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NOL-DO Compliance Branch

May 22, 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

Re: Response of Blue Bell Creameries, Inc., to FDA Form 483

Dear Ms. Dixon,

Blue Bell Creameries, Inc., (Blue Bell or the Company) appreciates the opportunity to respond to the Food and Drug Administration (FDA) Form 483 Inspectional Observations (the 483) issued to our ice cream processing facility in Sylacauga, Alabama. We also appreciate FDA extending the response deadline to May 22, 2015, to align the deadlines for responding to all 483s issued to our Company. Producing safe, wholesome products for our consumers to enjoy is Blue Bell's highest priority, and we are taking this situation very, very seriously. As you are aware, we have recalled all of our products from the marketplace and have voluntarily stopped production in all of our facilities so we can fully evaluate and respond to this situation. Our sole mission is to ensure all aspects of our facilities and production lines are clean and sanitary and will result in safe product for our consumers.

Please find enclosed our responses to each Observation on the 483, including corrective actions, as well as a letter to the Dallas District Office outlining steps we are taking companywide across all of our facilities, including Sylacauga. The comprehensive scope of our ongoing efforts necessitates that our responses remain a work in progress. For those actions that have not yet been completed, we have indicated anticipated completion dates. Moreover, we will provide FDA an update on the status of all outstanding corrective actions from the 483 in 60 days, and again in 120 days if needed. We also remain firmly committed to working cooperatively with FDA throughout this process. To assure FDA of the safety of our products and processes, we will not resume commercial distribution

from any of our facilities until both we and FDA (and applicable state regulators) are satisfied that we are producing safe, wholesome product.

We recognize that, within FDA, our Brenham and Broken Arrow facilities fall within the jurisdiction of the Dallas District Office, and that our Sylacauga facility falls within the jurisdiction of the New Orleans District Office. 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

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 A: Blue Bell Creameries, Inc., Letter to Mr. Reynaldo Rodriguez, District Director, Dallas District, May 22, 2015

Tab B: Blue Bell Creameries, Inc., Response to FDA Form 483 Issued to Sylacauga Facility on April 30, 2015

Blue Bell Creameries
Detailed Response to FDA 483

Sylacauga

Blue Bell Creameries (Blue Bell, or the Company) appreciates the opportunity to respond to the Food and Drug Administration's (FDA's) FDA Form 483 Inspectional Observations, issued to our Sylacauga, Alabama, facility on April 30, 2015 (the 483) (Attachment 1). We appreciate FDA extending the response deadline to May 22, 2015, to align the deadlines for responding to all 483s issued to our Company. We also appreciate the professionalism demonstrated by the FDA investigators when they inspected our Sylacauga facility from April 6, 2015, through April 30, 2015. We are taking to heart the observations noted on the 483 as well as the constructive feedback offered by the investigators during the inspection. We also appreciate FDA's willingness to work closely with us during recent events, and we want to maintain that cooperative approach going forward. We strongly believe that public health and food safety are best served when companies work cooperatively with FDA and state regulators.

We are in the process of comprehensively reviewing all aspects of operations at all of our ice cream processing facilities, including our facility in Sylacauga, Alabama. As FDA is aware, we have voluntarily stopped production at all of our other ice cream facilities, including Sylacauga. We made the decision on April 20, 2015, to stop introducing into commerce product from our Sylacauga facility. From April 20 to April 24, 2015, we produced product for evaluation and research, which we subsequently destroyed. Since stopping production at Sylacauga, we have been working tirelessly to identify and address issues such as those experienced by other facilities in our Company. We have been devoting substantial time and resources to identifying and implementing the most effective solutions so that we can return to producing safe, wholesome ice cream for our customers.

This process has led us to reassess everything about our operations across the Company—from facility and equipment layout to employee training. In the course of this process, we have identified a number changes we plan to make. Many of those changes are identified below in response to FDA's Observations on the 483. Please be assured, though, that we have not limited our review to only the Observations on the 483s; we are looking holistically at everything we do, and we are also making changes well beyond the scope of this response. Because we are taking such a broad, self-critical review, many of our corrective actions in response to the 483 remain a work in progress. For example, we have developed a revised environmental testing program for use across the Company, but the program cannot be finalized for each facility until planned facility, equipment-design, and mechanical changes are completed. Accordingly, in response to many Observations on the 483, we describe the program or procedure we have developed or the engineering changes we plan to make, but the program or changes will not be completed until other changes are made first. We recognize this holistic review may be a continuing process, and we are committed to providing FDA regular updates on our progress and copies of the procedures and programs once they are finalized. We wish to work closely with FDA and our state regulators throughout this process. We will provide our first update in 60 days.

Early in this process, we brought in a team of outside experts in microbiology and facility sanitation to help us identify the source of the *Listeria* contamination and develop strong programs to eliminate

it and prevent reoccurrence. Our key outside consultants have substantial experience with microbiological control in food processing:

- (b) (4), (b) (6) has more than thirty years of experience with food safety and microbiological control, including more than two decades of experience as a food safety consultant. (b) (4), (b) (6) is the (b) (4), (b) (6) (b) (4) . He also serves as (b) (4) (b) (4) has authored numerous publications on food safety, and lectures and presents widely on the topic. (b) (4), (b) (6) has visited and critically examined each of our facilities and is working closely in helping us develop revised testing, cleaning, and sanitation programs.
- (b) (4), (b) (6) also brings more than three decades of food safety experience. He is (b) (4) . (b) (4), (b) (6) publishes and speaks widely on food safety and has extensive experience with developing food safety programs.
- [redacted] also has nearly thirty years of food safety experience and is the (b) (4) (b) (4) for (b) (4) . (b) (4), (b) (6) has extensive operational experience with food safety and has overseen quality assurance and food safety programs in a wide range of companies across multiple sectors of the food industry.
- (b) (4), (b) (6) has more than thirty years of experience with food safety and microbiology. (b) (4), (b) (6) is the owner and (b) (4) , (b) (4) and also has extensive experience with laboratory management, food testing, and plant assessment.

We are also drawing on the full resources of each of our consultants' organizations, providing us a deep bench of microbiological and food safety expertise. Curricula vitae for our key experts are attached (Attachments 2–5).

We are working tirelessly to clean and sanitize our facility as well as reviewing our food safety systems, a process facilitated by our decision to completely stop production, and we will take into account the findings from root cause analyses for our Brenham, Texas, and Broken Arrow, Oklahoma, facilities. We are systematically cleaning and sanitizing our production areas and breaking down equipment for comprehensive cleaning and sanitization. We are also using this opportunity to identify additional areas for enhancement or upgrade throughout our facility. We identify specific corrective action steps in response to each remaining Observation on this FDA Form 483.

Below, we repeat each observation from the 483 (noting if we have shortened the Observation), followed by our corrective actions. Again, we remain committed to working closely with FDA in implementing these corrective actions, and we will be providing copies of the materials referenced in the response for FDA's review once they are complete.

Observation 1:

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

Specifically,

You stated the results of your sampling for environmental pathogens on non-food contact surfaces as defined in your (b) (4) written procedure entitled "Plant Environmental Testing" were used as an indicator in determining whether the cleaning and sanitization program was effective. However, this sampling program failed to include the following:

a. **Sampling of food contact surfaces**

b. **Determination of any preventive action needed in response to the possible contamination.**

c. **Determination of the impact on the products produced on the affected date.**

d. **Determination of the Listeria spp. associated with the presumptive positive results.**

Response:

Working with our expert consultants, we are developing an updated environmental testing procedure and a product testing procedure—including a test-and-hold program—that will be used at all of our ice cream plants throughout our Company (with tailoring as appropriate for each facility) to verify the effectiveness of our sanitation procedures. We will use the procedures to monitor on a (b) (4) basis our processing environment for *Listeria* and to verify the effectiveness of our cleaning and sanitation procedures in every area of the facilities and at every stage of processing. We are also critically reviewing our cleaning and sanitation procedures. We are continuing to refine these procedures as we use our temporary manufacturing shutdown as an opportunity to carefully review our facility, equipment, and processes. The draft procedures attached to this response reflect our current thinking and may be modified further before we resume production.

Environmental Monitoring Program

In its current draft form, our updated environmental monitoring procedure calls for taking at least (b) (4) (b) (4) (b) (4). Samples will be collected (b) (4), and sample collection will (b) (4). Sample locations will be randomly selected from a predetermined list of potential sites. Samples will be tested for *Listeria spp*. and, in certain areas, *Salmonella*, using (b) (4) methods.

Presumptive positive test results will trigger corrective actions; we are not proceeding to confirmation but will act on presumptive findings, as this is a more conservative approach. Quality control supervisors will review the site and determine and document the appropriate response. Employee traffic through the area where the presumptive positive was found will be restricted to reduce the potential for spreading *Listeria*. Corrective actions can include, depending on the situation, increased cleaning and sanitation of the area; disassembly, inspection, and cleaning and sanitization of the equipment; review of cleaning procedures; (b) (4) treatment; removing or replacing equipment; or redesign of equipment. If a presumptive positive is found on equipment that is in production and the situation presents a risk of product contamination, we will immediately shut down

the piece of equipment pending further review and corrective action. Product or ingredients deemed potentially at risk will be placed on hold for further analysis, which could include (b) (4) testing, product testing, product rework, or product disposal. In all cases, corrective actions and product disposition will be documented.

After taking corrective action, we will (b) (4) surrounding the location of the original presumptive positive to ensure the microbe has not spread to other parts of the facility. We will continue this follow-up (b) (4) all return negative results. Once that happens, we will return to normal environmental monitoring. If any of the follow-up swabs test presumptive positive, we will take corrective action in the same manner.

We intend to collect and code our environmental samples in a manner that will allow us to conduct trend analyses on our findings so we can identify and take action on any recurring presumptive positive results. A draft environmental monitoring procedure is attached (Attachment 6). Note that we will continue to evaluate this procedure as we make changes in our facility. We will compile a list of potential sample locations once we have completed our facility renovations and engineering work.

Food Contact Surface Testing and Product Testing

In addition to our environmental monitoring program, we will implement a test-and-hold program for food contact surfaces (b) (4) and finished products. The testing program will feature two tiers: routine sampling and enhanced sampling. Each tier will evaluate our cleaning process, our sanitation process, and finished product safety. All product will be placed on hold pending the results of finished product testing and (b) (4) testing for *Lm*.

Under the routine sampling program, (b) (4) we will collect (b) (4) samples from randomly chosen locations on food contact surfaces on each production line, which we will test for (b) (4) readings. We will apply a threshold of (b) (4) and (b) (4) for all other surfaces. If all samples test below the appropriate threshold, we will consider the cleaning process successful. If any sample exceeds the threshold, we will re-clean the equipment or area and re-sample until the results come in under the threshold. Only after cleaning has been verified as successful will we move onto our (b) (4) procedure.

Following our (b) (4) procedure, we will collect (b) (4) samples from randomly chosen locations on food contact surfaces on each production line, which we will test directly for *Lm*. If a test returns presumptive positive for *Lm*, we will destroy all product produced on the prior production run on that line along with that day's production run and will immediately shut down the production line. We will thoroughly investigate, clean, and sanitize the production line and the surrounding equipment and areas, taking additional samples as part of the investigation. Production will not resume on that line until we are fully satisfied the source of contamination to the line has been eliminated and the samples have returned negative for *Lm*. When production resumes, we will follow our enhanced sampling program.

Finally, under the routine program, we will collect (b) (4) finished product samples from (b) (4)

(b) (4)), and test each composite sample for *Lm* using a validated method. If finished product tests presumptive positive for *Lm*, we will destroy all product produced on that line during the production run and will shut down the production line for investigation (including additional sampling), cleaning, and sanitizing. Once we are satisfied the production line is clean and sanitary, we will restart production under our enhanced sampling program. A draft routine test and hold procedure is attached (Attachment 7). Note that we will continue to evaluate this procedure as we make changes in our facility.

Under our enhanced sampling program, we will continue to sample for (b) (4) (b) (4) (b) (4) and for *Lm* (b) (4), as under the routine program. We will collect (b) (4) finished product samples, which we will (b) (4) and test for *Lm* using a validated method. Any presumptive positive results will be handled as described for the routine testing program. Intensified sampling will continue until (b) (4) consecutive production runs have tested negative, after which we will revert to our routine sampling program. Enhanced sampling will also be conducted (b) (4) for each product line. A draft enhanced test and hold procedure is attached (Attachment 8). Note that we will continue to evaluate this procedure as we make changes in our facility.

As noted, all (b) (4) and finished product sampling will be conducted as part of a test-and-hold program. No product will be shipped without first confirming that the (b) (4) testing and finished product testing has returned negative for *Lm*. In addition to our finished product testing programs, we are reviewing ingredient-specific requirements for each supplier, including microbiological and other food safety parameters.

Cleaning and Sanitation Procedures

We are carefully reviewing and revising our cleaning and sanitation procedures in light of FDA's observations as well as intensifying our procedures by implementing a more robust testing program to verify cleaning. (b) (4), we will clean all processing equipment to remove organic buildup and other residue, disassembling any equipment as necessary. After cleaning, we will sample randomly selected food contact surfaces on equipment and test them for (b) (4) to verify cleaning, as described above. If any samples exceed our thresholds, the equipment will be re-cleaned and re-sampled until it meets our specifications.

(b) (4), a sanitation team will conduct a (b) (4) sanitation procedure to ensure the production area is sanitary. (b) (4) sanitation, we will sample randomly selected food contact surfaces for *Lm* to verify sanitation, again as described above. Any presumptive positives for *Lm* will trigger immediate corrective action as well as the destruction of any affected product.

We are continuing to refine our cleaning and sanitation procedures in light of our ongoing company-wide facilities review. We will share the revised procedures with FDA once they are complete and before resuming production operations.

Observation 2:

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

Specifically on 4/20/2015,

An employee's shirt came into direct contact with the interior liner of an ingredient container while the employee was loading the ingredients into (b) (4) on the (b) (4) line during production of Bride's Cake Ice Cream. The employee, who was not dressed in the appropriate Blue Bell outer garment, was wearing a shirt which appeared soiled and with several holes.

Response:

We are comprehensively revising our good manufacturing practices (GMPs) to reinforce proper employee hygiene and sanitary interaction with manufacturing equipment. Employees will be instructed to ensure their clothes are clean and to minimize contact between their clothes and equipment and not to touch food-contact surfaces with anything except clean hands or clean gloves. We will also conduct detailed training on these requirements. All employees will undergo extensive GMP training before we resume operations.

In addition, we will institute a company-wide clothing policy. The Company is consulting with vendors to identify the most appropriate solution. Employees will be provided Company-issued coverings that they must don before entering the production area. Employees will remove their coverings as needed throughout the day as they leave processing areas. We will also implement a captive footwear policy. This program will mitigate the risk of employees' street clothes as a potential avenue for facility contamination.

Observation 3:

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

Specifically,

1) **On 4/20/2015, several pieces of filling equipment including an (b) (4) (b) (4) pipes, and gaskets were observed in an employee hand sink immediately following the disassembly of the (b) (4) line after production. The equipment was stored in the sink while a COP tank was available for adequate cleaning of equipment approximately (b) (4) from the sink.**

2) On 410/2015, the (b) (4) , used in the chocolate blending room, was stored in a unclean metal milk can between uses. The hose connecting the (b) (4) and pump was dirty and was located directly over the (b) (4) container.

Response:

The equipment mentioned in this Observation—(b) (4) —will be cleaned by placing it in the (b) (4) . Before resuming operations, we will retrain all employees on the proper handling of equipment parts during cleaning, including reinforcing that equipment parts are not to be placed in employee hand sinks, and will revise our procedures as necessary to reinforce proper handling of equipment during cleaning.

All utensils, including (b) (4) , will be stored in a sanitary container and will be included in our regular cleaning schedule.

Observation 4:

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

Specifically on 4/20/2015,

1) **A folded piece of (b) (4) at least (b) (4) and (b) (4) was observed to be wrapped with masking tape covering approximately half of the tool. The tool was being used (b) (4) on Cone Line # (b)(4) directly adjacent to exposed Nutzo Ice Cream Cones.**

2) A space heater was observed fastened to the production equipment with duct tape directly under the chocolate tray (b) (4) (b) (4) during production of Mooo Bars.

Response:

The folded piece of (b) (4) was a tool used to clean the (b) (4) that seals the cone wrapper. We are obtaining a new tool of more permanent and sanitary design to clean this piece of equipment when it is placed back into production.

We had experienced a malfunctioning (b) (4) on the (b) (4) . We will replace the (b) (4) (b) (4) with a new one before resuming operations. The (b) (4) will not touch a food contact surface and will be appropriate for this type of application. This repair will be completed before the machine goes back into operation, which we anticipate will be within (b) (4) . Our employee GMP training will cover how to address temporary repairs. We will not use space heaters for temporary repairs in the future.

Observation 5:

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

Specifically on 4/20/2015,

A maintenance employee, with visibly soiled arms and shirt, was observed leaning on a (b) (4) during production of Nutzo Ice Cream Cones. The employee's arms were resting on the packaging equipment and extending over exposed product and open packaging.

Response:

As noted in response to Observation 2, we will retrain all employees on proper hygiene and sanitary interaction with processing equipment. This training will include the importance of not extending unclean hands or clothing over product, open packaging, or food-contact surfaces of equipment. We are also updating our GMPs to reinforce this behavior.

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.

Specifically on 4/20/2015,

An employee was observed touching their visibly damp pant leg while wearing single-use gloves. The employee then proceeded to load sleeves of lids on the (b) (4) during production of vanilla and chocolate ice cream without washing hands or changing gloves.

Response:

Again, as noted in response to Observation 2, we will retrain all employees on proper handwashing procedures and on how to maintain clean and sanitary hands by washing their hands, sanitizing multi-use gloves, or changing single-use gloves after touching their clothes or non-sanitized surfaces. We will also develop a clothing policy that will involve wearing protective coverings over clothes.

Observation 7:

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

Specifically on 4/10/2015,

1) **The drop ceiling in the mixing room was damaged and in poor repair. Tiles appeared to be stained and broken throughout the mixing room.**

2) **Light fixture above mixing tank (b) (4) had condensate on it.**

Response:

We have hired a contractor specializing in industrial ceilings to replace the entire drop ceiling in the mixing room. The (b) (4) drop ceiling will be removed and replaced with a (b) (4) (b) (4). Our contractor is currently onsite conducting this repair. We anticipate this work being completed within (b) (4).

We have installed a temporary (b) (4) over Mixing Tank to prevent condensate or other materials from entering the mixer. Moreover, we are installing an (b) (4) in this room to better regulate air temperature during cleaning procedures, which will help control condensation. Finally, we anticipate that the new ceiling made of (b) (4) will minimize condensation as well. The (b) (4) will remain in place until the (b) (4) is installed and the potential for condensation has been minimized.

Observation 8:

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

Specifically on 4/10/2015,

1) (b) (4) **was rusty and had peeling/flaking paint.**

2) **Gasket** (b) (4) **was cracked, with cracks extending from** (b) (4) **shaft to outer edge of gasket.**

Response:

We will remove, inspect, and repair (b) (4), including removing any rust and peeling or flaking paint. We will replace non-stainless-steel mounts with stainless-steel versions to prevent them from rusting.

We are replacing all gaskets on our (b) (4) with new components. We are adding the gaskets to our routine preventative maintenance program.

Index of Attachments to This Response

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Curriculum Vitae for (b) (4), (b) (6) .	2
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End of Detailed Response