broken Arrow, OK 74014

Dates of inspection: 3/28/2012
Days in the facility: 1
Participants: Jennifer Owens Dowdy, Investigator

On 3/26/2012, I presented credentials and issued FDA Form 482-Notice of Inspection to Mr. Jeffery H. Martin, Quality Control Manager, who stated that he was the most responsible person at the firm, in the absence of the Plant Manager, who was (b) (6) on the day of this inspection. Mr. Martin accompanied me throughout this inspection and provided information for this report.

On 3/26/2012, I also provided Mr. Jeffery H. Martin, Quality Control Manager, with a copy of the FDA document entitled "Information Sheet — Assessment of Re-inspection and Recall User Fees for

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FY 2012 by the FDA” which provides the statutory authority granted to FDA to collect user fees for re-inspections by FSMA, who will be assessed user fees, and the rates.

Mr. Jeffery H. Martin, Quality Control Manager, accepted the FDA Form 483 Inspectional Observations, and he and Ms. Sandy G. Nunnally, Quality Control Supervisor, represented management during the close out meeting at the conclusion of this inspection.

HISTORY

The inspected firm is among four manufacturing plants owned and operated by the parent company, Blue Bell Creameries. Ownership of the inspected firm is a limited partnership formed in Texas, and the parent company was formed in 1930 in Brenham, TX. The original Blue Bell plant and an additional manufacturing facility are both located in Brenham, TX; the other plant is located in Sylacauga, AL. The company’s website is *www.bluebell.com* and the corporate address is 1101 S. Blue Bell Road, Brenham, TX 77833.

Blue Bell brand ice cream and ice cream novelty products are sold in (b) (4) states through their (b) (4) distribution branches, which are located (b) (4) from (b) (4) to (b) (4) (b) (4) and west to (b) (4), and south to (b) (4). The distribution centers and manufacturing facilities each operate between (b) (4) and (b) (4) refrigerated trucks, with a total fleet of (b) (4) trucks. The truck routes cover the (b) (4) including (b) (4) to (b) (4). The inspected firm operates (b) (4) refrigerated trailers that cover a (b) (4)-mile radius of the (b) (4) area, and the drivers are employees.

The inspected firm has not had any recall activity since the last inspection, and there is no consumer complaint history associated with the firm.

The inspected firm has (b) (4) employees working (b) (4)
(b) (4)

Production hours are generally (b) (4)
Dairy receiving occurs (b) (4)
Business office hours are 7:00 AM – 4:30 PM, Monday – Friday.

FDA correspondence including FMD 145 letter should be addressed to:

Mr. Marty Kilgore, Plant Manager
Blue Bell Creameries, LP
8201 E. Highway 51
Broken Arrow, OK 74014

The firm is also inspected by the Oklahoma Dept. of Agriculture, OSHA, the US Army, and (b) (4)

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(b) (3) (A)

INTERSTATE COMMERCE

The firm receives raw milk (b) (4) from dairy farms located within a (b) (4) mile radius that includes (b) (4). Other ingredients, such as flavored syrups, nut mixes, etc., are received from the corporate supply/distribution location in Brenham, TX. Some ingredients such as sliced, frozen strawberries are (b) (4) and received through a food broker, (b) (4). (b) (4) See Exhibit 1: Copy of Straight Bill of Lading No. (b) (4), dated 1/4/2012, from (b) (4).

The firm produces ice cream and sherbet products that are distributed by company trucks, which deliver on routes and to distribution centers located within a (b) (4) mile radius of the firm's Broken Arrow, OK location. The delivery area includes (b) (4). See Exhibit 2: Copy of Picking Slip for Truck Route (b) (4) to (b) (4) dated 3/22/2012.

JURISDICTION

The inspected firm produces ice cream and sherbet products under the Blue Bell Creameries brand name that are packaged in half-gallon, quart, pints, and 3-oz size containers. The firm is (b) (4) % wholesale. Mr. Martin, QC Manager, estimated that approximately (b) (4) % of the products manufactured by the firm are distributed outside of OK, to distribution branches located within a radius of (b) (4) miles from Broken Arrow, OK, which includes (b) (4) and (b) (4) but also to company-owned warehouses in (b) (4). The firm also receives novelty ice cream products manufactured in Brenham, TX, and distributes these items within their service area.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Mr. Jeffrey H. Martin, Quality Control Manager, has been with the firm for 16 years. Mr. Martin introduced himself as the most responsible person at the firm in the absence of the Plant Manager, who was on personal leave on the day of this inspection. Mr. Martin accompanied me during the entire inspection and provided information for this report. Mr. Martin represented management in the close out meeting, and accepted the FDA Form 483 Inspectional Observations at the conclusion of this inspection. He is responsible for overall quality, and manages (b) (4) employees. He was formerly responsible for the QC/QA lab and the mixed processing area for seven years. He reports to Mr. Marty Kilgore, Plant Manager.

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Ms/ Sandy G. Nunnally, Quality Control Supervisor, has been with the firm for 14 years. She previously worked in the QC Lab, and has been in her current role for the past six months. She supervises the (b) (4) QC technicians, and reports directly to Mr. Jeff Martin, QC Manager.

Mr. Marty L. Kilgore, Plant Manager, was not at the firm during this inspection. Mr. Martin explained that Mr. Kilgore was (b) (6) and was not expected at the facility. Mr. Martin stated that the management team (processing, quality, and traffic) report directly to Mr. Kilgore. Mr. Kilgore reports to the Vice President of Operations, Mr. Greg Bridges, whose office is at the corporate headquarters in Brenham, TX.

FIRM'S TRAINING PROGRAM

Mr. Martin explained that the HR training and orientation is conducted by the corporate trainers. Production, receiving, warehouse, and lab employees receive (b) (4) food safety training in a classroom setting that covers food GMPs, allergens, HACCP, and chemical safety. All employees also receive OTJ training, as needed, provided by the department supervisors.

MANUFACTURING/DESIGN OPERATIONS

The production facility covers (b) (4) sq ft and is situated on a fenced premises that includes paved parking for the firm's rotating fleet of (b) (4) trailers, (b) (4) bay dairy receiving house (b) (4) door refrigerated warehouse (b) (4) door dry-goods receiving area, and a Welcome Center that is used for tours and other public relations. The firm was built by Blue Bell in 1992, and Mr. Martin stated that the parent company has plans to (b) (4). Construction is cinder block, a composite/membrane roof, and concrete floors. Equipment throughout the facility is stainless steel. The refrigerated warehouse, cooler, (b) (4) freezer, and dry warehouse are all equipped with wall and floor-mounted shelving. The ceilings throughout are plastic grid, and lighting is ceiling-mounted fluorescent with safety bulbs. The "2nd floor" includes the office spaces and the QC lab; the basement level holds the (b) (4) which is the firm's term of the (b) (4) stainless steel holding tanks. See **Exhibit 3**: Diagram of plant.

The firm receives approximately (b) (4) gallons of raw milk and cream from dairy farmers (b) (4) (b) (4) located in (b) (4) and stores the liquids in (b) (4) gallon silos on the northeast side of the facility. According to Ms. Nunnally, the incoming milk is tested for (b) (4). She stated that all milk is used within (b) (4) and then silos are cleaned every (b) (4). The firm has an HTST pasteurizer that operates at (b) (4) gallons per hour. After pasteurization, some of the raw milk is (b) (4) held in a (b) (4) gallon tank. Milk is (b) (4) on (b) (4) if necessary. Even though the (b) (4) has been (b) (4) the firm considers (b) (4) (b) (4) to be (b) (4) so it will be (b) (4) before being used in ice cream.

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The firm receives dry ingredients (such as chocolate chips, nuts, candies, flavoring mixes, etc.) and packaging from the corporate supply center in Brenham, TX. Bulk corn syrup is received directly from suppliers (such as (b) (4)) and pumped into the interior holding silo. Some ingredients (such as strawberries, peaches, cookie dough pieces, etc.) are received frozen then staged to thaw under ambient conditions. Ms. Nunnally stated that bulk commodities such as cocoa are received at the Brenham corporate location accompanied by a certificate of analysis. The firm practices (b) (4) (b) (4) and FIFO rotation so that (b) (4) Mr. Martin estimated that the firm usually has less than (b) (4) worth of food ingredients on hand.

As we walked through the storage and staging areas, I observed multiple white plastic, lidded buckets on shrink-wrapped pallets that had dark brown residue on the sides, near and on the lids of the buckets. When I asked Mr. Martin about this residue, he explained that the buckets are filled at the Brenham supply location, using hoses that apparently drip, which creates the deposits of dried material. Subsequently, I observed that contents of the buckets (flavorings such as cherries, peaches, strawberries, fudge mixtures, etc.) are dumped into the blender tanks and mixed into the ice cream mix in the processing room. While in the blending room, buckets were observed full, thawing, and/or partially full; empty buckets and lids were observed being washed out and re-used to mix fruits with sugar/syrup, and for combining measured contents. Additionally, in the (b) (4) "Room" (cooler) three pallets of multiple buckets were observed to be unlabeled, and the lids and sides of numerous buckets were observed with a dried, crusty residue. See **Exhibit 6**: Photos of unlabeled and filthy buckets in Cooler (2 pages). When I asked Mr. Martin about these buckets, he could not identify the contents of the buckets, and he again stated that the residue on the outsides of the buckets was likely due to the same cause he had mentioned before (that the buckets are filled with hoses and arrive to the inspected facility in this condition). See **Objectionable Condition #2 of OBJECTIONABLE CONDITIONS & MANAGEMENT'S RESPONSE** section.

Ice cream/sherbet production has (b) (4) lines, which generally operate from (b) (4) until (b) (4). Mr. Martin described the manufacturing process for the firm's ice cream products as follows:

(b) (4) milk and cream are pumped into the pasteurizer >> into the blend room, where all ingredients (except for (b) (4) and solid additives) for the ice cream are combined into the batch tank (# (b) (4) or # (b) (4), (b) (4) (b) (4) >> (b) (4) >> the product mix is cooled and stored in the holding tank (stainless steel holding tanks # (b) (4) - # (b) (4) in the basement level of the firm until needed for freezing and packaging.

At this point, the product is held (b) (4) (minimum of (b) (4)) before further processing. Ms. Nunnally stated that this pasteurized mix is evaluated and tested for (b) (4) homogenization, (b) (4) plate counts, and (b) (4) counts by the firm's Quality Control lab.

The pasteurized mix is pumped from a holding tank in the basement into a (b) (4) gallon mix tank (stainless steel mixing tanks # (b) (4) - # (b) (4) into the Processing Room, where the (b) (4) and/or flavorings are added to the product mix. After these additions are blended into the mix, it is

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pumped to the freezer (lowers temperature from approximately (b) (4) to approximately (b) (4)). Mr. Martin explained that the firm can currently produce (b) (4) varieties of ice cream at one time, using different lines. He also stated that, depending on the size of the product containers, mixing tanks can be filled and processed every (b) (4). Production is generally based on demand, and Mr. Martin stated that the firm prepares some seasonal flavors periodically, but because the plant has multiple production lines, the plant can produce up to **Exhibit 4: Copy of Weekly Production Schedule for 3/26-30/2012**

The (b) (4) product is pumped from the processing room into the filling lines, where it is either a) pumped directly into round consumer-sized half-gallon, quart, pint, and 3-oz containers; or b) mixed briefly with added "inclusions" (dry flavorings such as nuts, marshmallows, mixes, candies, cookies, etc.) in in-line fillers, immediately prior to being pumped into the containers. When producing half-gallon product (b) (4) feed (b) (4) when making 3-oz cups of ice cream (b) (4) is used (b) (4). See **Exhibit 5: Labels of products manufactured on the day of this inspection** (4 pages).

The finishing and filling processes for the Nutty Chocolate ice cream, lot number 032814Q, was observed during this inspection, as follows:

Chocolate ice cream mix pumped from the processing room into the freezer >> (b) (4) ice cream product pumped into the filler machine >> box of Nutty Chocolate inclusions mixture (combination is almonds, pecans, walnuts and chocolate chips) (b) (4) opened & dumped into the hopper (See Observation #1 of **OBJECTIONABLE CONDITIONS & MANAGEMENT'S RESPONSE** section) >> inclusions mixture blended into ice cream at filler >> filler nozzle squirts (b) (4) amount of finished product into container on rotating wheel as Best By date is stamped on bottom >> lid applied to filled container >> filled containers roll off filler onto conveyor >> employee packs container into shipping sleeve >> code stamp checked on every (b) (4) container >> sleeve of four half-gallon containers carried to pallet >> pallet moved to (b) (4) freezer (b) (4) temperature (b) (4) to "harden" i.e., (b) (4) core temperature >> Frozen finished product conveyed to (b) (4) palletizing system >> pallets shrink-wrapped >> pallets moved to holding freezer (b) (4) until loaded onto refrigerated transport trucks.

The firm routinely retains (b) (4) which Mr. Martin explained is the product (b) (4) (b) (4). The (b) (4) is not out-of-limits or compromised; it serves as a (b) (4). After (b) (4) the (b) (4) (b) (4) and then through the (b) (4). This (b) (4) is only added to batches of products containing the same type of allergen, either (b) (4) collection/processing, or it is frozen for later use. On the day of this inspection, chocolate ice cream (b) (4) was observed being held in dedicated, plastic-line barrels, which were being rolled into the cooler, and Mr. Martin explained that it would be mixed into an up-coming batch for 3-oz cups.

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The firm uses colors to denote allergens in the warehouse and in the production areas. Brightly colored paper labels (in plastic covers) were observed on rework buckets and tanks. Once received into the warehouse, the pallets of allergens (pecans, almonds, etc.) are labeled with brightly colored 8"x10" papers with the allergen printed in black ink. The firm also uses clearly printed adhesive labels to mark white (b) (4) product mix and chocolate (b) (4) product mix.

Since the firm was (b) (4) milk, pasteurizing product, and cooling/freezing product during this inspection, Ms. Nunnally described the cleaning procedures. First, she explained that the firm has (b) (4) CIP systems for cleaning equipment holding and/or circulating raw product and a separate CIP system that is used to clean equipment handling and/or circulating pasteurized product. (b) (4) equipment is CIP; however, some tank doors are removable for cleaning. Ms. Nunnally stated that cleaning (and repairs, when needed) occurs on a schedule that is opposite the production schedule; CIP occurs (b) (4) and is routed to the equipment that is empty and idle. The firm's master cleaning chart was reviewed during this inspection. Cleaning procedures follow steps for raw and pasteurized milk/cream/buttermilk, and (b) (4) milk, including:

- The in-coming milk and cream silos are cleaned every (b) (4)
- The HTST pasteurizers are cleaned (b) (4)
- The (b) (4) tank is cleaned (b) (4) which occurs (b) (4) usually;
- The batch tanks are cleaned after (b) (4) or at least every (b) (4)
- Upon a completed run, the pasteurized ice cream product is flushed to clear the production tanks and tubes and (b) (4) followed by hot water flushes, then cleanser and sanitizers.

The firm uses (b) (4) cleaners and sanitizers in the CIP systems. The equipment in the firm was observed to be in good condition; pasteurizers were sealed, recording thermometers en tact, and no leaks were observed.

At the end of (b) (4) the tubes carrying ice cream product are flushed to the filler head, where the mixers and hoppers used to add "inclusions" (such as marshmallows, chip and nut mixes, cookie dough nuggets, etc.) are located. This equipment is used at the final step prior to packaging, and is semi-COP (partially disassembled and rinsed, flushed, and sanitized) along with the filler hoses and nozzles, after the run has been completed. Mr. Martin explained that these mixers are not used on every production run because only certain product formulas call for inclusions. During this inspection, (b) (4) of these mixers and fillers were observed idle in the filling section; the mixers were clean and covered with small plastic tarps. Ms. Nunnally reiterated that before the equipment is used, the line leader is responsible for a visual check, programming the filler for the product size, then visually inspecting for condition and assembly, and then the line leader initials the production log sheet, which is posted at the filler line.

Pest control is supplied by (b) (4), and visits are every (b) (4). Mr. Martin stated that he meets with the serviceman personally. Pest control logs for the past 12 months were reviewed; no deviations were noted. Treatments are for rodents and insects. No pests and no evidence of pests were observed during this inspection.

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A reconciliation exam was conducted for Frozen Sliced Strawberries, Lot # (b) (4), (b) (4) (b) (4) through the broke (b) (4), received by the firm on 1/4/2012, and no deviations were noted.

A label review of the Blue Bell Mixed Berries Sherbet product was conducted, and no deviations were noted. The product contains the allergen Red #40 which is named as an ingredient on the label.

MANUFACTURING CODES

The firm stamps the manufacturing code onto the bottom of each carton of ice cream as the carton is filled with product. During this inspection, I observed that the code stamped on the first carton through the coding machine is removed from the carton and stapled to the batch record for the product. From the batch record, the firm can determine the lot number of everything used in the product, including packaging.

An example of a batch record in use on the day of the inspection was:

03 28 14 Q

03 indicates month of production/best by date

28 indicates date of production/best by date

14 indicate (b) (4)

Q indicates operation & plant (i.e., Broken Arrow plant)

The inspected plant uses the letters O, P, Q, R, S, and T. The letter (b) (4) denotes the (b) (4)

(b) (4) Mr. Martin explained that when the firm (b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

When the firm is (b) (4)

, the (b) (4)

Mr. Martin further explained that the Blue Bell Creameries plant in Brenham, TX uses the letters A through G in their product codes, and the Sylacauga, AL plant uses the letters U through Z in their product codes. He also stated that the inspected firm is known internally (corporately) as (b) (4)

COMPLAINTS

The firm has written procedures for handling complaints. Mr. Martin explained that the containers are labeled with the firm's website, and that consumers can obtain a phone number to file product complaints. He stated that when a customer complaint is received by the corporate headquarters in Brenham, TX, corporate sends a 'customer concern alert' to the plant where the product was made.

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The information may include a photo of the issue. Then the plant conducts an investigation into the cause of the complaint. He stated that he knew of one complaint received regarding "a piece of a gasket" in a product. No other complaints were received, however, and equipment was inspected to verify good condition, and corporate replaced the product for the customer. All complaints must be addressed; however, only the corporate office has direct contact with consumers.

RECALL PROCEDURES

The firm has written recall protocol, which is referred to by the firm as a "Withdrawal." Mr. Martin stated that the firm conducts (b) (4) recall exercises. Ms. Nunnally stated that, since the date of manufacture can be determined by the "Best by" code, all products can be traced using the lot numbers of the ingredients used in the manufacturing process. The firm has no time limit to accomplish the recall, but tries to complete it within (b) (4) and reports the result to corporate. She also stated that since all product made at the inspected facility is transported to Blue Bell distribution branches, the corporate office would be directly coordinating an actual recall. She further explained that the plant would perform the trace-back and report progress via email to the corporate office. Mr. Martin stated that, in the event of a recall, the firm would likely recall the entire amount of product on hand at the distribution branch. See **Exhibit 6**: Copy of the "Withdrawal Summary" for mock recall conducted on 6/15/2011.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE**Observations listed on form FDA 483**

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 described 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.

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Reference: 21 CFR 110.80(b)(2)

Supporting Evidence and Relevance:

While observing the production line for the "Nutty Chocolate" flavor, packaged in half-gallon containers, an employee was seen to routinely touch non-food-surfaces and then touch the food 'inclusions' (the nutty chocolate pre-mix) that were being poured directly into the hopper which feeds the inclusions into the ice cream at the final mixing stage, immediately prior to filling the half-gallon containers with finished product. Further, the same employee was subsequently observed to scratch his head and scalp and then adjust his cap (he was wearing a hairnet under the cap), and to also adjust his pants waistline. The employee did not change gloves after each of these activities.

Discussion with Management:

Upon noting the activity of this employee, I asked Mr. Martin to also watch the employee, and Mr. Martin agreed that the employee was touching the exterior of the boxes, the plastic bags inside the boxes, and then sweeping the remaining contents of the plastic-lined boxes into the hopper with his gloved hand; however, the glove was not changed between boxes. Mr. Martin acknowledged that the employee's behavior was unacceptable, and then he pointed out the behavior to the line supervisor, who immediately corrected the employee by demonstrating how to empty the boxes without touching the food inclusions.

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 (b) (4) 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.

A brown, dried residue was observed on the lids and down the sides of at least 3 of the (b) (4) unmarked five-gallon buckets on one pallet, and a yellowish, dried residue was observed on the lid of one of the (b) (4) unmarked five-gallon buckets on the other pallet. A third partial pallet of (b) (4) 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.

Reference: 21 CFR 110.80(b)(7)

Supporting Evidence and Relevance:

Ingredients or "inclusions" for flavoring the ice cream products are brought into the production area in lidded, white, 5-gallon buckets. These buckets were observed in the receiving area as well as in production areas during this inspection. Mr. Martini explained that most buckets arrive (on shrink-

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wrapped pallets) directly from the corporate supply in Brenham, TX, but other buckets are washed and re-used when combining or preparing the inclusions. While in the (b) (4) degree room' (cooler) during this inspection, multiple buckets on two pallets were observed to lack labels that identify the contents of these buckets. These pallets were in the southeast corner of the first section of the room; one pallet contained (b) (4) buckets and the other pallet contained (b) (4) buckets.

Further, each of these pallets had at least one bucket with dried, crusty residue on the lid and/or along the sides of the buckets. Additionally, a third pallet holding buckets labeled "Maraschino Cherries" also had dried residue on the lids and sides of at least two of the buckets. Mr. Martin could not identify the residue on the lids or sides of the buckets. See **Exhibit 7**: Photo of unlabeled and filthy buckets in Cooler.

Discussion with Management:

Mr. Martin acknowledged that all containers should be labeled and also explained that the buckets are received from the corporate plant supply facility in Brenham, TX, and frequently arrive with residues on the exteriors, since the buckets are "filled using hoses." He further explained that the firm washes and re-uses buckets and lids regularly; the original adhesive labels usually get washed off entirely, and sometimes the buckets, although cleaned and sanitized, could be discolored from the previous contents. After consulting with the production and receiving departments at the firm, Mr. Martin subsequently stated that the buckets would be shrink-wrapped and a label placed on the shrink wrap, indicating the contents of the buckets on each pallet. He further stated that the buckets would be visually checked for filth and residue, and wiped off before being brought into production, as well as after being re-filled and taken into the cooler for staging.

REFUSALS

No refusals were encountered during this inspection.

GENERAL DISCUSSION WITH MANAGEMENT

Discussion with management occurred throughout the current inspection, and a close out meeting was held with Mr. Jeffrey Martin, Quality Control Manager, and Ms. Sandy Nunnally, Quality Control Supervisor.

We discussed the documentation gathered during this inspection, and verified the manufacturing process. Then I presented the FDA Form 483 – Inspectional Observations to Mr. Martin. See **OBJECTIONABLE CONDITIONS & MANAGEMENT'S RESPONSE** section. Following our discussion, I reiterated the information regarding the FSMA notification and provided a copy of the RFR brochure. I also referred them to the FDA website for current information, as needed. Then I asked whether they had any questions, and since they did not, I thanked them for their time and concluded the inspection.

Establishment Inspection Report

Blue Bell Creameries, LP
Broken Arrow, OK 74014-2900

FEI: 1000118167
EI Start: 03/28/2012
EI End: 03/28/2012

SAMPLES COLLECTED

No samples were collected during this inspection.

VOLUNTARY CORRECTIONS

One objectionable condition was discussed as a result of the previous FDA inspection in 3/2011:

No soap at the hand sink in the (b) (4) area.

Management promised to correct this observation. The product in the (b) (4) area of the firm is enclosed. During the current inspection, this condition was verified to be corrected.

EXHIBITS COLLECTED

Exhibit 1: Copy of Straight Bill of Lading No. (b) (4), dated 1/4/2012, from (b) (4) (b) (4)

Exhibit 2: Copy of Picking Slip for Truck Route (b) (4) to (b) (4), dated 3/22/2012

Exhibit 3: Diagram of plant

Exhibit 4: Copy of Weekly Production Schedule for 3/26-30/2012

Exhibit 5: Labels of products manufactured during this inspection (4 pages)

Exhibit 6: Photos of unlabeled and filthy buckets in Cooler (2 pages)

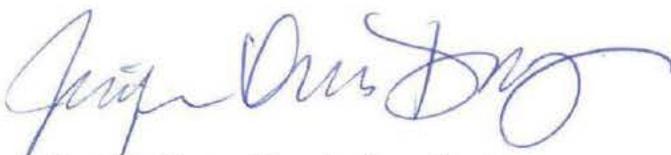
Exhibit 7: Copy of the "Withdrawal Summary" for mock recall conducted on 6/15/2011

Exhibit 8: CD of photographs taken during the inspection on 3/28/2012

ATTACHMENTS

Attachment 1: FDA Form 482 – Notice of Inspection issued to Mr. Jeffrey H. Martin, Quality Control Manager at Blue Bell Creameries, LP, Broken Arrow, OK on 3/28/2012

Attachment 2: FDA Form 483 – Inspectional Observations issued to Mr. Jeffrey H. Martin, Quality Control Manager at Blue Bell Creameries, LP, Broken Arrow, OK on 3/28/2012



Jennifer Owens Dowdy, Investigator