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November 13, 2015

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

Re: Updated Response of Blue Bell Creameries, Inc., to FDA Form 483 Issued to Brenham Facility

Dear Mr. Rodriguez:

Blue Bell Creameries, Inc., (Blue Bell or the Company) appreciates the opportunity to provide this updated response on the status of the corrective actions we 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 Brenham, Texas.

Producing safe, wholesome products remains Blue Bell's top priority, and we are taking the time to get this right. Our Brenham facility has remained shut down voluntarily for more than six months for this very reason. Blue Bell employees have been working diligently over the past months to thoroughly clean and sanitize our facility and equipment, review and revise procedures, and identify and implement facility enhancements. As we explained in our initial response to the 483, we have not limited ourselves to only the Observations noted in the 483, but rather have taken a broad, hard look at all aspects of our facilities, equipment, and procedures.

After suspending operations at all of our facilities, we decided to focus our efforts on first preparing our smaller facilities in Sylacauga, Alabama, and Broken Arrow, Oklahoma, for operation, recognizing that cleaning and sanitization efforts and corrective actions necessarily would take longer and be potentially more complex in our larger Brenham facility. After gaining experience with our enhanced procedures and redesigned processing lines in our smaller facilities, we believe we are now prepared to resume operations at our Brenham facility. As we explained earlier to your office and to the State of Texas, we are preparing to resume ice cream production at our Brenham facility on or after November 17, 2015.

As we bring our final ice cream processing facility online, 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 the Brenham facility. Importantly, we plan to resume production at our Brenham facility in (b) (4) similar to how we approached startup at our other facilities, (b) (4) (b) (4) . Moreover, we will operate under our (b) (4) (b) (4) program for a period of at least (b) (4) and we will not release product until we are confident it is safe for our consumers to enjoy.

Importantly, we have focused our initial startup efforts for ice cream production on (b) (4) (b) (4) (b) (4) In contrast, (b) (4) (where the (b) (4) was located) and the (b) (4) (b) (4) (b) (4) . We continue to (b) (4) . Similarly, we are (b) (4) resuming operations in the Brenham facility's (b) (4) (b) (4).

Blue Bell remains firmly committed to compliance with 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
Dallas District Office

William Correll, Director
Office of Compliance, Center for Food Safety and Applied Nutrition

Joseph A. Levitt
Counsel to Blue Bell Creameries, Inc.

Enclosures

Blue Bell Creameries
Update to FDA Regarding Corrective Actions in Response to 483
Brenham, Texas

November 13, 2015

Blue Bell Creameries (Blue Bell or the Company) appreciates the opportunity to provide this update to the Food and Drug Administration (FDA) regarding corrective actions taken at our ice cream manufacturing facility in Brenham, Texas, 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 your office an interim update on those actions 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 the corrective actions identified in our response to the 483 issued to our Brenham facility for the areas and equipment that will be used when operations resume.[2]

As we earlier notified FDA and the state of Texas, we plan to resume operations at the Brenham facility on or after November 17, 2015. As we explained, we plan to resume operations (b) (4) (b) (4) similar to how we resumed production at our facilities in Sylacauga, Alabama, and Broken Arrow, Oklahoma. In particular, the Brenham facility is large, and we have focused our initial startup efforts for ice cream production on (b) (4) (b) (4).

In contrast, (b) (4) (where the (b) (4) was located) and the (b) (4) (b) (4). We continue to (b) (4). Similarly, we are (b) (4) resuming operations in the Brenham facility's (b) (4).

As an added measure to further ensure we have appropriate controls over the processing environment, we plan to work (b) (4) to treat the Brenham facility with (b) (4) (b) (4) shortly before we plan resuming operations. The (b) (4) is designed to destroy foodborne pathogens including *Listeria monocytogenes* (*Lm*). We believe the (b) (4) (b) (4) will be effective in helping to ensure we are resuming operations with a sanitary environment. We will monitor the effectiveness of the (b) (4) using (b) (4) and (b) (4) throughout the facility, and we will continue to monitor the environment on an ongoing basis through our environmental monitoring program. We will maintain copies of the results of these verification steps for FDA to review upon request.

As with our other facilities, production will begin with (b) (4) (b) (4). In resuming production, we are drawing

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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 plan to focus our initial production (b) (4). We accordingly have (b) (4).

on our Company's experience with operations at our other two operating facilities, and we will also continue to work with our team of expert consultants. All production will be carried out under (b) (4) (b) (4) program for a period of at least (b) (4), and all lots of finished product will be tested for the presence of *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).

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 Brenham facility.

Observation 2: The procedure used for cleaning and sanitizing of equipment has not been shown to provide adequate cleaning and sanitizing treatment.

We previously provided FDA with copies of the Environmental Monitoring Procedure, (b) (4) (b) (4) Program, and (b) (4) Program that we plan to use at our Brenham facility. As part of preparing to resume operations at the Brenham facility, we have prepared lists of potential sample locations for each procedure. Updated procedures that include the lists of sample locations are enclosed as Attachment B.

We committed to providing revised cleaning and sanitation procedures to FDA. We have focused our attention on those cleaning and sanitation procedures necessary to support the initial production operations as we bring the Brenham facility back into production. 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 have also worked to standardize procedures across our processing facilities. We can provide additional procedures to FDA upon request.

We are enclosing the following procedures:

1. Clean-up of Allergen Ingredients (Dry Storage / Receiving)
2. General Housekeeping - Cleaning (Receiving) (Dry Storage / Receiving)
3. Clean Up of Dry Ingredient Spills (Dry Storage / Receiving)
4. Trailer Wash Out (Fleet Maintenance)
5. Environmental Clean Up for Floors (Ingredient Processing)
6. Environmental Clean Up for Walls (Ingredient Processing)
7. Kitchen Environmental Clean up - Entry and Exit (Ingredient Processing)
8. Kitchen Rework (Ingredient Processing)
9. Washing (b) (4) (Ingredient Processing)
10. Drain Cleaning (Mix Processing)
11. Environmental Room Cleaning (Mix Processing)

12. HTST Cleaning (Mix Processing)
13. Inline Strainer Cleaning (Mix Processing)
14. (b) (4) Line Circuit Cleaning (Mix Processing)
15. (b) (4) Storage Tank Cleaning (Mix Processing)
16. (b) (4) Cleaning (Mix Processing)
17. Raw Line Circuit Cleaning (Mix Processing)
18. Raw Storage Tanks Cleaning (Mix Processing)
19. Cleanup of Bodily Fluids (Multi-Department)
20. Locker Cleanout (Multi-Department)
21. Cleaning of HVAC (Plant Maintenance)
22. (b) (4) Area Drain Back-up (Plant Maintenance)
23. Shop Sanitation (Plant Maintenance)
24. Tool Sanitize-Wash (Plant Maintenance)
25. (b) (4) (Production)
26. Freezer SSOP (Production)
27. (b) (4) Feeder SSOP (Production)[3]
28. Inclusion Utensil Cleaning (Production)
29. Sanitation for (b) (4) Filling Machine (Production)
30. (b) (4) Cleaning of Equipment (Production)
31. Plant (b) (4) (Production)
32. AM Sanitation (Production)
33. (b) (4) Fruit Feeder (Production)
34. Dedicated Cleaning Utensils (Production)
35. Drain Cleaning (Production)
36. Environmental (b) (4) (Production)
37. Environmental (Production)
38. (b) (4) Fruit Feeder (Production)
39. Testing/Documenting Chemical Concentrations (Production)

These procedures are enclosed as Attachment C and are numbered within Attachment C according to the order listed above.[4] Employees will be trained on these and other procedures as they return to work. Employee training materials will be maintained on file at the facility.

Observation 3: The plant is not constructed in such a manner as to prevent condensate from contaminating food and food-contact surfaces.

We previously identified a number of steps in response to this Observation, which we have completed for equipment and lines that would be used in initial production after startup:

- Reconfigure pipe and line layout to minimize potential for condensation to come into contact with food or food contact surfaces. We completed this work by October 28, 2015, for areas and lines that would be used during an initial startup production. We will continue

[3] (b) (4)

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

addressing other areas and lines as they are brought into operation. Supporting documentation is maintained on file at the facility.

- Insulate pipes or install splash guards when reconfiguration is not feasible. Having reconfigured pipe and line layout as indicated above, we must await resumption of operations to identify any remaining areas that may require special attention to prevent dripping or condensation under real-world operating conditions. We have prepared troughs to use as needed. Supporting documentation for any additional splash guards or insulation added will be maintained on file at the facility.

- Add (b) (4) to Line (b) (4) Molds. We completed this work on June 11, 2015. Supporting documentation is maintained on file at the facility.

- Add (b) (4) on Line (b) (4) Molds to master sanitation schedule. We have determined that the (b) (4) should be cleaned on (b) (4). Therefore, we will address cleaning and sanitation for this item through an SSOP covering this equipment rather than the master sanitation schedule. Line (b) (4) and the corresponding (b) (4) equipment is (b) (4), so we have not finalized the relevant SSOPs. Attached, however, are two draft SSOPs we have prepared that address cleaning for this equipment, including the (b) (4). (Attachment D). We will continue to review and finalize this procedure before using this equipment.

- Modify (b) (4) Line (b) (4) filling equipment to address potential for condensation drip. We added this (b) (4) on November 9, 2015. Supporting documentation is maintained on file at the facility.

- Replace (b) (4) on (b) (4) Line (b) (4) We completed this work on August 13, 2015. Supporting documentation is maintained on file at the facility.

- Insulate overhead lines in sandwich mezzanine. As noted in an earlier submission, after further consideration, the (b) (4). (b) (4) (b) (4) (b) (4). This corrective action is therefore (b) (4). Should we (b) (4), we will ensure it is done in a sanitary manner and that condensation is controlled appropriately.

- Engineering review for condensation control. We received recommendations for (b) (4) (b) (4) from an engineer on July 8. Installing a new (b) (4) is a substantial undertaking, and we anticipate this work continuing for (b) (4). Although we anticipate that the new (b) (4) will enhance our ability to control condensation in our processing environment, we believe that resuming operations at this point is appropriate because the cooler fall and winter temperatures will help reduce condensation potential. We have focused first on completing interior work for the (b) (4) (b) (4) so as to minimize any disruption inside the facility during operations; (b) (4) is substantially complete We are now focusing on completing the installation of the components on (b) (4). We anticipate completing the installation on or about (b) (4). Supporting documentation will be maintained on file at the facility.

Observation 4: Failure to clean food-contact surfaces as frequently as necessary to protect against contamination of food.

We indicated we had replaced ingredient hoppers with (b) (4) (b) (4). To confirm, we completed this work on April 21, 2015, and will maintain documentation on file at our Brenham facility. We also include the hoppers on our master sanitation schedule. (Attachment E). The ingredient hoppers can be found under the tab associated with Mix Processing and are referred to as "Ingredient Containers." They will be cleaned (b) (4).

Observation 5: Failure to wear beard covers in an effective manner.

We indicated we would update our good manufacturing practices (GMPs) to make clear that beard nets must be worn by employees with facial hair. We also described a company-wide clothing and uniform policy requiring that employees wear beard nets in specified areas of the plant. We previously provided FDA with interim versions of the GMPs and uniform policy. Updated GMPs are enclosed as Attachment F, and an updated uniform policy is included as Attachment G. Employees are being retrained on GMPs and the new uniform policy before production resumes. Supporting documentation for the training will be maintained on file at the facility.

Observation 6: Failure to maintain buildings in repair sufficient to prevent food from becoming adulterated.

As explained in a prior submission, we cleaned, repaired, and repainted the ceiling vent above Blender (b)(on March 29, 2015. Supporting documentation will be maintained onsite at the Brenham facility. In addition, we stated we would examine surfaces for chipped, cracked, or peeling paint and would make any necessary repairs. We completed that work on October 28, 2015, for Areas (b) (4) (b) (4) with additional areas following as production (b) (4). Supporting documentation is maintained on file at the facility.

We also indicated we would replace (b) (4) with a (b) (4). We completed that work on October 30, 2015. Supporting documentation is maintained on file at the facility.