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RECEIVED
JUL 22 2015
NEW ORLEANS DISTRICT
DD'S OFFICE

July 21, 2015

Ms. Ruth Dixon
District Director
New Orleans District Office
U.S. Food and Drug Administration
404 BNA Drive
Building 200, Suite 500
Nashville, TN 37217

RECEIVED
JUL 22 2015
NOL-DO Compliance Branch

Re: 60-Day Update on Response of Blue Bell Creameries, Inc., to FDA Form 483s

Dear Ms. Dixon,

Blue Bell Creameries, Inc., (Blue Bell or the Company) appreciates the opportunity to provide this 60-day update on the status of the corrective actions we identified in our response to the Food and Drug Administration (FDA) Form 483 Inspectional Observations (the 483s) issued to our ice cream processing facility in Sylacauga, Alabama.

Producing safe, wholesome products remains Blue Bell's top priority, and we are taking the time to get this right. We have remained shutdown voluntarily for more than two months precisely for this reason, among others. Blue Bell employees have been working diligently over the past two months to thoroughly clean and sanitize our facilities and equipment, review and revise procedures, and identify and implement facility modifications. As we explained in our initial response to the 483s, 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.

As we have moved forward with our corrective action plans, we have determined that it is most appropriate to focus our efforts on bringing our facilities back into production (b) (4) As you know, we currently hope to begin with (b) (4) in our facility in Sylacauga, Alabama.

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As we begin to (b) (4) startup, 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. Importantly, as we move to resume (b) (4) at our Sylacauga facility, we will operate under our (b) (4) program, and we will not release any product from inventory until we, FDA, and the states are comfortable the product is safe for our consumers to enjoy.

As with our earlier responses, to help assure coordination and transparency, we are copying Reynaldo Rodriguez, Director of the Dallas District Office, to this response.

Blue Bell remains firmly committed to compliance with all FDA requirements and to ensuring we are producing the 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

Reynaldo Rodriguez, Director
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.

Gary Jay Kushner
Counsel to Blue Bell Creameries, Inc.

Enclosures

Tab I: Blue Bell Creameries, Inc., Update to FDA Regarding Corrective Actions in Response to 483 Issued to Sylacauga, Alabama, Facility

Tab II: Blue Bell Creameries, Inc., Letter to Mr. Reynaldo Rodriguez, District Director, Dallas District, July 21, 2015

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Blue Bell Creameries
Update to FDA Regarding Corrective Actions in Response to 483
Sylacauga, Alabama

July 21, 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 Sylacauga, Alabama, in response to the FDA Form 483 Inspectional Observations (the 483) issued to our facility on April 30, 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 committed to providing an update on our corrective actions in 60 days. We thank FDA for providing us the opportunity to provide this 60-day update.

Since our initial response, we have remained hard at work reviewing, cleaning, and modifying our facility and equipment and carefully assessing and enhancing our procedures. As we explained, since voluntarily stopping production, we have taken a holistic look at our operations across the entire company and identified a number of steps to take, many extending beyond specific Observations noted in the 483. Accordingly, although we had identified specific corrective actions that we planned to take in response to each Observation, we explained that many of those corrective actions would by necessity have to take place at a future date due to the sequencing of our broader process of reviewing and enhancing our facilities, equipment, and procedures. For example, some of the corrective actions identified specific modifications to production equipment. But, to address *potential Listeria* contamination on equipment more broadly, we decided to (b) (4) and clean the production equipment and to then make the identified modifications as (b) (4).

This update identifies the current status of the corrective actions identified in our initial 483 response but not yet completed when that response was submitted. As we have explained to FDA and to the *state of* Alabama, we plan to resume production on (b) (4). Some equipment will not be needed at first, and may not be needed for quite some time, depending on (b) (4) once operations resume. We have therefore prioritized ensuring that the equipment necessary for producing (b) (4) is clean, sanitized, and ready for operation – and that corrective actions necessary for the production of the products being produced (b) (4) have been completed – before we resume production. We have made addressing equipment that will not be used for some time a follow-on priority, but we remain fully committed to following through on all corrective actions for each piece of equipment before (b) (4). We include projected completion dates for the corrective actions that pertain to these lines or pieces of equipment, but these projections remain subject to change. We will ensure that the equipment not in use is stored away from production areas and in a manner that will not expose the equipment, our

[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).

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facility, or product, to potential contamination, and we will keep FDA informed should this plan or these projected dates change. Moreover, we plan to provide another update 60 days from today (120 days from our original 483 response) informing FDA of the status of any remaining corrective actions.

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 as of and as explained in our initial response. 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.

We appreciate the continued close and open working relationship with FDA and remain committed to full cooperation as we continue to implement these corrective actions and work toward bringing safe and wholesome product back to market.

Observation 1: Failure to perform microbial testing where necessary to identify possible food contamination.

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 (b) (4) 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 (b) (4) We can provide additional procedures to FDA upon request.

We are enclosing the following procedures:

1. Clean-up of Allergen 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. Washing & Storing Plastic Pallets (I/P - Kitchen)
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)

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21. (b) (4) Area Drain Back-Up Procedure (Plant Maintenance)
22. (b) (4) Area Entry Procedure For Maintenance (Plant Maintenance)
23. Shop Sanitation (Plant Maintenance)
24. Tool Sanitize - Wash Procedure (Plant Maintenance)
25. Working On Equipment in Production Areas (Plant Maintenance)
26. Cleaning 1/2 Gallon Operation (Production)
27. SSOP Gram 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 SSOP (Production)
32. Environmental Cleaning (Production)
33. Environmental (b) (4) (Production)
34. Production Sanitation SSOP 1/2 Gallon (Production)
35. Dedicated Cleaning Tools (Multi. Departments)
36. Enhanced Cleaning SOP (Multi. Departments)
37. (b) (4) SOP (Multi. Departments)
38. SOP for COP (Mix Processing & Production)
39. (b) (4) Oil Wand Cleaning & Storage (Mix Processing)
40. (b) (4) Cleaning Procedure (Mix Processing)
41. Inclusion Utensil Cleaning (Production)
42. Enhanced Cleaning of Filling Equipment (Production)

The procedures are enclosed as Attachment A and are numbered within Attachment A according to the order listed above.[2]

Observation 2: Suitable outer garments are not worn that protect against contamination of food and food contact surfaces.

We explained that we were revising our good manufacturing practices (GMPs) and enhancing employee training to reinforce proper employee hygiene and sanitary interaction with manufacturing equipment, among other objectives. Our updated GMP policy requires the use of hair and (when necessary) beard nets, requires that all uniforms be clean and in good repair, and requires that employees comply with a smock and captive footwear program. The policy reinforces the importance of proper handwashing before entering processing areas and after contacting potential sources of contamination such as an employee's clothing, as well as the importance of ensuring that potential sources of contamination, such as clothing or unclean hands or gloves, do not contact equipment. The revised GMP Policy is attached at Attachment B. We trained employees on the new policy on July 6 and July 9. A copy of the training materials and attendance information will be maintained at the facility for review.

We also explained that we would institute a new company-wide clothing policy. The company-wide policy establishes general requirements and expectations and standardizes aspects such as smock and hairnet colors (b) (4)). Under the company-wide policy, all employees are required to show up for work in clean shirt and pants. Employees will be

[2] For example, the document entitled "Clean-up of Allergen Ingredients Spills (Dry Storage/Receiving)" is included as Attachment A.1.

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required to wear hairnets in the Production, Ingredient Processing, Mix Processing, (b) (4) and Bakery 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, (b) (4), Ingredient Processing, Bakery) will have to wear smucks 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 company-wide policy also includes a captive footwear component: employees working in "(b) (4) " areas (Production, (b) (4), Ingredient Processing, Bakery) must wear plant-issued shoes in those areas. Employees working in other areas of the plant who should have need to enter a (b) (4) area will be required to don shoe covers. A copy of the company-wide uniform program is included at Attachment C.

Observation 3: Failure to maintain food contact surfaces to protect food from contamination by any source, including unlawful indirect food additives.

We explained that the equipment mentioned in this Observation—(b) (4) pipes, and gaskets—would be cleaned by placing it in the (b) (4) We trained employees on this practice on July 6 and July 9. A copy of the training materials and attendance information will be maintained at the facility for review. We also updated our GMP Policy to clarify that items such as these are not to be placed in employee handwash sinks and that utensils are to be stored in a sanitary manner. (Attachment B).

Further, the specific utensil identified in this Observation—(b) (4) (b) (4) —has been added to the cleaning procedure for the machine. The new procedure instructs employees to clean the utensil using the (b) (4) . The (b) (4) machine is not used in manufacturing (b) (4) flavors we plan to produce, so we have taken it out of production. The revised procedure is attached in draft form; we will finalize it before the (b) (4) machina is brought back into operation at an undetermined date in the future, taking into account any learnings from our (b) (4) production runs. (Attachment A.39).

Observation 4: The design and materials of equipment and utensils does not allow proper cleaning.

This Observation identified two pieces of equipment: a folded (b) (4) used to clean the (b) (4) equipment tha (b) (4) and a chocolate drip pan whose malfunctioning (b) (4) had been temporarily repaired using a space heater. Both pieces of equipment—the (b) (4) equipment and the chocolate drip tray—have been taken out of service for the foreseeable future, as they will not be required for the (b) (4) production and we do not know when they might be needed again. Before each piece of equipment is brought back into service, though, we will ensure that an appropriate cleaning tool is obtained for the (b) (4) equipment and that the chocolate drip tray is repaired with an appropriate (b) (4) . Moreover, we conducted focused employee training on July 6 and July 9 that included the appropriate way to repair equipment. A copy of the training materials and attendance information will be maintained at the facility for review.

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Observation 5: All reasonable precautions are not taken to ensure that production procedures do not contribute contamination from any source.

We explained that we would retrain employees on proper hygiene and sanitary interaction with processing equipment, including not extending dirty hands over food or food-contact surfaces. We completed this retraining on July 6 and July 9. A copy of the training materials and attendance information will be maintained at the facility for review. Our updated GMP Policy reinforces the importance of keeping hands and gloves clean, wearing gloves when involved with food handling, and being careful not to touch equipment with clothing. (Attachment B).

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

We committed to retraining employees on proper handwashing and the appropriate use of gloves as well as developing a company-wide uniform and shoe program to require outer coverings in sensitive processing areas. We completed this retraining on July 6 and July 9. A copy of the training materials and attendance information will be maintained at the facility for review. Our company-wide uniform policy is attached. (Attachment C.) Further, proper handwashing, glove use, attire, and personal hygiene are all addressed in our GMP Policy. (Attachment B).

Observation 7: The plant is not constructed in such a manner as to prevent condensate from contaminating food-contact surfaces.

We indicated that we would replace the entire drop ceiling in the mixing room. This was completed on May 27, 2015. We also explained that we had installed a temporary (b) (4) over Mixing Tank (b)(4) to prevent condensate or other materials from entering the mixer. To confirm, that was completed on April 30, 2015. Supporting documentation for each corrective action will be maintained on file at the facility.

We further committed to installing an (b) (4) in this room to better regulate air temperature during cleaning procedures. This capital improvement is a significant undertaking and will take time to complete. Work is underway, and we anticipate installation will be completed by (b) (4). We will maintain supporting documentation on file at the facility once this is complete. In the meantime, we will keep in place the temporary (b) (4) over Mixing Tank (b)(4) until the (b) (4) is installed.

Observation 8: Non food-contact equipment in manufacturing areas is not constructed so that it can be kept in a clean condition.

We explained that we would remove, inspect, and repair (b) (4), including removing any rust and peeling or flaking paint. As of July 15, 2015, all (b) (4) with rust or peeling paint were repainted, replaced, or taken out of service. We will use properly maintained—rust-free with intact paint—(b) (4) when resuming production. (b) (4) taken out of service will be repaired in the same manner before being brought back into service. We will maintain documentation of these repairs at our facility, and we will supplement that documentation as additional (b) (4) are brought back into

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service. Given the uncertainty surrounding (b) (4) production timeframes, we do not know when additiona (b) (4) might be brought back into service.

We also explained that we would replace non-stainless-steel mounts with stainless-steel versions to prevent them from rusting. As with the (b) (4) , we prioritized making these modifications for equipment that would be used when production is (b) (4) . We completed those modifications as of July 16, 2015, and will maintain supporting documentation of this activity at the facility. We will continue to make these modifications, and will supplement the documentation on file, before additional equipment is brought back into production. Again, given the uncertainty surrounding (b) (4) production timeframes, we do not know when additional equipment might be brought back into service.

Further, we committed to replacing all gaskets on our (b) (4) with new components. Specifically, these gaskets are the (b) (4) As of July 16, 2015, we had completed this modification for equipment that would be used for (b) (4) production. We will maintain documentation of this modification on file at our facility. We will continue to implement this modification for the (b) (4) that may be brought back into production and will add documentation for these modifications to the file maintained at the facility. Again, we cannot predict at this point when additiona (b) (4) will be brought online.

Finally, we indicated we would add the (b) (4) to our routine preventative maintenance program. As the attached preventive maintenance form indicates, we will check the (b) (4) (b) (4) , and this review will include inspecting the motors for rust and flaking paint, as well as checking the (b) (4) for any defects. A copy of the preventive maintenance form is attached. (Attachment D).

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