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August 28, 2015

Mr. Reynaldo Rodriguez
District Director
Dallas District Office
U.S. Food and Drug Administration
4040 North Central Expressway
Dallas, Texas 75204-3128

Re: Second Update on Response of Blue Bell Creameries, Inc., to FDA Form 483 Issued to Our Broken Arrow Facility

Dear Mr. Rodriguez,

Blue Bell Creameries, Inc., (Blue Bell or the Company) is pleased to provide this second update on the progress of the corrective actions identified in our response to the Food and Drug Administration (FDA) Form 483 Inspectional Observations (the 483) issued to our ice cream processing facility in Broken Arrow, Oklahoma.

Producing safe, wholesome products remains Blue Bell's top priority, and our facility in Broken Arrow has remained voluntarily shut down for nearly five months while we implemented remediative action, including a number of corrective actions taken in direct response to the 483. As we explained to your office earlier, we believe we are now ready to resume operations at Broken Arrow. We are accordingly providing this update on the corrective actions taken at our Broken Arrow facility. Importantly, as reflected in the attached update, we have engaged in a robust set of actions to address the items identified in the 483.

As we move toward resuming operations, we want to assure FDA that we remain committed to cooperating fully and communicating openly with FDA and our state regulators. We want to be sure that FDA is fully comfortable with the steps we are taking at all of our facilities. We plan to resume production starting with (b) (4) (b) (4) our procedures. All ice cream will be produced under a (b) (4) program, and we will not release any product from inventory until we are confident it is safe for our consumers to enjoy.

Blue Bell remains firmly committed to compliance with all FDA requirements and to ensuring we are producing safe and wholesome products for our customers to enjoy. Thank you for considering these responses, and please do not hesitate to contact us if you have any questions.

Sincerely,

Paul W. Kruse
CEO and President
Blue Bell Creameries, Inc.

cc

Edmundo Garcia, Deputy Director
Dallas District Office

Shari Shambaugh, Director of Compliance
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Enclosures

Blue Bell Creameries
Second Update to FDA Regarding Corrective Actions in Response to 483
Broken Arrow, Oklahoma

August 28, 2015

Blue Bell Creameries (Blue Bell or the Company) is pleased to provide this update to the Food and Drug Administration (FDA) regarding corrective actions taken at our ice cream manufacturing facility in Broken Arrow, Oklahoma, in response to the FDA Form 483 Inspectional Observations (the 483) issued to our facility on May 1, 2015.[1] In our May 22, 2015, response to the 483, we outlined a number of corrective actions in response to FDA's observations, and we provided updated information on those corrective actions in our update on July 21, 2015. We appreciate the opportunity to provide this additional update, as well as FDA's consideration of these materials. We are pleased to report that we have completed all corrective actions identified in our response to the 483 issued to our Broken Arrow facility.[2]

We earlier notified FDA and the state of Oklahoma of our intent to resume operations at our Broken Arrow facility. As we explained, we plan to resume operations similarly to how we resumed production at our Sylacauga, Alabama, facility, beginning with (b) (4) (b) (4) our procedures. When we resume production, we will draw on our Company's experience with operations at our Sylacauga, Alabama, facility, and we will also continue to work with our team of expert consultants. All production will be carried out under a (b) (4) program, and all lots of finished product will be tested for the presence of *Listeria monocytogenes* (*Lm*).

Below, we provide updates on all outstanding corrective actions from our response to the 483, organized by Observation number in the 483. If an Observation is not listed, the corrective action was completed previously, as explained in one of our earlier responses. We include as attachments to this response any final procedures referenced in this update. For infrastructure or equipment modifications and for employee training, we will maintain supporting documentation at our facility for review by FDA; we are prepared to submit that documentation to FDA upon request. Moreover, we are including a chart summarizing all corrective actions completed in response to the 483 (Attachment A).

In preparation for resuming operations, to monitor the effectiveness of our cleaning and sanitation efforts, and to help identify any potential reintroduction of *Listeria* to our facility, we have been conducting substantial environmental testing in our facility. During the period from August 1 through

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[1] Blue Bell considers all of the attachments to this response and all descriptions of procedures, processes, facility designs and modifications, and marketing plans to be trade secrets and confidential commercial information and therefore exempt from disclosure under the Freedom of Information Act, 5 U.S.C. § 552(b)(4).

[2] As explained further below, we have completed training employees who will be involved in startup operations. During our voluntary shutdown, we placed a number of employees on furlough; those furloughed employees will be trained on our new procedures as they are brought back to work. Moreover, in response to Observation 5, we indicated we would evaluate replacing some metal components with plastic ones. We have decided that we will (b) (4) (b) (4).

August 24, 2015, we collected (b) (4) environmental samples, all of which—with the exception of one sample that remains in testing[3]—tested negative for the presence of *Listeria spp*. We are enclosing a chart detailing this sampling. (Attachment B). We believe these sampling results are a reflection of our hard work cleaning and sanitizing the facility and our equipment, which has laid a solid groundwork for resuming operations.

We appreciate the continued close and open working relationship with FDA and remain committed to full cooperation as we prepare to resume operations at our Broken Arrow facility.

Observation 3: The procedure used for cleaning and sanitizing of equipment and utensils has not been shown to provide adequate cleaning and sanitizing treatment.

We committed to providing revised cleaning and sanitation procedures to FDA once the procedures are complete. We have focused our efforts on reviewing the cleaning and sanitation procedures that pertain to the equipment and processing lines we hope to bring back into operation first. To that end, we are providing Sanitation Standard Operating Procedures (SSOPs) that are primarily relevant to producing product and that would be used in the initial trial production run. We can provide additional procedures to FDA upon request.

We are enclosing the following procedures:

1. Clean-up of Allergens Ingredients Spills (Dry Storage/Receiving)
2. General Housekeeping/Cleaning (Dry Storage/Receiving)
3. Clean-Up of Dry Ingredient Spills (Dry Storage/Receiving)
4. Cups Cleaning Procedure (Dry Storage/Receiving)
5. Trailer Wash Out (Fleet Maintenance)
6. Kitchen Rework Clean Up (I/P - Kitchen)
7. Cleaning Kitchen Area Floor Entrance/Exit (I/P - Kitchen)
8. Environment Clean-Up For Floors (I/P - Kitchen)
9. Environment Clean-Up For Walls (I/P - Kitchen)
10. (b) (4) Program for (b) (4) Areas (Multi. Departments)
11. Blend Room Environmental Cleaning (Mix Processing)
12. Ceiling Cleaning (Mix Processing)
13. Floor Cleaning (Mix Processing)
14. HTST Cleaning (Mix Processing)
15. Inline Strainer Cleaning (Mix Processing)
16. (b) (4) Line Circuit Cleaning (Mix Processing)
17. (b) (4) Storage Tanks Cleaning (Mix Processing)
18. (b) (4) Cleaning (Mix Processing)
19. Wall Cleaning (Mix Processing)
20. Cleaning of HVAC System Procedure (Plant Maintenance)
21. (b) (4) Area Drain Back-Up Procedure (Plant Maintenance)
22. (b) (4) Area Entry Procedure For Maintenance (Plant Maintenance)

[3] No result has been reported for the sample still in testing; we anticipate receiving that result in the coming days.

23. Shop Sanitation (Plant Maintenance)
24. Tool Sanitize - Wash Procedure (Plant Maintenance)
25. Working On Equipment in Production Areas (Plant Maintenance)
26 Cleaning Half Gallon Operation (Production)
27. SSOP (b) (4) Fruit Feeder (Production)
28. AM Sanitation (Production)
29. Testing/Documenting of Chemical Concentrations and Water Temperature (Production)
30. SSOP (b) (4) Fruit Feeder (Production)
31. Drain Cleaning with (b) (4) & (b) (4)SSOP (Mix Processing & Production)
32. Environmental and Drain Cleaning (Production)
33. Environmental (b) (4) (Production)
34. Production Sanitation SSOP 1/2 Gallon (Production)
35. (b) (4) Cleaning of Filling Equipment (Multi. Departments)
36. Plant (b) (4) SOP (Multi. Departments)
37. SOP for COP (Mix Processing & Production)
38. Inclusion Utensil Cleaning (Production)

These procedures are enclosed as Attachment C and are numbered within Attachment C according to the order listed above.[4]

Observation 4: Failure to provide running water at a suitable temperature for cleaning of equipment, utensils and food-packaging materials.

We indicated we would (b) (4) to the clean-in-place (CIP) (b) (4) as well as install a (b) (4) our CIP and clean-out-of-place (COP) operations As explained in our first update, we completed installation of the (b) (4) on July 15, 2015. We completed training on its use on August 25, 2015. We completed installation of the (b) (4) on our CIP and COP systems on August 26, 2015 We are maintaining supporting documentation for both actions on file at our Broken Arrow facility.

Observation 5: The plant is not constructed in such a manner as to prevent drip and condensate from contaminating food, food-contact surfaces, and food-packaging materials.

We previously identified various planned modifications in response to this Observation:

- Reconfigure pipe and line layout to minimize potential for condensation to come into contact with food or food contact surfaces. We completed this action on August 26, 2015. Supporting documentation is maintained on file at the facility.
- Insulate pipes or install splash guards when reconfiguration is not feasible We have installed troughs under pipes that run above food contact surfaces. We completed this action on August 27, 2015. Supporting documentation is maintained on file at the facility

[4] For example, the document entitled "Floor Cleaning (Mix Processing)" is included as Attachment C.13.

- Add troughs under pipes to master sanitation schedule. We will clean the troughs as part of our (b) (4) cleaning program. This is currently reflected on the attached (b) (4) Master Sanitation Schedule. (Attachment D). We completed this action on August 27, 2015.
- Evaluate gaskets to ensure proper fit and replace gaskets as needed. These gaskets are the seals around the (b) (4) on the (b) (4). We completed this evaluation and replaced all of these gaskets as of August 18, 2015. Supporting documentation is maintained on file at the facility.
- Lower temperature in production area. We plan to make this adjustment when we resume production. We will have a better idea of what temperatures are attainable once operations resume and we can evaluate temperature-control capabilities under real-world conditions.
- Train employees on proper handling of equipment. We completed this component of our employee training on August 26, 2015. Training for employees who will be involved in the initial production will be completed as of August 28, 2015. New hires or employees brought back from furlough will be trained as they come back to work. Supporting documentation is maintained on file at the facility.
- Evaluate ways to adjust cleaning procedures to minimize likelihood that the (b) (4) (b) (4) could contaminate product. We are training employees to clean the (b) (4) (b) (4) using (b) (4), rather than (b) (4) when appropriate. Training for employees who will be involved in the initial production will be completed as of August 28, 2015. New hires or employees brought back from furlough will be trained as they come back to work. Supporting documentation is maintained on file at the facility.
- Assess filling machines and (b) (4) filling machines. After evaluating our equipment design and setup, we determined it would be most feasible to (b) (4) (b) (4) the filling machines to (b) (4) that is in close proximity to the machines. We believe this will help minimize the potential for condensation to contact the machines. As noted above, we completed (b) (4) on August 26, 2015. We also redesigned the chute that feeds lids to the machine. Supporting documentation is maintained on file at the facility.
- Evaluating the feasibility of using non-metal components for parts of machines. After further consideration, we believe we will be able to (b) (4) using non-metal components (b) (4). We will monitor our equipment during production for areas of potential concern and will make changes as appropriate. We will maintain supporting documentation on file at the facility.
- Move packaging equipment to allow staging of boxes not under pipes. We completed this action on August 25, 2015. Supporting documentation is maintained on file at the facility.

Observation 6: Employees did not wash and sanitize hands thoroughly in an adequate hand-washing facility after each absence from the work station and at any time their hands may have become soiled or contaminated.

We committed to retraining employees before startup on topics including proper identification of food-contact surfaces and the importance of wearing proper attire. Training for employees who will

be involved in the initial production will be completed as of August 28, 2015. New hires or employees brought back from furlough will be trained as they come back to work. Supporting documentation is maintained on file at the facility.

We shared a company-wide uniform policy with our July 21, 2015, update. We have since modified that policy to apply specifically to the Broken Arrow facility. Under the policy, all employees are required to show up for work in clean shirts and pants. Employees will be required to wear hairnets in the Production, Ingredient Processing, Mix Processing, and (b) (4) areas of the plant, with the hairnets color-coded to indicate whether the wearer is an employee working in a raw area, an employee working in another production area, or is a visitor, vendor, or contractor. Employees with facial hair will be required to wear beard nets. Employees and visitors, vendors, or contractors entering areas designated "(b) (4) " (Production, Ingredient Processing) will have to wear smocks over their uniforms. The smocks will be color coded to indicate whether the wearer is an employee working in that area, a maintenance employee, or a visitor, vendor, or contractor. The uniform policy also includes a (b) (4) program. Employees will be required to wear a (b) (4) in certain areas of the facility and will not be permitted to wear the (b) (4) outside those areas. Visitors and employees who do not routinely work in areas that require (b) (4) will be required to wear a shoe cover when entering (b) (4) areas. Moreover, all employees and visitors will be required to (b) (4) when entering specific parts of the facility. The updated policy is included as Attachment E.

Finally, we indicated we would install (b) (4) at entrances to (b) (4) processing areas. We completed this action on August 25, 2015. Supporting documentation is maintained on file at the facility.

Observation 7:

Failure to store cleaned and sanitized portable equipment in a location and manner which protects food-contact surfaces from contamination.

We indicated we would identify a permanent location for storing equipment that is not in use as well as a dedicated location for cleaning and sanitizing equipment coming on and off the line. We have (b) (4) in our facility that will be capable of (b) (4) . Adjacent to this (b) (4) is a dedicated dry area for storing and staging equipment. The (b) (4) was operational by July 30, 2015, and we continued to optimize it through August 25, 2015. Supporting documentation is maintained on file at the facility.

Observation 9: The design of equipment does not allow proper cleaning and maintenance.

We explained that we would discontinue the use of (b) (4) in production and processing areas and that we would identify a replacement. We have elected to (b) (4) for these areas and plan to implement (b) (4) . We completed the transition to the (b) (4) (b) (4) on August 25, 2015. Supporting documentation for the (b) (4) is maintained on file at the

facility. Enclosed is a procedure entitled (b) (4) for (b) (4) Areas," which governs how (b) (4) are to be used and sanitized. (Attachment C.10).

Observation 12: Failure to take apart equipment as necessary to ensure thorough cleaning.

We explained that we would ensure that the front face plate of (b) (4) freezer and their corresponding gaskets are cleaned regularly. We have incorporated these items into our (b) (4) cleaning program. We are attaching a job plan printout from the computer software that we use to manage our preventative maintenance program and (b) (4) work schedules. This printout shows that preventative maintenance will be performed on the freezers every (b) (4), including cleaning, inspecting, and, if needed, replacing the (b) (4) (highlighted in the attachment). (Attachment F). We have also added these components to the list of potential swab sites for our environmental monitoring program.