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Blue Bell Creameries, L.P.

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Attn: Mr. Reynaldo Rodriguez
FDA District Director
4040 North Central Expressway, Suite 300
Dallas, TX 75204



Date: April 9, 2012

Dear Mr. Rodriguez,

On March 28, 2012, FDA Consumer Safety Officer Jennifer Owens Dowdy conducted an inspection of our facility, Blue Bell Creameries, L.P. in Broken Arrow, OK. During the inspection, Mrs. Dowdy reviewed numerous records and did a walk-through inspection of the entire production/dry storage/cold storage facility as well as the grounds surrounding the building. We appreciated the professionalism and attention Mrs. Dowdy gave to our questions and concerns.

Ms. Dowdy noted the following observations during her inspection:

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 the 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.

Corrective Action: Employee was corrected immediately on the spot. GMP's are in place and practiced in our production areas. I (Jeff Martin) have observed the employee on two separate instances since Mrs. Dowdy's inspection and the employee did not touch the ingredients in either instance with his hands.



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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 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.

Corrective Action: The two partial pallets observed with no label were labeled with a brown tape on the handle and a code date. The tape also has a color coded reference line at the bottom of the tape. The departments that move or use these buckets can follow a reference sheet to determine what product is in the bucket from this tape. I (Jeff Martin) met with Production management after Mrs. Dowdy's inspection to discuss labeling the partial pallets more clearly to make them easier to identify. The partial pallets will be re-wrapped and the ingredient will be identified in writing across the wrap or a printed label attached to the wrap. The cleanliness and appearance of the outside of the buckets after being filled was also addressed in the Production meeting.

Blue Bell Creameries strives to produce safe, high quality products. We viewed the inspection as an opportunity to improve our operations and make us better. Hopefully this follow up letter clarifies our prompt efforts to correct the observations that were noted during the inspection. If there is anything further that you would like for us to do, please don't hesitate to let us know.

Sincerely,

Jeff Martin
Quality Control Manager
Blue Bell Creameries, L.P.